United States Environmental Protection Agency

Prevention, Pesticides And Toxic Substances (7508W)

EPA 738-R-94-022 September 1994



# EPA Reregistration **Eligibility Decision (RED)**

## Hexazinone



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### **CERTIFIED MAIL**

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case hexazinone. The enclosed <u>Reregistration Eligibility Decision</u> (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. The first set of required responses are due 90 days from the receipt of this letter. The second set of required responses are due 8 months from the date of this letter. Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Andrew Ertman at (703) 308-8063.

Sincerely yours,

Louis P. True, Jr., Acting Director Special Review and Reregistration Division

**Enclosures**:

#### **SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)**

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--A Product Specific Data Call-In is enclosed with this RED and must be completed and submitted within 90 days of receipt of this package. The response consists of a "Data Call-In Response" form and a "Requirements Status and Registrant's Response" form. Additional generic may also be required to confirm or support the assessment of the active ingredient. If generic data are required, Generic Data Call-Ins are being sent only to certain manufacturing use registrants. Generic Data Call-Ins are **not** being sent to end use product registrants. However, please note that instructions for completing the Data Call-Ins, which are incorporated as an Appendix to the RED, may address both generic and product specific data. If you are an end use registrant, be sure to follow the instructions for product specific data.

2. **<u>TIME EXTENSIONS AND DATA WAIVER REQUESTS</u>** No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

## 3. <u>APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"</u> You must submit the following items for each product within eight months of the RED issuance date (the cover letter date).

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; 703-487-4650).

c. <u>Generic or Product Specific Data</u>. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. <u>Certification With Respect to Citation of Data</u>. Complete and sign this form (EPA form 8570-29) for each product. Cite-all is not a valid option for reregistration.

#### 4. COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE

Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

#### 5. WHERE TO SEND ALL DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)

#### By U.S. Mail:

Document Processing Desk (**RED-SRRD-0266**) Office of Pesticide Programs (H7504C) EPA, 401 M St. S.W. Washington, D.C. 20460-0001

#### By express:

Document Processing Desk **(RED-SRRD-0266)** Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Hwy. Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

### **REREGISTRATION ELIGIBILITY DECISION**

#### **HEXAZINONE**

### LIST A

**CASE 0266** 

ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS SPECIAL REVIEW AND REREGISTRATION DIVISION

## **TABLE OF CONTENTS**

HEX	AZINON	NE REI	REGISTE	RATI	ON	I EI	LIGI	BIL	IT	ΥI	)E(	CIS	IO	ΓN	Έ.	AN	[.]	•	•••		•			. i
EXE	CUTIVI	E SUM	MARY		•••		•••				•	••	••	•	•••	•••	•••	•						vi
I.	INTR	ODUC	TION .		•••		••	•••		• •	•	••	••	•		••	••	•						. 1
II.	CASE	OVE	RVIEW				•••				•	•••	••											. 2
	А.	Chem	ical Ove	rview	v		•••				•	•••	•••					•						. 2
	В.	Use P	rofile .				•••				•	••	••											. 2
	С.	Estim	ated Usa	ige of	f Pe	esti	cide				•	••	••	•				•						. 5
	D.	Data 1	Requirer	nents	5.		•••				•	••	••											. 5
	Е.	Regul	atory Hi	story	<i>'</i> .	•••	•••	•••		• •	•	••	••	•	••	•••	••	•	••	•••	•	•••	••	. 6
III.	SCIE	NCE A	SSESSM	ENT	•																			. 7
	<b>A</b> .		cal Chen																					
	В.	•	an Health	•																				
		1.	Toxicol																					
				Acute																				
				Chro																				
				Carci				•																
				Devel		<u> </u>		·																
				Repro	-					v														
				Muta																				
			0	Metal	<u> </u>		•																	
				Other																				
				Refer																				
		2.	J. Exposu																					
		~.		Dieta																				
				Occuj																				
		3.	Risk As																					
		0.		Dieta																				
					•																			
		4.	Data R																					
	C.		onmenta																					
	С.	1.	Enviro					•••																
		1.		Envir																				
				Envir																				
		2.	Ecologi																					
		6.	•																					
				Ecolo	0		ene estr																	
				(1) (9)																				
				(2)	A	<b>xqu</b>	auc	Da	la .	• •	•	••	••	•	••	•••	•••	•	•••	•••	•	•••	•••	25

				(3)	Non-Target Insects Data	. 27
				(4)	Non-Target Plant Data	. 28
			b.	Ecolo	ogical Effects Risk Assessment	. 29
		3.		Requir	rements	. 46
		4.	Sum	mary of	f LOC Exceedance and Risk Characterization	. 47
			a.	Ecolo	ogical Effects	. 47
			b.	Grou	ind Water	. 47
IV.	RISI	K MAN	AGEM	ENT A	ND REREGISTRATION DECISION	. 48
	А.	Dete	rminati	ion of E	Eligibility	. 48
		1.	Eligi	bility D	Decision	. 49
		2.	Eligi	ble and	I Ineligible Uses	. 49
	В.	Reg			n	
		1.	Tole	rance R	Ceassessment	. 49
		2.	Resti	ricted U	Jse Classification	. 52
		3.	Refe	rence D	Dose	. 52
		4.	Canc	er Clas	ssification	. 52
		5.	Risk	Mitigat	tion	. 52
		6.			Label Advisory	
		7.			Species Statement	
		8.			ationale	
			a.	Čomj	pliance with Worker Protection Standard (WPS)	. 54
V.	АСТ	TIONS	REQUI	RED B	Y REGISTRANTS	. 57
	А.				e Products	
		1.			Generic Data Requirements	
		2.			equirements for Manufacturing-Use Products	
	В.	End	-Use Pr	oducts		. 58
		1.	Addi	tional F	Product-Specific Data Requirements	. 58
		2.	Labe	ling Re	equirements for End-Use Products	. 58
			a.		ker Protection Standard (WPS)	
			b.	Grou	Ind Water Labeling	. 58
			c.		ace Water Labeling	
		3.	Othe	r Grou	nd Water Requirements	. 59
		4.	Risk	To Nor	n-Target Plants	. 59
	С.	Exis	ting Sto	cks .		. 59
VI.	APPE	ENDIC	ES			. 61
	APP	ENDIX	KA. Ta	ble of <b>I</b>	Use Patterns Subject to Reregistration	. 63
					the Generic Data Requirements and Studies Used to	
					ration Decision	
	APP				Considered to be Part of the Data Base Supporting	
		Rere	egistrati	on of H	Iexazinone	117
	APP	ENDIX	KD. Li	st of Av	vailable Related Documents	135

<b>APPENDIX E.</b>	)
<b>PR Notice 86-5</b>	l
<b>PR Notice 91-2</b>	)
APPENDIX F. Combined Generic and Product Specific Data Call-In 165	5
Attachment 1. Chemical Status Sheets	5
Attachment 2. Combined Generic and Product Specific Data Call-In	
<b>Response Forms (Form A inserts) Plus Instructions</b>	)
Attachment 3. Generic and Product Specific Requirement Status and	
<b>Registrant's Response Forms (Form B inserts) and Instructions</b>	
Attachment 4. EPA Batching of End-Use Products for Meeting Data	
<b>Requirements for Reregistration</b>	3
Attachment	
<b>1. EPA Acceptance Criteria</b>	1
Attachment 2. List of All Registrants Sent This Data Call-In (insert) Notice	
$\ldots \ldots $	l
Attachment 3. Cost Share Data Compensation Forms, Confidential	
Statement of Formula Form and Instructions	3
<b>APPENDIX G. FACT SHEET</b>	3

#### HEXAZINONE REREGISTRATION ELIGIBILITY DECISION TEAM

#### **Office of Pesticide Programs:**

#### **Biological and Economic Analysis Division**

James Saulmon Eric Maurer Margaret Cogdell

Health Effects Division

Bill Dykstra Susan Hummel Bart Suhre Jeff Evans

Jennifer M. Wintersteen Charles Frick

**Environmental Fate and Effects Division** 

Conchi Rodriguez Paul Mastradone

Gail Maske

Estella Waldman

Henry Nelson

Kathy Monk

**Registration Division** 

Eugene Wilson Joanne Hayes

#### Special Review and Reregistration Division

Andrew Ertman Walt Waldrop Niloufar Nazmi Biological Analysis Branch Economic Analysis Branch LUIS Staff

Toxicology Branch Chemistry Branch Chemistry Branch Occupational and Residential Exposure Branch Science Analysis Branch Chemical Coordination Branch

Ecological Effects Branch Environmental Fate and Groundwater Branch Science Analysis and Coordination Staff

Fungicide-Herbicide Branch Registration Support Branch

Reregistration Branch Reregistration Branch Special Review Branch

## Office of Compliance Monitoring:

Rose Lew

#### **Office of Water:**

Amal Mahfouz

## **GLOSSARY OF TERMS AND ABBREVIATIONS**

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GRAS	Generally Recognized As Safe as designated by FDA
НА	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested

## **GLOSSARY OF TERMS AND ABBREVIATIONS**

LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>lo</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

## **GLOSSARY OF TERMS AND ABBREVIATIONS**

PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
$\mathbf{Q}_{1}^{*}$	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WPS	Worker Protection Standard

#### **EXECUTIVE SUMMARY**

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide hexazinone, 3-cyclohexyl-6-(dimethylamino)-1-methyl-S-triazine-2,4-(1H,3H)-dione.

Hexazinone is a triazine-dione herbicide registered for use on alfalfa, pasture and range grasses, pineapples, sugarcane, and blueberries. It is also registered for use on ornamental plants, forest trees, and non-crop areas. Hexazinone is registered for pre-emergent, post-emergence, layby, directed spray, and basal soil applications. There are presently 20 end-use hexazinone products and one technical (manufacturing-use) product registered.

Hexazinone was first registered by the Agency in November, 1975 for general weed control in non-cropland areas. A Registration Standard for Hexazinone was issued in February, 1982 (NTIS# PB87-110292) that identified data gaps according to guidelines then in place. After issuance of the 1982 Standard, new uses for hexazinone were established on blueberries, rangeland, pasture grasses, and pineapple. A second Registration Standard was issued in September, 1988 (NTIS# PB89-126080). The 1988 Standard summarized available data supporting the registration of products containing hexazinone as the active ingredient and required additional product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate data.

The Agency has now completed its review of the hexazinone target data base including data submitted in response to the 1988 Registration Standard and has determined that the uses of hexazinone as currently registered will not cause unreasonable adverse effects to humans or the environment. All uses of hexazinone are eligible for reregistration. Existing tolerances for blueberries, pineapple and sugarcane were reassessed. Tolerances for several other crops and commodities could not be reassessed; however, enough data were available to conduct a risk assessment. The Agency believes that existing tolerances are protective until data are available for reregistration. The Agency is requiring additional studies in the residue chemistry, ecological effects, and environmental fate disciplines that will be called in on a confirmatory basis. The following data are required: residue analytical methods (ruminant only), magnitude of the residue grass hay and alfalfa seed screenings, magnitude of the residue grass hay and alfalfa seed screenings, magnitude of the residue in meat/milk, storage stability (alfalfa and metabolite C for grass), rotational crops, seed germination/seedling emergence, vegetative vigor, a batch equilibrium study, aquatic sediment dissipation, a prospective groundwater monitoring study and spray drift data.

OPP's Carcinogenicity Peer Review Committee classified the carcinogenic potential of hexazinone as "Group D" on July 27, 1994. The Peer Review Committee concluded that the evidence was inadequate and could not be interpreted as showing either the presence or absence of a carcinogenic effect. However, further testing is not likely to provide any additional clarification. Based on these findings, the Agency cannot conclude that hexazinone has been found to induce cancer within the meaning of the Delaney clause and therefore food and feed additive regulations are not barred by the Delaney clause of the Federal Food Drug and Cosmetic Act.

On February 11, 1993, the OPP Reference Dose Committee established a Reference Dose (RfD) for hexazinone of 0.05 mg/kg/day based upon a No Observed Effect Level (NOEL) of 5 mg/kg/day from a one-year feeding study in dogs. An Uncertainty Factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variance. The Anticipated Residue Contribution (ARC) for the general U.S. population was calculated by using anticipated residues. The ARC was determined to be 7% of the RfD. The subgroup most highly exposed, non-nursing infants (< 1 yr) has an ARC from all uses of 40% of the RfD. A Health Advisory (HA) was issued by the Agency's Office of Water in August, 1988. A lifetime HA was set at 0.21 mg/L, or 200 ppb.

Hexazinone meets the Agency's exposure criteria for requiring both handler (mixer/ loader/applicator) and postapplication/reentry data. However, because there are no acute or chronic toxicological endpoints of concern with the exception of acute eye irritation (Toxicity Category I), handler and postapplication/reentry data are not required to support the reregistration of hexazinone. Because hexazinone is in Toxicity Category I for primary eye irritation, a 48 hour Restricted Entry Interval (REI) is required.

Hexazinone exceeds the Levels of Concern (LOCs) for both terrestrial and aquatic plants. The unrefined risk quotients range from 4.6 to 2142.8 depending on the application rate. Hexazinone also exceeds the LOC for small mammals at several of the higher application rates, however, using typical residues as the EEC estimates, the risk quotients range from < 0.1 to 0.6.

Based on laboratory data, hexazinone appears to be persistent and mobile in soil and aquatic environments. Field and forestry dissipation data confirm this. In addition, hexazinone was reported in runoff water (80 to 140 ppb) up to 6 months posttreatment in the forestry dissipation study. Therefore, field and laboratory data are consistent and indicate that hexazinone may be of concern for groundwater and surface water contamination. Groundwater detections have been reported in Hawaii (0.06-0.72 ppb), Florida (0.12-2.90 ppb), Maine (0.2-29 ppb), and North Carolina (0.74-34 ppb); levels well below the Health Advisory (200 ppb).

Hexazinone exceeds the following Levels of Concern (LOCs) for groundwater: groundwater quality, and non-target aquatic and terrestrial plants. Hexazinone exhibits many of the properties and characteristics associated with chemicals that have been detected in ground water. Considering the mode of activation of the chemical; i.e., rainfall within two weeks of an application, there is a strong possibility of movement to ground water, especially in vulnerable areas. For these reasons, hexazinone use is likely to have a significant impact on ground-water quality. In areas where irrigation water is contaminated with hexazinone, or where ground water discharges to surface water, hexazinone residues in ground water could pose a threat to plants. Following discussions with the technical registrant, duPont, several risk mitigation measures were agreed upon. These measures include a ground water label advisory, Agency notification of **any** domestic hexazinone detections in ground water, submission to the Agency of a report compiled by duPont and the state of Maine regarding ground water contamination, the development and submission of educational materials regarding product stewardship (with an emphasis on groundwater issues) and a lowering of the maximum application rate from 13.5 lb ai/acre to 8 lb ai/acre.

Before reregistering the products containing hexazinone, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

#### I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of hexazinone. The document consists of six sections. Section I is the introduction. Section II describes hexazinone, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for hexazinone. Section V discusses the reregistration requirements for hexazinone. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

#### II. CASE OVERVIEW

#### A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

•	Common Name:	Hexazinone
•	Chemical Name:	3-cyclohexyl-6-(dimethylamino)-1-methyl-S- triazine-2,4-(1H,3H)-dione
•	Chemical Family:	Triazine-dione
•	CAS Registry Number:	51235-04-2
•	<b>OPP Chemical Code:</b>	107201
•	Empirical Formula:	$C_{12}H_{20}N_4O_2$
•	Trade and Other Names:	Velpar
•	Basic Manufacturer:	DuPont Agricultural Products

#### **B.** Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of hexazinone can be found in Appendix A.

Type of Pesticide: herbicide

**Mechanism of Action:** 1,3,5-Triazine-2,4-dione contact herbicide, inhibitor of photosynthesis

**Use Groups and Sites:** 

#### **TERRESTRIAL FOOD CROP** Blueberry

#### **TERRESTRIAL FOOD AND FEED CROP** Pineapple, sugarcane

#### **TERRESTRIAL FEED CROP**

Agricultural rights-of-way/fencerows/hedgerows, alfalfa, grass forage/fodder/ hay, pastures, rangeland

#### **TERRESTRIAL NON-FOOD CROP**

Agricultural fallow/idleland, Christmas tree plantations, industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, recreational areas

#### AQUATIC NON-FOOD INDUSTRIAL

Drainage systems

#### FORESTRY

Conifer release, forest plantings (reforestation programs), forest trees (all or unspecified)

**Pests:** Alexandergrass, aspen, barnyardgrass, blackgum, blue mustard, bristly foxtail, brown panicum, chickweed, common groundsel, dallisgrass, deerbrush caenothus, dogbane, dogwood, elm, fiddleneck, filaree, fireweed, fleabane, fuzzy crotalaria, goosegrass, Great Plains yucca, green ash, guineagrass, hackberry, hawthorn, heath aster, henbit, hickory, honeysuckle, Jim Hill mustard, jimsonweed, junglerice, juniper, lambsquarters, lantana, London rocket, lotebrush condalia, manzanita, mexicantea, minerslettuce, morningglory, oak, osageorange, Pennsylvania smartweed, perennial bluegrass, periwinkle, persimmon, pigweed, plantain, purslane, radiate fingergrass, ricegrass paspalum, sandbur, sensitive plant, shepherdspurse, showy crotalaria, signalgrass, small broomrape, smartweed, snowbrush caenothus, sour paspalum, sowthistle, spanishneedles, speedwell, swollen fingergrass, tarweed cuphea, Texas millet panicum, Texas whitebrush, vaseygrass, wild carrot, wild mustard, wild parsnip, willow, willowweed, woodsorrel, yellow foxtail, yellow rocket. (Partial control or suppression only: curly dock, dandelion, dogwood, marestail, milkweed, nutsedge, pricklylettuce, quackgrass, redcedar, red maple, ryegrass, sumac, sweetgum, trumpet creeper).

#### **Formulation Types:**

Granular--10 to 75% Pelleted/tableted--10 to 90% Emulsifiable concentrate--25% Liquid ready to use--1.25% Soluble concentrate/solid--90% Technical Grade Active Ingredient--98.7%

#### **Methods and Rates of Application:**

<u>Granular</u> In any season, at pre- or postplant, pre- or posttransplant, or when needed, broadcast by aircraft or ground equipment or granule applicator at 1.25 to 12 lb active ingredient (ai)/acre. In summer or winter, apply spot soil treatment by hand at 0.005 lb ai/1" stem diameter. At pre- or postplant, apply band treatment by ground equipment at 2 lb ai/acre.

<u>Pelleted/tableted</u> In any season or at preharvest, apply spot soil treatment by hand at 0.002 to 0.005 lb ai/1" stem diameter. In summer, winter, or at preharvest, apply soil treatment by hand at 3.8 to 5.8 lb ai/ acre. In any season or when needed, broadcast by hand, aircraft or ground equipment at 2 to 12 lb ai/acre. When needed, apply tree injection treatment by appropriate equipment.

Emulsifiable concentrate In any season, at dormant, delayed dormant, stubble, or seed crop stages, or when needed, spray by sprayer, boom sprayer, ground, or aircraft equipment at 1 to 8 lb ai/acre. In fall, winter, or spring, at pre- or postplant, or posttransplant, apply band treatment by sprayer, boom sprayer, or ground equipment at 2 to 3 lb ai/acre. In any season, in Feb to June, at preharvest, or when needed, apply basal spray by hand held sprayer at 0.002 lb ai/1" stem diameter or 4 to 6 lb ai/acre. In Feb to June, apply bark cut treatment by sprayer. In Feb to June, fall, winter, or spring, at pre- or postplant, or when needed, broadcast by sprayer, boom sprayer, ground or aircraft equipment, or hand held sprayer at 2 to 12 lb ai/acre. In Feb to June, summer, or winter, apply soil treatment (specialized) by hand held sprayer at 6 to 12 lb ai/acre. In Feb to June or summer, treat trees by injection with appropriate equipment at 0.0005 lb/4" interval.

Liquid ready to use In summer, fall, or winter, apply basal spray by hand held sprayer at 0.2 to 0.3 gal ai/1,000 sq ft. In summer, fall, or winter, apply directed spray by sprayer at 6.6 to 8.3 gal ai/ acre. When needed, broadcast by hand held sprayer, sprayer, or boom sprayer at 10 to 12.45 gal ai/acre.

Soluble concentrate/solid At postemergence, layby, or when needed, apply directed spray by sprayer, boom or knapsack sprayer at 0.9 to 13.5 lb ai/acre. In spring, summer, at stubble, pre- or postemergence, dormant, or seed crop stages, or when needed, spray by boom sprayer, aircraft equipment, or sprayer at 0.9 to 5.4 lb ai/acre. In any season, at pre- or postplant, pre- or postemergence, postharvest, stubble, or dormant stages, or when needed, broadcast by boom or hand held sprayer, ground or aircraft equipment at 0.9 to 13.5 lb ai/acre. In fall, winter, or spring, at pre- or postplant, apply band treatment by boom sprayer, sprayer, or ground equipment at 0.9 to 2.7 lb ai/acre. When needed, apply spot treatment by sprayer or knapsack sprayer at 1.8 to 3.6 lb ai/acre. When needed, apply basal spray by hand held or power sprayer at 7.2 lb ai/acre.

#### **Use Limitations:**

Do not apply through any type of irrigation system. Do not apply within 30 to 60 days before grazing, harvest, or feeding.

#### C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of hexazinone. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Site <sup>1</sup>	Acres Grown <sup>2</sup> (000)	Acres Treated (000)	Percent Crop Treated	Pounds AI Applied (000)
Alfalfa	25,048	200-450	1-2	100-300
Blueberry	22	2-5	9-23	2-20
Pineapple <sup>3</sup>	29	Unknown	Unknown	Unknown
Rangeland	N/A	80-650	N/A	10-60
Sugarcane	875	< 1-< 1	< 1-< 1	< 1-< 1
Woodland	483,319	20-50	< 1-< 1	10-35
Other	N/A	25-45	N/A	5-15
Total		327-1,200		127-430

The table below summarizes the pesticides use by site.

<sup>1</sup> Site identification based on REFS. <sup>2</sup> 1990 1992 average (USDA /NASS)

1990-1992 average (USDA/NASS).

<sup>3</sup> There is no known usage data available for pineapple.

#### D. Data Requirements

Data requested in the 1988 Registration Standard for hexazinone include studies on product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

#### E. Regulatory History

Hexazinone is the accepted common name for the chemical 3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5 triazine-2,4(1H,3H)-dione. Hexazinone is a proprietary chemical of E.I. duPont de Nemours and Company, Inc. which is the sole producer and primary registrant of this broad spectrum herbicide. Hexazinone was first registered by the Agency in November 1975 for general weed control in noncropland areas. Use in the culture of Christmas trees and forest trees was added in 1977. Use patterns for the culture of sugarcane and alfalfa were conditionally registered in 1980 and 1981, respectively.

In February 1982, the Agency issued a Pesticide Registration Standard for hexazinone. At that time the registered food uses were for the culture of sugarcane and alfalfa; and the non-food uses were identified as non-cropland, Christmas tree plantations, and reforestation areas. Formulations of hexazinone products consisted of a 90% soluble powder, a 0.5% liquid, a 25% liquid, a 10% pellet and a 60% dry flowable. Three of the registered pesticide products were marketed under the duPont trademarked name Velpar<sup>®</sup>.

The Agency's Office of Drinking Water issued a drinking water Health Advisory for hexazinone in August 1988. A Lifetime Health Advisory (HA) was determined to be 0.21 mg/L (200 ppb) for an adult consuming 2 liters of water per day. For a 10 kg child a one- and ten-day health advisory was determined to be 2 mg/L.

A second Registration Standard was issued in September, 1988 (NTIS# PB89-126080). The 1988 Standard summarized available data supporting the registration of products containing hexazinone as the active ingredient and required additional product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate data.

OPP's Carcinogenicity Peer Review Committee classified the carcinogenic potential of hexazinone as "Group D" on July 27, 1994. They recommended for purposes of risk characterization that the Reference Dose (RfD) approach should be used for quantification of human risk. Their determination was made on the basis of a weight-of-evidence analysis with particular emphasis on carcinogenic potential.

There are presently 20 end-use hexazinone products and one technical (manufacturing-use) product registered.

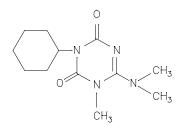
Hexazinone may be used as a non-selective herbicide in non-cropland areas, and it may be used as a selective herbicide for pine release in reforestation practices and in the culture of alfalfa, blueberries, pineapples, rangeland and pastures, and sugarcane. It controls a broad spectrum of annual biennial and perennial weeds, including undesirable woody plants. It is used as a harvesting aid in harvesting wood pulp, used in the manufacture of paper.

#### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

#### DESCRIPTION OF CHEMICAL

Hexazinone [3-cyclohexyl-6-(dimethylamino)-1-methyl-S-triazine-2,4-(1H,3H)dione] is a triazine-dione herbicide. The molecular structure of hexazinone is illustrated below:



Other identifying characteristics and codes are:

Empirical Formula:	$C_{12}H_{20}N_4O_2$
Molecular Weight:	252.3
CAS Registry No.:	51235-04-2
Shaughnessy No.:	107201

#### **IDENTIFICATION OF ACTIVE INGREDIENT**

Technical hexazinone is a white crystalline solid with a melting point of 113.5 C and a bulk density of 0.61 g/mL. Its solubility in water at 25 C is 2.98 g/100g. Hexazinone solubilities in methanol, acetone, and hexane are 265,79, and 0.3 g/100 g, respectively.

#### CONCLUSIONS

All pertinent product chemistry data requirements for the hexazinone 98% technical (EPA Reg. No. 352-399) have been satisfied.

#### B. Human Health Assessment

#### 1. Toxicology Assessment

#### a. Acute Toxicity

Guideline	Results	Toxicity Category	Citation (MRID)
Acute Oral LD <sub>50</sub> Rat	1200 mg/kg	III	41235004
Acute Dermal LD <sub>50</sub> Rabbit	> 5278 mg/kg	IV	00104974
Acute Inhalation LC <sub>50</sub> Rat	3.94 mg/L	IV	41756701
Primary Eye Irritation Rabbit	Severe	Ι	00106003
Dermal Irritation Rabbit	Mild	IV	00106004
Dermal Sensitization Guinea Pig	Not a sensitizer	$N/A^1$	41235005

The table below summarizes the results and categories for the acute toxicity studies.

 $^{1}$  N/A = Not Applicable

\* Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

#### b. Subchronic Toxicity

<u>90-Day Feeding in Rats:</u> Sprague-Dawley rats were fed diets containing 0, 200, 1000 or 5000 ppm of technical grade hexazinone for three months. The only treatment-related effect was a decrease in body weight gain of males (7%) and females (15%), when compared with the controls, in the 5000 ppm group. Other parameters examined (mortality, toxic signs, food consumption, clinical pathology, organ weights and histopathology) were not affected. Based on these findings, the systemic NOEL for both sexes was 1000 ppm (50 mg/kg) and the systemic LOEL was 5000 ppm (250 mg/kg) (MRID 00104977).

<u>90-Day Feeding in Dogs</u>: Beagle dogs were fed diets containing 0, 200, 1000 or 5000 ppm of technical grade hexazinone for three months. At the 5000 ppm level, body weight gains and albumin/ globulin values were decreased, and alkaline phosphatase activity and absolute and relative liver weights were increased, each in both sexes. There were no compound-related histological effects. Based on these findings, the systemic NOEL for both sexes was 1000 ppm (25 mg/kg) and the systemic LOEL was 5000 ppm (125 mg/kg) (MRID 001114484).

<u>21-Day Dermal Toxicity in Rabbits:</u> Technical hexazinone was applied to the intact skin of New Zealand white rabbits, using 5 rabbits/sex/ dose. The levels of hexazinone tested were 0, 50, 400 or 1000 mg/kg/day. The rabbits were exposed for 6 hours/day, for 21 days. The NOEL for both sexes was > 1000 mg/kg/day (HDT)(MRID 41309005).

#### c. Chronic toxicity

Chronic Feeding/Carcinogenicity in Rats: Male and female Sprague-Dawley rats were fed diets containing 0, 200, 1000 or 2500 ppm of hexazinone for two years. Nothing remarkable was observed in the lowdose group. In the mid-dose group, females had a slight decrease (about 5%) in body weight gain and food efficiency, compared with the controls. The following treatment-related effects were reported for the high-dose group: decreased body weight gains of males and females; decreased food consumption of males and food efficiency of females; increased white blood cells and eosinophil in males; alkaline urine in males and females; decreased absolute and relative weights of liver, heart and kidneys in males; and increased relative weights of brain, kidneys and stomach in females. Based on these findings, the systemic NOEL for both sexes was 200 ppm (10 mg/kg/day) and the systemic LOEL was 1000 ppm (50 mg/kg/day)(MRID 00108638).

Chronic Feeding in Dogs: Beagle dogs were fed diets containing 0, 200, 1500 or 6000 ppm of hexazinone for 12 months. Nothing remarkable was observed in the low-dose group, in both sexes. In the mid-dose group, the following findings were observed in males: increased serum alkaline phosphatase and globulin, decreased albumin, increased incidence of hepatocellular vacuolation and thinness (in one dog). The only findings reported for the mid-dose females were pale kidneys (in one dog) and an increased incidence of cytoplasmic inclusions and pigmented Kupffer cells in the liver. In the high-dose group, the following effects were observed in both sexes: decreased body weight gain and food consumption; decreased serum albumin, calcium, cholesterol, glucose and inorganic phosphorus; increased blood urea nitrogen (BUN), globulin, mean corpuscular volume (MCV) and mean corpuscular hemoglobin concentration (MCHC); and increased serum aspartate amino transferase (AST or SGOT), alanine amino transferase (ALT or SGPT) and alkaline phosphatase activities. Red blood cells, hematocrit and hemoglobin were decreased only in the males, total protein was decreased only in the females, whereas creatinine was increased only in the females. Also, relative liver weight (liver weight/body weight ratio) was increased in the males (57.1%) and the females (62.5%). Non-neoplastic liver histopathology was present in both sexes at the high-dose. Based on the above findings, the systemic NOEL for both sexes was 200 ppm (5 mg/kg/day) and the systemic LOEL was 1500 ppm (37.5 mg/kg/day) (MRID 42162301).

#### d. Carcinogenicity

Chronic Feeding/Carcinogenicity in Rats: Sprague-Dawley rats were fed diets containing 0, 200, 1000 or 2500 ppm of hexazinone for two years. Hexazinone was not carcinogenic in this study (MRID 00108638).

Carcinogenicity in Mice: CD-1 mice were fed diets containing 0, 200, 2500 or 10000 ppm of hexazinone for two years. The average consumption of hexazinone in mg/kg/day was 28, 366 or 1635, respectively, for males and 34, 450 or 1915, respectively, for females. Nothing remarkable was observed in the low dose-group. In the middose group, body weight gains were decreased in both sexes and there was an increased incidence of liver hypertrophy and hepatocellular adenomas and carcinomas in the males, when the treated mice were compared with the concurrent controls. Relative to the control values, the following findings were reported for the high-dose group: decreased body weight gains in both sexes; increased mean absolute liver weight in males; increased mean relative weight (liver weight/body weight ratio) in males and females; increased incidence of hepatocellular hypertrophy in males and females; increased incidence of hepatic focal necrosis and hyperplastic nodules in males; increased incidence of hepatocellular adenomas and adenomas plus carcinomas in both sexes (when compared with concurrent and historical controls). Based on the above findings, the systemic NOEL was 200 ppm (28 mg/kg/day for males and 34 mg/kg/day for females) and the systemic LOEL was 2500 ppm (1635 mg/kg/day for males and 1915 mg/kg/day for females). Also, hexazinone appeared to be carcinogenic in this study (MRID 00079203, 41359301 and 42509301).

<u>Peer Review:</u> The carcinogenic potential of hexazinone was evaluated by OPP's Carcinogenicity Peer Review Committee (CPRC) on July 27, 1994. The Committee concluded that hexazinone should be classified as a Group D chemical. It was also recommended that, for the purpose of Risk Characterization, the Reference Dose (RfD) approach should be used for quantification of human risk.

The CPRC decision to re-categorize hexazinone as Group D was based on the registrant's submission of a reevaluation of mouse liver sections (based on the latest diagnostic criteria for mouse liver neoplasms). Based on these new data, there was only a statistically significant increasing trend in combined adenoma/carcinoma in female CD-1 mice. It was noted though, that combined adenoma/carcinoma hepatocellular tumors in female CD-1 mice occur at a low rate (< 5% in historical controls, and the incidence in these concurrent controls was only 1-2%) whereas the incidence for combined liver tumors at the HDT was 9%.

Overall, it was felt that the animal evidence was equivocal (not entirely negative, but yet not convincing) based on the new readings. Based on these data, the only statistically significant increase was in the female mice (by trend test, but not by pairwise comparison with controls). Additional testing would not provide any clarification, therefore hexazinone was re-categorized as a Group D; not classifiable as to human carcinogenicity.

#### e. Developmental Toxicity

Developmental Toxicity in Rats: Mated Sprague-Dawley rats were administered single oral daily doses of hexazinone by gavage during gestation days 7 through 16. The following dose levels were tested: 0, 40, 100, 400 and 900 mg/kg/day. Treatment-related effects, observed only in dams from the 400 mg/kg/day and 900 mg/kg/day groups, included alopecia, and stained chin and nose; decreased body weight gain and food consumption during and after dosing, until the termination of the study; and increased relative liver weight (liver weight/body weight ratio). Treatment-related developmental effects, observed only in the 400 mg/kg/day and 900 mg/kg/day groups, included decreased fetal body weights; and increased incidence of fetuses with no kidney papilla and with unossified sternebrae. Maternal and developmental toxic effects observed in the 900 mg/kg/day group were, in most instances, statistically significant (p # 0.05) when compared with those observed in the control group. Maternal and developmental toxic effects observed in the 400 mg/kg/day group were minimal and only occasionally statistically significant (p #0.05) when compared with those noted in the controls. Based on the above findings, maternal NOEL and LOEL were 100 mg/kg/day and 400 mg/kg/day, respectively. The developmental NOEL and LOEL were also 100 mg/kg/day and 400 mg/kg/day, respectively (MRID 40397501).

Developmental Toxicity in Rabbits: Pregnant New Zealand white rabbits were administered single oral daily doses of hexazinone by gavage during gestation days 6 through 19. The following dose levels were used: 0, 20, 50 and 125 mg/kg/day. Treatment-related maternal toxic effects were observed only in the high-dose group and included increased incidence of depression and discharge from the eyes; decreased body weight gain; and increased resorptions. Treatmentrelated developmental effects were observed also only in the high-dose group and included decreased fetal body weight gain and delayed ossification of extremities. Based on these findings, the NOEL and LOEL for maternal toxicity were 50 mg/kg/day and 125 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity were also 50 mg/kg/day and 125 mg/kg/day, respectively (MRID 00028863).

#### f. Reproductive Toxicity

<u>2-Generation Reproduction Rat:</u> In the one study available, male and female Sprague-Dawley rats were administered hexazinone continuously in the diet for two successive generations at the following dose levels: 0, 200, 2000 or 5000 ppm. Treatment-related effects were observed only in the mid-dose and high-dose groups and included decreased body weight gain in P1 and F1 females during growth and gestation; decreased food consumption in F1 females during gestation; decreased pup weight in F1, F2<sub>a</sub> and F2<sub>b</sub> litters; and decreased pup survival in F2<sub>b</sub> litters (only in the high-dose group). Based on these findings, the systemic NOEL and LOEL were 200 ppm (10 mg/kg/day) and 2000 ppm (100 mg/kg/day), respectively. The NOEL and LOEL for reproductive toxicity were also 200 ppm and 2000 ppm, respectively (MRID 42066501).

#### g. Mutagenicity

Hexazinone was found to be positive for mutagenicity in one chromosome aberration assay (<u>in vitro</u> cytogenetic assay), but was negative in the remaining studies.

<u>Gene Mutation Assay in Ames Test:</u> Hexazinone was tested with metabolic activation (rat liver microsomal fraction commonly known as S-9 fraction, plus cofactors) at concentrations ranging from 400 to 2000 ug/plate and without metabolic activation at concentrations ranging from 200 to 1000 ug/plate. The strains of <u>Salmonella typhimurium</u> used were TA1535, TA1537, TA1538, TA98 and TA100. No increases in reverse mutations were observed at any concentration. Positive results were obtained with standard reference mutagens (positive controls)(MRID 00098982).

<u>Gene Mutation Assay in Mammalian Cells:</u> Hexazinone was tested in the Chinese hamster ovary (CHO) cells/hypoxanthine - guanine -

phosphoribosyl transferase (HGPRT) assay, with and without metabolic activation. No mutagenic response was observed up to cytotoxic doses (13.9 mM without metabolic activation and 9.9 mM with metabolic activation (MRID 00076956).

Structural Chromosome Aberration Assay; In vitro Cytogenetic Assay: The mutagenic potential of hexazinone was evaluated in vitro, using Chinese hamster ovary (CHO) cell system with and without metabolic activation. The concentrations of hexazinone tested (which were not toxic to cells) ranged from 1.58 to 19.82 mM, without metabolic activation and from 0.32 to 15.85 mM, with metabolic activation. Hexazinone was mutagenic in this study. Relative to the control (solvent) values, there was a significant (p< 0.01) increase in structural chromosomal aberrations/cell at hexazinone concentrations of 15.85 mM (and above), without and with metabolic activation (MRID 00130709).

Structural Chromosome Aberration Assay; In vivo Cytogenetic Assay: Single doses of hexazinone (0, 100, 300 or 1000 mg/kg) were administered by oral gavage to mature male and female Sprague-Dawley rats, and their bone marrow cells were examined for clastogenic (chromosome-damaging) effect. Relative to the control (solvent) values, no significant increase of chromosomal aberrations was observed in any of the treated groups. However, a highly significant number of chromosomal aberrations was observed in the bone marrow cells of rats treated with cyclophosphamide, a standard reference mutagen (MRID 00131355).

Other Genotoxic Effects Assay; Unscheduled DNA Synthesis in Rat <u>Hepatocytes</u>: Primary hepatocytes, obtained from the livers of 8-week old male Sprague-Dawley rats, were exposed to eight hexazinone concentrations ranging from 1x10<sup>-5</sup> mM to 30 mM. Hexazinone did not elicit unscheduled DNA synthesis at any level of concentrations tested. Positive results were obtained with 7,12-Dimethylbenz(a) anthracene -DMBA, a standard reference compound (positive control)(MRID 00130708).

#### h. Metabolism

<u>General Metabolism</u>: In the one study available, three groups of male and female Sprague Dawley rats were treated as follows: (1) Group A received a single intragastric low dose of <sup>14</sup>C-hexazinone (14 mg/kg) without preconditioning (treatment with non-radioactive hexazinone); (2) Group B received a single intragastric dose of <sup>14</sup>C-hexazinone (14 mg/kg) after three weeks of preconditioning with 100 ppm of nonradioactive hexazinone in the diet; and (3) Group C received a single intragastric high-dose of <sup>14</sup>C-hexazinone (1000 mg/kg) without preconditioning.

Hexazinone was rapidly metabolized by hydroxylation and demethylation, and eliminated by the rats in urine and feces during the 3 to 6-day testing periods. About 77% and 20% (of the administered dose) of <sup>14</sup>C-hexazinone was excreted in urine and feces, respectively. Practically all radioactivity was recovered in the first 24 hours after treatment. Very low levels of radioactivity (about 0.2% of the administered dose) were detected in the G.I. tract, hide, organs (heart, lungs, liver, spleen, kidneys, brain, and testes or ovaries), muscle, fat and blood. Eight metabolites were identified in urine and feces. The major metabolites in both urine and feces were (1) 3-(4-hydroxycyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)dione and (2) 3-(4-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5triazine-2,4(1H,3H)-dione (MRID 00247874).

#### i. Other Toxic Endpoints

<u>Dermal Penetration/Absorption</u>: This study is not required. Based upon a comparison of the results of a Developmental Toxicology Study in rabbits (MRID 00028863, Developmental NOEL = 50 mg/kg/day) and a 21-Day Dermal Toxicity Study in Rabbits (MRID 41309005, NOEL = 1000 mg/kg/day), little or no absorption of hexazinone through the skin is anticipated.

<u>Domestic Animal Safety:</u> Data are not required for the use patterns of hexazinone (a selective herbicide used to control grasses, broadleaf weeds, and woody plants).

#### j. Reference Dose (RfD)

OPP's RfD Committee recommended that an RfD should be established based upon a NOEL of 5 mg/kg/day for changes in clinical chemistry and histopathological parameters observed at 37.57 mg/kg/day in males and females in the one-year feeding study in dogs (MRID 42162301). An Uncertainty Factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variance. On this basis, the RFD was calculated to be 0.05 mg/kg/day. Based on available information, there does not appear to be any reference to an evaluation of hexazinone by JMPR/International Programme on Chemical Safety (IPCS).

#### 2. Exposure Assessment

#### a. Dietary Exposure

<u>Confined Rotational Crops:</u> A study was submitted, reviewed, and found supplemental; additional data were required on onions, and new studies were required on sorghum (small grain) and a leafy vegetable crop.

The supplemental onion data have been submitted, reviewed, and the root crop portion of the confined rotational crop requirement is considered satisfied. A rotational restriction of 12 months for root crops is required and no tolerances are needed for root crops rotated into fields 12 months after treatment with hexazinone. If the registrant desires plant back intervals of less than 12 months, appropriate tolerances for root crops may need to be established. Depending on the results of the confined rotational crop studies in sorghum and leafy vegetables, additional data may be needed to fulfill §165-2, Field Rotational Crop Studies. The sorghum and leafy vegetable data are due to the Agency by 5/31/95 (MRID 41008401, 42824001).

Plant Metabolism: The initial Hexazinone Registration Standard dated 2/82 concluded that the qualitative nature of the residue in plants is adequately understood. Studies conducted on sugarcane, alfalfa, and pineapple indicate that root uptake is the principal mechanism for the absorption of hexazinone by plants from soils. Hexazinone is translocated through the xylem to the foliage where it blocks the photosynthetic process. The data indicate that hexazinone is metabolized by hydroxylation to metabolite A which is then metabolized to metabolite C by demethylation and to metabolite E after oxidation. Residues of concern are hexazinone and its metabolites A [3-(4hydroxycyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1H,3H)-dione)], B [3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5triazine-2,4-(1H,3H)-dione], C [3-(4-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1H,3H)-dione], D [3cyclohexyl-1-methyl-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione], and E [3-(4-hydroxycyclohexyl)-1-methyl-1,3,5-triazine-2,4,6-(1H,3H,5H)trione] (MRID 00078047, 00104846, 00126127).

<u>Animal Metabolism:</u> The nature of the residue of hexazinone in livestock commodities is adequately understood. Metabolites of concern are those containing the triazine ring. Hexazinone and metabolites A, B, C, D, E, and F [3-cyclohexyl-6-amino-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione] will be regulated. Recovery data are needed for metabolite F.

In poultry, the maximum residue expected in poultry tissues would be 0.005 ppm, an order of magnitude below the limit of detection for hexazinone metabolites. The Agency concludes that tolerances for hexazinone in poultry commodities are not required and the existing tolerances for these commodities should be revoked. Additional raw data are required to support the goat metabolism study (MRID 41524801, 42187901, 42219301, 42248901, 42690601, 43074201).

<u>Residue Analytical Methods - Plants:</u> An adequate method for purposes of data collection and enforcement of tolerances for hexazinone residues and metabolites A, B, C, D, and E in or on plant commodities is available. The GLC/nitrogen-detection method for determining trifluoroacetic anhydride-derivatized residues of hexazinone is described in PAM, Vol. II, as Method I. The combined limit of quantitation for hexazinone residues by the method in PAM, Vol. II, is 0.55 ppm (41572101, 41572102, 41572103, 41572104, 41572105, 41572106, 42987201, 43025401).

<u>Residue Analytical Methods - Animals:</u> There are no existing tolerance enforcement methods available for ruminant commodities in PAM, Vol. II. The registrant has proposed to develop methods to detect marker compounds in ruminants using six markers. Data collection and tolerance enforcement methodology for ruminant commodities must be capable of determining hexazinone residues of concern. Because the chemical structures of metabolite F and B are similar, it may also be possible to adapt the method for determining plant metabolites to determine ruminant metabolites.

Storage Stability: The available storage stability data indicate that residues of hexazinone and its metabolites A, B, C, D, and E are stable under frozen (-10 to -20 EC) storage conditions in blueberries for up to 13 months, in pineapple fruit for up to 8 months, in pineapple juice for up to 6 months, in sugarcane for up to 12 months, and in sugarcane processed commodities for up to 6 months. Additional data are required on storage stability of metabolites A, C, and E in pineapple bran. Hexazinone and metabolites A, B, D, and E are stable under frozen storage conditions in grass for up to 24 months; additional data are required on storage stability of metabolite C in grass matrices for 34 months. A 2-year interim report is due by 1/31/95 and the final study is due by 1/31/96. The requirement for storage stability data on alfalfa remains outstanding; these data are due to the Agency by 4/30/96 (MRID 42867501, 42535601, 42492101, 42423001, 42276001, 42867501).

<u>Magnitude of the Residue in Meat, Milk, Poultry, and Eggs:</u> A cattle feeding study is still required. The most recent metabolism studies indicated a very significant transfer of residues to meat and milk. The existing tolerances for meat/meat byproducts and milk do not reflect the current metabolic profile and the current tolerance levels cannot be reassessed until the cattle feeding study is completed. The existing tolerances are protective until the new data are evaluated. This study is due to the Agency by 5/30/95.

Poultry feeding studies are not required because the maximum residue expected in poultry tissues would be 0.005 ppm, an order of magnitude below the limit of detection for hexazinone metabolites.

<u>Magnitude of the Residue in Plants</u>: Data have been submitted on magnitude of the residue in plants for all registered crops. Additional information or data are required on alfalfa seed and seed screenings, grass hay and processed commodities of pineapple. Certain label changes were required for alfalfa, blueberries, pineapple, pineapple forage, and sugarcane. These uses are only on duPont labels and all have been or are being amended. Data show that hexazinone concentrates in certain processed fractions of alfalfa, pineapple, and sugarcane. The Agency has determined that establishing food and feed additive tolerances for these commodities is appropriate and consistent with the Delaney Clause of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (MRID 43074401, 43074402, 41964101, 41964102, 41898301, 42418001, 42419101, 42867501, 42492101, 42535601, 42322701, 42417901, 42276001, 43074401, 43074402).

#### b. Occupational and Residential Exposure

Postapplication/reentry data and handler (mixer/loader/ applicator) data are required when both toxicity and exposure criteria are met. Hexazinone is a selective herbicide used to control undesirable herbaceous plants in forage grasses, sugarcane, and alfalfa. Hexazinone is also used to control herbaceous and woody plants in Christmas tree plantations and non-crop areas, and to control undesirable plant species in forestry site preparation and conifer release programs. Agricultural crops are treated using groundboom equipment, aircraft, and wiper/wick applicators. Label directions also include directions for impregnating dry bulk fertilizer with hexazinone. Undesirable small trees growing in rangeland and pasture sites are treated using exact delivery handgun applicators.

Non-crop areas such as highway right-of-ways, petroleum tank farms, ditch banks, industrial plant sites, and railroads are treated using handgun or fixed boom sprayers for liquid formulations. A pelleted formulation provides for treating undesirable species by placing one or two pellets next to the tree or shrub to be controlled.

Forestry applications include the use of aircraft, groundboom equipment, handguns, and the use of back-pack equipment modified for granular applications. Undesirable trees may also be treated by injection using hypo-hatchet type equipment primarily along ditch banks or in areas with high water tables.

Hexazinone is not intended for use in residential areas.

#### Uses Within the Scope of the Worker Protection Standard (WPS)

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (nonhomeowner) and research uses on farms, forests. nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of hexazinone are within the scope of the WPS and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on pastures or rangelands;
- on plants grown for other than commercial or research purposes;
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS);

• in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other non-crop areas.

# **Toxicity Information**

**Acute Toxicity:** The toxicological data base for hexazinone is adequate and will support reregistration. Acute toxicity studies indicate that technical hexazinone is category III for acute oral toxicity, category IV for acute dermal toxicity, category IV for acute inhalation toxicity, category IV for skin irritation potential, and category I for eye irritation potential. It is not classified as a skin sensitizer.

**Other Adverse Effects:** For occupational/residential exposure, there are no toxicological end-points of concern for hexazinone. The Agency notes that it is classified as Group D for carcinogenic potential with a reference dose of 0.05 mg/kg/day and is poorly absorbed through the skin with little or no absorption anticipated. Since both the handler and post-application exposure concerns are predominantly related to skin contact, the toxicity criteria for either occupational or residential exposure assessments are not triggered.

# 3. Risk Assessment

### a. Dietary

Toxicological Endpoint: The DRES chronic analysis used a Reference Dose (RfD) of 0.05 mg/kg body weight/day, based on a No Observable Effect Level (NOEL) of 5.0 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was based on a one year feeding study in dogs (MRID 42162301) which demonstrated liver effects in both males and females at 38 mg/kg bwt/day (OPP RfD Peer Review Committee on February 11, 1993). Hexazinone was classified as a Group D chemical by the OPP Carcinogenicity Peer Review Committee on July 27, 1994.

<u>Residue Information</u>: Food uses in this analysis include all published tolerances listed in the Tolerance Index System (TIS) and 40 CFR §180.396. All published tolerances are being supported in the reregistration of hexazinone. New values for anticipated residues (ARs) have been prepared by the Chemistry Branch-Reregistration Support (CBRS). Tolerances exist for animal feed commodities which result in secondary residues in meat of cattle, goats, horse, poultry, hogs and sheep as well as milk and eggs (the database from which the ARs were calculated is incomplete and a reassessment of the ARs may be necessary in the future). The anticipated residues for blueberries, milk, and sugarcane (DRES commodities cane sugar and sugar-molasses) are higher than the tolerance residues in this analysis. According to the Agency these anticipated residues (except milk) were determined as onehalf the combined limit of quantitation of the residues regulated.

Results: The DRES chronic analysis used tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 DRES subgroups. Anticipated residues were used for further refinement to calculate the Anticipated Residue Contribution (ARC) for those same population groups. The ARC for the overall U.S. population from all tolerances is  $3.5 \times 10^{-3}$  mg/kg bwt/day or 7% of the RfD. The subgroup most highly exposed, non-nursing infants (< 1 yr) has an ARC from all uses of 2.0 x  $10^{-2}$  mg/kg bwt/day, representing 40% of the RfD. The children (1-6 yrs) subgroup has an ARC from all tolerances of 1.0 x 10<sup>-2</sup> mg/kg bwt/day, or 20% of the RfD. There are no pending or new tolerances being proposed for the reregistration of hexazinone. Anticipated residues were used for all commodities. However, a source of overestimation exists in that 100 percent crop treated was assumed for all commodities. The dietary risk from hexazinone through the published tolerances appears to be minimal. However, residue chemistry data gaps for hexazinone remain and data submitted in the future could alter estimated dietary exposure to hexazinone residues.

### b. Occupational and Residential

Agency review of the complete toxicological data submitted to support reregistration indicates that for hexazinone the toxicology criteria for a post-application exposure assessment are not met. Therefore, no occupational exposure assessment is required. Hexazinone is not used in residential areas.

No changes in the personal protective equipment required by the WPS are being imposed in this document. However, the REI is being changed from 24 to 48 hours because hexazinone is in toxicity category I for primary eye irritation.

### 4. Data Requirements

The following data required for the reregistration of hexazinone are considered confirmatory:

**Residue Chemistry**:

•	171-4d	Residue Analytical Method Ruminant
---	--------	------------------------------------

- 171-4e Storage Stability (Alfalfa, Metabolite C for Grass)
- 171-4j Magnitude of the Residue in Meat/Milk
- 171-4k Magnitude of the Residue in Grass Hay and Alfalfa Seed Screenings

# C. Environmental Assessment

#### **1. Environmental Fate**

#### a. Environmental Chemistry, Fate and Transport Data

<u>Hydrolysis:</u> Hexazinone will not hydrolyze under normal environmental conditions. Hexazinone was reported to be stable in pH 5, 7, and 9 buffer solutions when incubated in the dark at 25 C. Unchanged hexazinone comprised from 99 - 100% of total radioactivity recovered in all samples (MRIDs 00064620, 41587301).

Photodegradation in Water: No photodegradation half-life in water for hexazinone was reported. Hexazinone did not appear to degrade significantly in buffered pH 7 solution when exposed to an artificial light source. Hexazinone accounted for 86.6 to 96.0% of applied radioactivity over the 30 day testing period. Dark controls were reported to have similar results with hexazinone accounting for 91.3 to 97.2% of applied radioactivity over the 30-day testing period. Analytical methods were not sufficient to characterize the remaining 2.6 to 9.9% of applied radioactivity (MRID 41300801).

<u>Photodegradation on soil:</u> Hexazinone had a reported half-life of 82 days, which is equivalent to a half-life of approximately 228 days at latitude 30° to 50° N with 12 hours of natural sunlight, when applied to sandy loam soil and exposed to an intermittent (xenon arc lamp) light source for 30 days. However, hexazinone did not appear to degrade significantly in dark control samples. At least 6 degradates were discernible, with only one product, 3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione, accounting for at least 10% applied radioactivity. Of the degradation products, <sup>14</sup>CO<sub>2</sub> accounted for

only 0.2% of the total applied radioactivity. The remaining minor degradation products, none of which comprised more than 2.6% of the total applied radioactivity, did not appear to correspond to any of the other reference compounds (MRID 41300802).

Aerobic soil metabolism: Hexazinone had reported half-lives of 216 days and 1440 days when applied to non-sterile and sterile sandy loam soil and exposed to aerobic conditions in the dark at 25EC, respectively. The non-sterile and sterile soil data indicated that degradation was mainly a result of microbiological activity. There were 4 metabolites formed in non-sterile soil. The major degradation products were 3hydroxy-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,-3H)-dione, accounting for at least 18.7% (2.24 ppm) of applied radioactivity after 365 days posttreatment and 3-(ketocyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione, accounting for at least 10.9% (1.31 ppm) of applied radioactivity after 365 days posttreatment. Two minor metabolites, Metabolite B and Metabolite D, reached a maximum concentration of 2.3% (0.28 ppm) and 4.8% (0.58 ppm), respectively, of the applied radioactivity (MRID 41807401, 42635001).

Anaerobic aquatic metabolism: Hexazinone had reported half-lives of 230 days and > 1500 days when applied to non-sterile and sterile sediment pond water, respectively, and exposed to anaerobic conditions in the dark at 25EC. The non-sterile and sterile soil data indicated that degradation was mainly a result of microbiological activity. There were 4 metabolites formed in non-sterile soil. The major degradation products were 3-hydroxyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione, accounting for approximately 5.5% (0.66 ppm) of applied radioactivity after 365 days posttreatment and 3-(ketocyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione, accounting for approximately 25.0% (3.00 ppm) of applied radioactivity after 365 days posttreatment. Another metabolite, 3-cyclohexyl-1-methyl-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione, accounted for at least 24.0% (2.88 ppm) of the applied radioactivity (MRID 41807402, 42657301).

<u>Aerobic aquatic metabolism</u>: Hexazinone had a reported half-life of > 2 months under both sterile and non-sterile conditions incubated at 25EC. Three major metabolites and one minor metabolite were identified. The major metabolites [3-(4-ketocyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione; 3-(2-hydroxycyclohexyl)-6-(dimethylamino-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione; 3-(cyclohexyl-6-(methylamino)-1-methyl-1,3,5- triazine-2,4(1H,3H)-dione] were present each at concentrations less than 7% of the applied radioactivity. One minor metabolite, 3-(cyclohexyl-1-methyl-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione, reached a maximum concentration of 1.3% of applied radioactivity. The reported data indicated there were no significant differences in the sterile and non-sterile data. This lack of significant differences could be related to the duration of the test period (56 days). The aerobic soil metabolism study which was carried out for 1 year had reported half-lives of 216 days and 1440 days when applied to non-sterile and sterile soils, respectively (MRID 41811801).

<u>Leaching/Adsorption/Desorption</u>: Based on batch equilibrium, radioactive hexazinone weakly adsorbs on Hanford sandy loam and Cecil sandy loam soils (Ka = 0.24 - 0.45). However, it appeared to weakly adsorb on Flanagan silt loam soil (Ka = 1.03) and strongly adsorb on Madera loam soil (Ka = 10.8). Adsorbed radioactivity was relatively easily desorbed from these soils (1/nD = 0.36 to 0.72). Furthermore, based on supplemental soil thin layer chromatography data, the soil mobility of hexazinone (Rf = 0.05 to 0.60) and its major soil degradates (Rf = 0.02 to 0.73), ranged from immobile (EPA Class 1) to mobile (EPA Class 4). In general, the relative mobility of hexazinone degradates appeared to be similar or identical to that of the parent material. The batch equilibrium study is scientifically valid and is acceptable to partially fulfill the data requirement. Aged mobility data (preferably batch equilibrium) for hexazinone metabolites are required. These data are due by 4/1/95 (MRIDs 00646262, 41528101).

<u>Field dissipation</u>: Hexazinone had dissipation half-lives of 123 to 154 days in bare ground silt loam soil in Newark, DE and bare ground silty clay loam soil in Greenville, MS. Metabolites A, A-1, B, C, and 1 were identified in soils at maximum concentrations of 0.04, 0.21, 0.31, 1.23, and 0.71 ppm, respectively. The reported data indicate that hexazinone did not move below the top 30 cm of soil (> 95% confined to the upper 30 cm of soil) at the Newark, DE site. However, hexazinone did move to a depth of 60-75 cm at the Greenville, MS site. In addition, hexazinone metabolites (listed above) leached to a depth of 75 cm in soil during the testing period.

Two of the bare soil field dissipation studies (MRID 42377901) are scientifically valid and provide acceptable data to fulfill the field dissipation data requirement. However, the bare soil field dissipation study done in California (MRID 42379201) is of uncertain value. Although the study was conducted on bare soil, < 30% recovery of the theoretical application rate was detected in the Day 0 posttreatment sample. This recovery is inadequate to confirm the validity of the study.

However, no further field dissipation data for hexazinone are needed at this time (MRID 42377901).

<u>Forestry dissipation</u>: Hexazinone dissipated with reported half-lives of 26 to 59 days and 19 to 36 days in plants for the ULW end-product site and the Velpar L end-product site, respectively. Similar half-lives of 55 to 77 days were reported for litter and soil (except litter covered soil) for the two sites. For litter covered soil, a half-life of 265 days was reported by the author. By day 365 posttreatment, hexazinone was discernible only in sediment samples. In addition, metabolites A, B, C, D, E, G, and H were discernible in various matrices (soil, water, litter and/or vegetation) samples. However, metabolite G was not confirmed by mass spectrometry. Hexazinone moved off-site through leaching and runoff. Hexazinone (0.01 to 0.04 ppm) was observed in soil at depths > 30 cm. In addition, hexazinone was detected (80 to 140 ppb) in runoff water up to 6 months post-application (MRIDs 00072664, 42336401).

# b. Environmental Fate Assessment

Based on laboratory data, hexazinone appears to be persistent and mobile in soil and aquatic environments. Field and forestry dissipation data confirm this. In addition, hexazinone was reported in runoff water (80 to 140 ppb) up to 6 months posttreatment in the forestry dissipation study. Therefore, field and laboratory data are consistent and indicate that hexazinone may be of concern for groundwater and surface water contamination. Groundwater contamination has been reported in Hawaii (0.06-0.72 ppb), Florida (0.12-2.90 ppb), Maine (0.2-29 ppb), and North Carolina (0.74-34 ppb). Hexazinone can contaminate surface waters by spray drift at application and probably for several months post-application via runoff (primarily by dissolution in runoff water). It may be persistent in some receiving surface waters (particularly those with low microbiological activities and long hydrological resident times). Based upon its low soil/water partitioning, it will probably exist primarily dissolved in the water column. Based on the octanol/water coefficient (15), hexazinone is not expected to accumulate in fish. However, supplemental confined rotational crop data indicated that hexazinone does accumulate in crops grown on treated soil. Even though additional data are needed on the mobility of degradates, the data reviewed suggests that the degradates are also persistent and mobile.

### 2. Ecological Effects

# a. Ecological Effects Data

### (1) Terrestrial Data

<u>Acute Avian Oral Toxicity:</u> Study results indicate that hexazinone is practically non-toxic to birds on an acute oral basis. Using 98% pure test material resulted in an  $LD_{50}$  of 2251 mg/kg (MRID 00073988).

Avian Subacute Dietary Toxicity: The results summarized in the table below indicate that on a subacute dietary basis, hexazinone is practically non-toxic to birds (MRIDs 00104981, 00072663, 00107878).

Test Species	Test Material	LC <sub>50</sub>	Citation (MRID)	
Mallard	97.5%	> 5,000 ppm	00104981	
Bobwhite	Bobwhite 99%		00072663	
Bobwhite	97.5%	> 5,000 ppm	00107878	

 $^1$  An LC50 of 11,346 ppm was calculated based on 3 out of 10 mortalities in the highest dose tested, which was 5000 ppm.

Avian Reproduction: Two avian reproduction studies conducted show that the No Observed Effect Concentration (NOEC) for the bobwhite quail is < 100 and for the mallard duck is > 1000 ppm. The NOEC for the bobwhite quail was based on effects to the 14 day survivors weight at 100 ppm. No effects were seen at the other doses. The mallard duck study showed no statistically significant effects. A weight reduction trend was observed in the male body weight change (MRIDs 41764901, 41764902, 41938001).

# (2) Aquatic Data

<u>Acute Freshwater Fish Toxicity - TGAI:</u> The results of studies conducted show that technical hexazinone is practically nontoxic to freshwater fish in acute exposures. The table below summarizes the results of these studies (MRIDs 00104980, 00076959).

Test Species	Test Material	LC <sub>50</sub>	Citation (MRID)	
Rainbow Trout	97.5%	> 320 ppm	00104980	
Bluegill Sunfish	97.5%	> 370 ppm	00104980	
Fathead Minnow	97.5%	274 ppm	00104980	
Bluegill Sunfish	<b>95</b> %	505 ppm	00076959	

<u>Acute Freshwater Fish - TEP:</u> The results of the studies summarized in the table below show that the 25% hexazinone product is practically non-toxic to freshwater fish in acute exposures.

Test Species	Test Material	LC <sub>50</sub>	Citation (MRID)	
Bluegill Sunfish	25%	> 1000 ppm	41235001	
Rainbow Trout	25%	> 585.6 ppm	41235002	

Early Life Stage Fish - TGAI: The results of a study done with the fathead minnow with 98% pure hexazinone resulted in a Maximum Allowable Toxicant Concentration (MATC) of 24.6 ppm. The MATC is the geometric mean of the No Observed Effect Level (NOEL), which was 17 mg/l and the Lowest Observed Effect Level (LOEL), which was 35.5 mg/l. Fish length was the parameter affected in the study (MRID 41406001).

Acute Aquatic Invertebrate Toxicity - TGAI: A study on *Daphnia magna* with 95% pure hexazinone resulted in an EC<sub>50</sub> of 151.6 ppm. This demonstrates that hexazinone is practically nontoxic to freshwater invertebrates in acute exposures (MRID 00116269).

<u>Acute Aquatic Invertebrate Toxicity - TEP:</u> A study on *Daphnia magna* with 25% pure hexazinone resulted in an  $EC_{50}$  of 339.9 ppm. This study shows that hexazinone typical end-use product is practically nontoxic to freshwater invertebrates in acute exposures (MRID 41235003).

Life Cycle Aquatic Invertebrate - TGAI: The table below summarizes the results of two studies conducted.

Test Species	Test Material	MATC	Citation (MRID)	
Daphnia magna	89.3%	20-50 ppm	00078041	
Daphnia magna	> 98%	48.5 ppm	41406002	

In the first study the affected parameter was reproduction. This study was classified as supplemental because a description of the dilution water was not sufficient, and no description of the dilution preparation was provided. The second study was also classified as supplemental because data on the dry weight of the first generation daphnids was not provided. The affected parameter was daphnid survival. The MATC is the geometric mean between the NOEL (29 mg/l) and the LOEL (81 mg/l). The combination of both studies fulfills the guideline requirements for an aquatic invertebrate reproductive test (MRIDs 00078041, 41406002).

Estuarine and Marine Toxicity - TGAI: The table below summarizes the results of three separate studies.

Test Species Test Material		Results	Citation (MRID)	
Eastern oyster	95%	48 hour EC <sub>50</sub> > 320 ppm	00047164	
Grass shrimp	<b>9</b> 5%	96 hour LC <sub>50</sub> = 78 ppm	00047164	
Fiddler crab <sup>1</sup>	<b>9</b> 5%	96 hour LC <sub>50</sub> > 1000 ppm	00047164	

<sup>1</sup>The test organism was not a recommended species.

These studies demonstrate that hexazinone is practically nontoxic to mollusks and slightly toxic to crustaceans. The estuarine/marine fish study was waived based on the low toxicity of hexazinone to freshwater fish (MRID 00047164).

## (3) Non-Target Insects Data

<u>Honey Bee Acute Contact</u>: A study conducted with 98% pure hexazinone on *Apis mellifera* resulted in an  $LD_{50}$  of > 100 Fg/bee. The results show that hexazinone is relatively nontoxic to honey bees (MRID 41216502).

# (4) Non-Target Plant Data

The acceptable phytotoxicity data on hexazinone are summarized below. The first three studies are for terrestrial plants and the remaining studies are for aquatic plants.

Test/Species	% <b>ai</b>	Results	MRID #
Seed Germination <sup>1</sup>	100	EC25 > 12.0 lbs ai/acre	43162501
Seedling Emergence <sup>2</sup>	100	See Table 1	43162501
Vegetative Vigor <sup>3</sup>	100	See Table 2	43162501
Navicula pelliculosa	100	EC50 = 12 ppb	43302701
Lemna gibba	100	EC50 = 37.4 ppb	43225101
Anabaena flos-aquae	100	EC50 = 0.21 ppm	43302701
Selenastrum capricornutum	100	EC50 = 7.0 ppb	41287001
Skeletonema costatum	100	EC50 = 12 ppb	43225102

Study is classified as core except for cucumber which is invalid. A new study is not required.

1

<sup>2</sup> Study is core for all species except for cucumber (invalid) and onion and pea (supplemental). A new study is required for cucumber and additional information is required for onion and pea.

<sup>3</sup> The study is core for all species except for cucumber. A new study for cucumber is required.

Table 1. Results of the Seedling Emergence Test					
Species	Parameter	EC25 (lbs ai/a)			
Onion <sup>1</sup>	Visual Injury				
Corn	Weight	0.019			
Wheat	Weight	0.029			
Sorghum	Weight	0.019			
Sugar Beet	Weight	0.010			
Soybean	Weight	0.055			
Pea <sup>1</sup>	Visual Injury				

Table 1. Results of the Seedling Emergence Test							
Species	Parameter	EC25 (lbs ai/a)					
Tomato	Weight	0.0064					
Rape	Weight	0.013					
Cucumber <sup>2</sup>							

<sup>1</sup> The EC25 for these two species cannot be determined because the raw data were not in a format to allow for a statistical test.

 $^{2}\;$  The results for cucumber are invalid because seeds were treated with pesticides other than hexazinone.

Table 2. Results of the Vegetative Vigor Study					
Species	Parameter	EC25 (lb ai/a)			
Onion	Shoot Weight	0.046			
Corn	Total Weight	0.071			
Wheat	Total Weight	0.020			
Sorghum	Total Weight	0.025			
Sugar Beet	Total Weight	0.012			
Soybean	Total Weight	0.025			
Pea	Shoot Weight	0.012			
Tomato	Shoot Weight	0.013			
Rape	Weight	0.011			
Cucumber <sup>1</sup>					

<sup>1</sup> The results for the cucumber are invalid because seeds were treated with pesticides other than hexazinone.

The guideline requirements for terrestrial studies are satisfied for all species except cucumber, onion and pea. New seedling emergence and vegetative vigor studies with cucumber are required. The guideline requirements for aquatic plant growth are satisfied.

# b. Ecological Effects Risk Assessment

This section consists of numerous risk assessments each covering a different combination of endpoint and exposure scenarios. Each risk assessment includes a risk quotient which combines the toxicity and exposure information. For each risk quotient there is an established value above which the risk is considered to be at a high level of concern (LOC). In addition to these high risk values, restricted use is considered when the risk quotient exceeds 0.1 for acute aquatic risk or 0.2 for acute avian risk. The generic risk quotients and their respective LOC's for each risk assessment are provided in the following table. Note that the same risk quotients are used for non-endangered and endangered species, but the acute LOC is lower for endangered species.

Endpoint/Scenario	Risk Quotient	Non-Endangered LOC	Endangered LOC
Mammalian Acute	EEC/LC <sub>50</sub>	0.5	0.1
Mammalian Chronic	EEC/LEL	1.0	1.0
Avian Acute	EEC/LC <sub>50</sub>	0.5	0.1
Avian Chronic	EEC/LEL	1.0	1.0
Aquatic Acute	EEC/LC <sub>50</sub>	0.5	0.05
Aquatic Chronic	EEC/LEL	1.0	1.0

#### **Established Levels of Concern (LOCs)**

#### **Risk to Terrestrial Animals**

Hexazinone is registered for numerous outdoor uses, including agricultural crops such as alfalfa and sugarcane, and nonagricultural uses including forests and ditch banks. Exposure to nontarget organisms can result from direct applications, spray drift from treated areas, and runoff from treated areas. Such exposures would be chronic as well as acute.

# Avian Acute Oral and Subacute Dietary Effects

**Granular Formulations:** The maximum application rate for a granular formulation is 12 lbs ai/acre. A broadcast application with no incorporation, which is the application scenario resulting in the greatest exposure, results in a risk quotient of 0.3 as shown in the calculation below.

 $mg/ft^2$  = application rate (lbs ai/acre) X 453,590 mg/lb ÷ 43,560  $ft^2/acre$ 

=  $[12 \text{ lbs ai/acre X } 453,590 \text{ mg/lb}] \div 43,560 \text{ ft}^2/\text{acre}$ 

 $= 124.96 \text{ mg/ft}^2$ 

 $LD50/ft^2 = mg/ft^2 \div [(LD50) X (bird weight in kg)]$ 

 $= 124.96 \text{ mg/ft}^2 \div [(2251 \text{ mg/kg}) \text{ X} (0.178 \text{ kg})]$ 

 $= 0.3 \text{ LD50/ft}^2$ 

The LOC for endangered species, which is 0.1, is triggered at this application rate. No other LOCs are exceeded for the granular formulation.

**Non-Granular Formulations:** The maximum Estimated Environmental Concentrations (EECs) for different substrates expected immediately after application of the non-granular formulations are presented in the following table. EECs were estimated for each use pattern.

EEC Immediately After Application for Different Application Rates in Different Substrates (in ppm from Hoerger and Kenaga (1972))								
Substrate	1.5 lbs	2 lbs	3.6 lbs	4 lbs	6 lbs	7.2 lbs	12 lbs	13.5 lbs
Short Grass	360	480	864	960	1440	1728	2280	3240
Long Grass	165	220	396	440	660	792	1320	1485
Leaves and Leafy Crops	187	250	450	500	750	900	1500	1687
Forage and Insects	87	116	209	232	348	417	696	783
Seeds	18	21	43	48	72	86	144	162
Fruits	10	14	25	28	42	50	84	94

The risk quotients = EEC/LC50, based on the above EECs are presented in the following table. The LC50 used in the calculation is 10,000 ppm. 10,000 ppm was used because all of the results of the dietary toxicity studies are expressed as greater than either 5,000 ppm or

10,000 ppm. However, the only study in which an effect was actually observed was for the bobwhite quail where there were 3 mortalities out of 10 at the highest dose tested, which was 5,000 ppm. Extrapolation to estimate an LC50 value from this information resulted in an estimate of 11,346 ppm. This together with the information available from the other studies suggests that 10,000 ppm is an appropriate estimate of the LC50.

Avian Acute Risk Quotients for Different Application Rates and Different Substrates									
Substrate         1.5 lbs         2 lbs         3.6 lbs         4 lbs         6 lbs         7.2 lbs         12 lbs         13.5 lbs									
Short Grass	< 0.1	< 0.1	< 0.1	0.1	0.1	0.2	0.2	0.3	
Long Grass	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	
Leaves and Leafy Crops	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.2	0.2	
Forage and Insects	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	
Seeds	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	
Fruits	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	

The restricted use LOC, which is 0.2, is exceeded for the three highest application rates for shortgrass, and for leaves and leafy crops for the two highest application rates. The only acute dietary study in which there were effects showed only 3 birds out of 10 dying at the highest dose tested, 5,000 ppm. No mortalities occurred in any of the studies at a dose around 3,240 ppm which is the highest residue level. In light of the responses seen in the studies there appears to be little concern for acute effects to grazing birds. The LOC for endangered species, which is 0.1, is triggered for short grass at application rates of 4 lbs. or greater; for long grass at application rates of 12 lbs. or greater; for leaves and leafy crops at 7.2 lbs. or greater; and for forage and insects at 13.5 lbs. However, due to the relatively low risk quotients for the unrefined assessment, this risk is not a major concern.

#### **Avian Chronic Effects**

The avian reproduction studies show that the NOEC for the bobwhite quail is < 100 based on effects to the 14 day survivors weight at 100 ppm. However, no effects were seen at the other doses tested which were 300 and 1,000 ppm. The NOEC for the mallard duck is > 1,000 ppm based on no statistically significant effects for any of the parameters tested. However, a weight reduction trend was observed in the parental male body weight. There was no significant dose response

in any of the avian reproduction studies. Testing at higher doses would provide more confidence in the NOEC value. However, based on the results of these two studies an NOEC of 1,000 ppm was used in the risk assessment.

Aviar	Avian Chronic Risk Quotients for Different Application Rates and Different Substrates									
Substrate	Substrate         1.5 lbs         2 lbs         3.6 lbs         4 lbs         6 lbs         7.2 lbs         12 lbs         13.5 lbs									
Short Grass	< 1	< 1	< 1	1.0	1.4	1.7	2.3	3.2		
Long Grass	< 1	< 1	< 1	< 1	< 1	< 1	1.3	1.5		
Leaves and Leafy Crops	< 1	< 1	< 1	< 1	< 1	1.0	1.5	1.7		
Forage and Insects	< 1	< 1	< 1	< 1	< 1	< 1	< 1	0.1		
Seeds	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1		
Fruits	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1		

A calculation of the risk quotients= EEC/LC50, based on the above EECs and an NOEC of 1,000 ppm is presented in the following table:

No chronic effects for birds are expected when the application rate is less than 4 lbs ai/A. Included in this use rate are alfalfa, sugarcane, pineapple, Christmas trees and conifer release. There may be a possibility of chronic effects at higher application rates, where the LOC is greater than 1, but this is not certain. Hexazinone is a persistent chemical but, considering a single application per year and its low bioaccumulation, the likelihood for chronic avian concerns even at rates greater than 6.0 lbs ai/A is minimal.

## Mammalian Acute Oral and Subacute Dietary Effects

The LC50 for small mammals is estimated from the LD50 of the rat (1200 mg/kg) and the body weight and food consumption of three representative small mammals. The LC50 is equal to the LD50 of the rat multiplied by the ratio of the body weight to the daily food consumption. A representative of a herbivore (meadow vole), a granivore (deer mouse), and of an insectivore (least shrew) are used to estimate the risk to small mammals. The estimated LC50s are shown in the following table:

Estimated LC	Estimated LC50 for Three Small Mammals Representing Different Food Habits								
Species	SpeciesBody WeightFoodEstimatedExpectedConsumptionLC50Food								
Meadow Vole	46 g	28.1 g	1964.4	grass					
Deer Mouse	13 g	2.1 g	7428.5	seeds					
Least Shrew	5 g	5.5 g	1090.9	insects					

The above estimated LC50s for each organism were used with the maximum residues [from Hoerger and Kenaga (1972)], resulting from each application rate to calculate the risk quotients (EEC/LC50) for small mammals. The results are shown in the following table:

Risk Que	otients and LOCs for '	Гhree Small Ma	mmals Assuming N	Aaximum Residues	
Use Sites	Application Rate	Species	Maximum EEC (expected food)	Risk Quotient (EEC/LC50)	LOC
Christmas Tree Plantations, Forest	2 lbs ai/acre	meadow vole	480 ppm (grass)	0.2	*HR > 0.5 *RU > 0.2
Plantings		deer mouse	21 ppm (seeds)	0.002	*ES <u>&gt;</u> 0.1
		least shrew	116 ppm (insects)	0.1	
Sugarcane, pineapple	3.6 lbs ai/acre	meadow vole	864 ppm (grass)	0.43	HR ≥ 0.5 RU ≥ 0.2
		deer mouse	43 ppm (seeds)	0.003	$\mathrm{ES} \ge 0.1$
		least shrew	209 ppm (insects)	0.19	
Forestry	6.0 lbs ai/acre	meadow vole	1440 ppm (grass)	0.73	${{\rm HR} \ge 0.5 \over {\rm RU} \ge 0.2}$
		deer mouse	48 ppm (seeds)	0.006	ES <u>&gt;</u> 0.1
		least shrew	417 ppm (insects)	0.38	
Drainage Systems, Industrial Areas, Non	12 lbs ai/acre	meadow vole	2280 ppm (grass)	1.16	$HR \ge 0.5 RU \ge 0.2$
Agricultural Rights of Way		deer mouse	144 ppm (seeds)	0.02	ES <u>&gt;</u> 0.1
		least shrew	696 ppm (insects)	0.63	

Risk Quotients and LOCs for Three Small Mammals Assuming Maximum Residues								
Use Sites	Application Rate	Species	Maximum EEC (expected food)	Risk Quotient (EEC/LC50)	LOC			
Industrial Areas, Non Agricultural Rights of	13.5 lbs ai/acre	meadow vole	3240 ppm (grass)	1.65	$HR \ge 0.5 RU \ge 0.2$			
Way, Fencerows, Hedgerows		deer mouse	162 ppm (seeds)	0.02	ES <u>&gt;</u> 0.1			
		least shrew	783 ppm (insects)	0.72				

\* HR = High Risk

\* RU = Restricted Use \* ES = Endangered Spec

ES = Endangered Species

The risk quotients range from < 0.1 to 1.65. Because some of these risk quotients exceed the established LOCs, a refined exposure assessment was done. Typical residues were used for the EEC's in the following table to calculate the risk quotients.

Risk	Risk Quotients and LOCs for Three Small Mammals Assuming Typical Residues								
Use Sites	Application Rate	Species	Typical EEC (expected food)	Risk Quotient (EEC/LC50)	LOC				
Christmas Tree	2 lbs ai/acre	meadow vole	184 ppm (grass)	0.09	HR <u>&gt;</u> 0.5				
Plantations, Forest Plantings		deer mouse	6 ppm (seeds)	0.0008	$\begin{array}{c} \text{RU} \ge 0.2\\ \text{ES} > 0.1 \end{array}$				
C C		least shrew	66 ppm (insects)	0.06					
Sugarcane, pineapple	3.6 lbs ai/acre	meadow vole	331.2 ppm (grass)	0.16	${{\rm HR} \ge 0.5 \over {\rm RU} \ge 0.2}$				
		deer mouse	10.8 ppm (seeds)	0.001	ES <u>&gt;</u> 0.1				
		least shrew	118.8 ppm (insects)	0.1					
Forestry	6.0 lbs ai/acre	meadow vole	552 ppm (grass)	0.28	HR <u>&gt;</u> 0.5				
		deer mouse	18 ppm (seeds)	0.002	$\begin{array}{c} \text{RU} \\ \hline > \\ \text{ES} \\ > \\ 0.1 \end{array}$				
		least shrew	198 ppm (insects)	0.18	_				
Drainage Systems,	12 lb ai/acre	meadow vole	1104 ppm (grass)	0.56	HR <u>&gt;</u> 0.5				
Industrial Areas, Non agricultural rights of		deer mouse	36 ppm (seeds)	0.004	$\begin{array}{c} \text{RU} \geq 0.2 \\ \text{ES} \geq 0.1 \end{array}$				
way		least shrew	396 ppm (insects)	0.36					

Risk Quotients and LOCs for Three Small Mammals Assuming Typical Residues								
Use SitesApplication RateSpeciesTypical EECRisk QuotientLOC(expected food)(EEC/LC50)								
Industrial areas, Non	13.5 lbs ai/acre	meadow vole	1242 ppm (grass)	0.6	HR > 0.5			
agricultural rights of way fencerows, hedge		deer mouse	40.5 ppm (seeds)	0.005	$\frac{\text{RU}}{\text{ES}} \ge \frac{0.2}{0.1}$			
rows		least shrew	445.5 ppm (insects)	0.41	_			

Using typical residues, the risk quotients range from < 0.1 to 0.6. The endangered species LOC of 0.1 is exceeded, for grass and insect eating mammals, at use rates of 3.6 lbs ai/acre or greater; the restricted use LOC of 0.2 is exceeded, for grass and insect eating mammals, at use rates of 6.0 lbs ai/acre or greater; and the high risk LOC is exceeded, for grass and insect eating mammals, at 12 and 13.5 lbs ai/acre. The use patterns represented by these application rates are likely to include the habitat or feeding grounds for small mammals.

**Risk to Aquatic Animals** 

**Estimated Environmental Concentrations** 

**Ground Application:** Using an application rate of 13.5 lb ai/acre, which is the highest application rate, estimated runoff to a 6 foot deep water body results in an EEC of 412 ppb for ground application, as illustrated in the calculations below.

Runoff of a pesticide from ground applications is estimated by multiplying the application rate (lbs ai/acre) by the percent runoff from a 10-acre drainage basin into a 1 acre water body. Based on hexazinone's solubility (2.98 g/100g) the maximum pesticide runoff, which is 5%, was assumed.

Runoff = application rate (lbs ai/acre) X % Runoff X 10-acre drainage basin

 $= 13.5 \text{ lbs } X \ 0.05 \ X \ 10$ 

= 6.75 lbs

EEC = runoff (lbs ai) X EEC (ppb) of a 1 lb ai/acre direct application for a 6-ft. deep water body

= 6.75 X 61 ppb = 411.75 ppb

**Aerial Application:** Using an application rate of 1.5 lb ai/acre, which is the lowest application rate, estimated residues in a 6 foot deep water body, resulting from aerial application, are 32 ppb. These calculations are illustrated below.

Residues of a pesticide from aerial applications are estimated by multiplying the application rate (lbs ai/acre) adjusted by the aerial application efficiency (60%); by the percent runoff (based on solubility) from a 10-acre drainage basin into a 1 acre water body; and adding this runoff amount to the estimated spray drift which is assumed to be 5% in the absence of spray drift data. Based on hexazinone's solubility (3.30 ppm) the maximum pesticide runoff, which is 5%, was assumed.

Runoff = application rate (lbs ai/acre) X application efficiency X %runoff X 10-acre drainage basin

 $= 1.5 \text{ lbs } X \ 0.6 \ X \ 0.05 \ X \ 10$ 

= .45 lbs

Drift = application rate X %drift

- $= 1.5 \text{ lbs } X \ 0.05$
- = 0.075 lbs

EEC = total lbs runoff + total drift X EEC (ppb) of a l lb ai/acre direct application for a 6 foot deep water body

= .525 X 61 ppb

= 32.0 ppb

The following table shows the EECs for ground and aerial applications using the maximum use rates for each use pattern.

EECs Expected Immediately After Application to a Six Foot Deep Water Body								
Use Pattern	Max. Application (lbs ai/A)	EEC Ground Application	EEC Aerial Application					
Terrestrial Feed Crop Use, Alfalfa	1.5	45.7 ppb	32 ppb					
Terrestrial Non-Food Crop, Christmas Tree	2	61 ppb	42.7 ppb					
Terrestrial Food Use, Sugarcane and Pineapple	3.6	109.8 ppb	72.8 ppb					
Forestry, Conifer Release	4	122 ppb	n/a					
Forestry	6	183 ppb	n/a					
Terrestrial Non-Food Crop, Non Agricultural Rights of Way, Florida Only	7.2	219.6 ppb	n/a					
Terrestrial Non-Food Crop and Aquatic Non-Food Drainage Systems	12	366 ppb	256.2 ppb					
Terrestrial Non-Food Crop and Aquatic Non-Food Industrial, Texas Only	13.5	411.7 ppb	n\a					

No LOC's for fish or aquatic invertebrates are exceeded by the highest EEC, which is 412 ppb for the 13.5 lb ai/acre application rate and using the most sensitive species in each category. The freshwater acute risk quotients (RQ) for this application rate are: 0 for aquatic invertebrates (RQ=.4/152) and 0 for fish (RQ=.4/274). The freshwater chronic risk quotients are: 0.02 (RQ=.4/20) for aquatic invertebrates and 0.02 (RQ=.4/24.6) for fish. The estuarine/marine risk quotient for the most sensitive species, the grass shrimp, is .01 (RQ=.4/78).

### **Risk to Terrestrial, Semi-Aquatic and Aquatic Plants**

Exposure of terrestrial and aquatic plants to hexazinone is estimated based on expected runoff from a maximum application rate for ground application; and from runoff and drift for aerial application. Direct applications by ground on forests and rights of way are also a concern because endangered and other non-target plants growing in forests and rights-of-way will be directly exposed to the pesticide.

**Terrestrial Plants:** The use of hexazinone exceeds the levels of concern for nontarget terrestrial endangered and non-endangered plants. The levels of concern are exceeded for all application rates for both ground and aerial application. The following table contains the EECs for different scenarios and the corresponding risk quotients. The runoff scenario used for areas adjacent to a use site is 1 treated acre draining into a 1 acre site. The scenario for wet areas is 10 treated acres draining into a 1 acre site. Aerial application is assumed to result in 5% drift.

Risk to Terrestrial and Semi-Aquatic Plants Resulting from the Use of Hexazinone										
Use Site	Application		EEC (lbs ai/acre) and Risk Quotients (EEC/EC25)						LOC	
	Rate	Adj	Adjacent to a Site			Wet Areas		ted Site irect ication)		
			EEC	RQ	EEC	RQ	EEC	RQ		
Agricultural Rights of Way	1.125 lbs ai/acre	Ground <sup>1</sup>	0.056	8.8	0.56	88.9	1.125	178.5	1	
Alfalfa	1.5 lbs ai/acre	Ground <sup>1</sup>	0.075	11.9	0.75	119.0	n/a	n/a		
		Aerial <sup>2</sup>	0.12	19	0.53	83.3	n/a	n/a		
		Aerial <sup>3</sup>	0.075	6.8	0.075	48.2	n/a	n/a		
Forestry	6.0 lbs ai/acre	Ground <sup>1</sup>	0.3	47.6	3.0	476	6.0	952		
		Aerial <sup>2</sup>	0.48	76.2	2.1	333	3.6 <sup>4</sup>	$327.2^{4}$		
		Aerial <sup>3</sup>	0.3	27.2	0.3	27.2				
Non- Agricultural Areas	13.5 lbs ai/acre	Ground <sup>1</sup>	0.675	107.1	6.75	1071	13.5	2142.8		

<sup>1</sup> (runoff), EC25 = 0.0063 lbs ai/acre Seedling Emergence Study <sup>2</sup> (runoff), EC25 = 0.0063 lbs ai/acre Seedling Emergence Study

<sup>2</sup> (runoff + drift), EC25 = 0.0063 Seedling Emergence Study <sup>3</sup> (drift or h) EC25 = 0.011 lbs si (or a Vostatius Visco Study)

<sup>3</sup> (drift only), EC25 = 0.011 lbs ai/acre Vegetative Vigor Study

<sup>4</sup> (direct), EC25 = 0.011 lbs ai/acre Vegetative Vigor Study

**Aquatic Plants:** The use of hexazinone exceeds the levels of concern for aquatic plants (freshwater and estuarine/marine). The levels of concern are exceeded for all application rates using ground or aerial application.

The EECs for all uses except alfalfa are calculated based on runoff from a 10 acre drainage basin into a 1 acre pond which is 6 inches deep. The alfalfa scenario is a 10 acre drainage basin into a 1 acre pond which is 6 feet deep. Aerial application is assumed to result in 5% drift.

Risk to Aquatic Plants Resulting from the Use of Hexazinone; RQ = EEC/EC50; EC50 is 7 ppb for <i>Selenastrum</i> capricornutum									
Use Site	Application	Direct/ Indirect	EF	EEC (ppb) and Risk Quotient					
	Rate	Application	Ground A	pplication	Aerial Ap	plication			
			EEC	RQ	EEC	RQ			
Agricultural	1.125 lbs	Indirect	411	58.7	n/a	n/a			
Rights of Way	ai/acre	Direct	852.8	117.9	n/a	n/a	1		
Alfalfa	1.5 lbs ai/acre	Indirect	47.8	6.5	32.3	4.6			
Forestry	6.0 lbs ai/acre	Indirect	2202	314.6	1541.4	220.2			
		Direct	4404	629.1	2642.4	377.4			
Non-Agricultural	13.5 lbs	Indirect	4954.5	707.8	n/a	n/a			
Areas	ai/acre	Direct	9909	1415.6	n/a	n/a			

EEC Calculation for Terrestrial Plant Exposure

### Application Rate - 1.125 lbs ai/acre

- 1. <u>Unincorporated Ground Application</u> 1.125 lbs ai/acre X 5% runoff X 1 acres = 0.056 lbs ai
- 2. <u>Direct Application</u> 1.125 lbs ai/acre

# Application Rate - 1.5 lbs ai/acre

- 1. Unincorporated Ground Application  $\overline{1.5 \text{ lbs ai/acre X 5\% runoff X 1 acres}} = 0.075 \text{ lbs ai}$
- 2. <u>Aerial Application</u>
  a. Runoff: (from site after application)
  1.5 lbs ai/acre X 60% efficiency X 5% runoff X 1 acres = 0.045 lbs ai
  - b. Drift: (from site during application) 1.5 lbs ai/acre X 5% (drift) = 0.075 lbs ai
  - c. Total Loading = Runoff + Drift
  - = 0.045 + 0.075 = 0.12 lbs ai

3. <u>Aerial Drift Calculation</u> Drift: (from site during application) 1.5 lbs ai/acre X 5% (drift) = 0.075 lbs ai

# Application Rate - 6 lbs ai/acre

1.	$\frac{\text{Unincorporated Ground Application}}{6.0 \text{ lbs ai/acre X 5\% runoff X 1 acres} = 0.3 \text{ lbs ai}$
2.	$\frac{\text{Aerial Application}}{\text{a. Runoff: (from site after application)}}$ 6 lbs ai/acre X 60% efficiency X 5% runoff X 1 acres = 0.18 lbs ai
	b. Drift: (from site during application) 6.0 lbs ai/acre X 5% (drift) = 0.3 lbs ai
	c. Total Loading = Runoff + Drift = $0.18 + 0.3 = 0.48$ lbs ai
3.	Aerial Drift CalculationDrift: (from site during application)6 lbs ai/acre X 5% (drift) = $0.3$ lbs ai
4.	Direct Application (ground)

- 6 lbs ai/acre5. Direct Application (aerial)
  - $\frac{2 \text{ local reprint (actual)}}{6 \text{ lbs ai/acre X 60\% efficiency}} = 3.6 \text{ lbs ai}$

# Application Rate - 13.5 lbs ai/acre

- 1. Unincorporated Ground Application 13.5 lbs ai/acre X 5% runoff X 1 acres = 0.675 lbs ai
- 2. <u>Direct Application</u> 13.5 lbs ai/acre

EEC Calculation for Semi-Aquatic Plant Exposure [Semi-Aquatic plants are plants that require saturated soils for some part of their life cycle (wetlands, marshes, bogs)]

#### Application Rate - 1.125 lbs ai/acre

- 1. Unincorporated Ground Application  $\overline{1.125 \text{ lbs ai/acre X 5\% runoff X 10}} = 0.56 \text{ lbs ai}$
- 2. <u>Direct Application</u> 1.125 lbs ai/acre

### **Application Rate - 1.5 lbs ai/acre**

- 1. Unincorporated Ground Application  $\overline{1.5 \text{ lbs ai/acre X 5\% runoff X 10 acres}} = 0.75 \text{ lbs ai}$
- 2. <u>Aerial Application</u>
  a. Runoff: (from site after application)
  1.5 lbs ai/acre X 60% efficiency X 5% runoff X 10 acres = 0.45 lbs ai

b. Drift: (from site during application)
1.5 lbs ai/acre X 5% (drift) = 0.075 lbs ai

c. Total Loading = Runoff + Drift = 0.45 + 0.75 = 0.53 lbs ai

3. <u>Aerial Drift Calculation</u> Drift: (from site during application) 1.5 lbs ai/acre X 5% (drift) = 0.075 lbs ai

### **Application Rate - 6 lbs ai/acre**

- 1. Unincorporated Ground Application  $\overline{6.0 \text{ lbs ai/acre X 5\% runoff X 10 acres}} = 3 \text{ lbs ai}$
- 2. <u>Aerial Application</u>
  a. Runoff: (from site after application)
  6 lbs ai/acre X 60% efficiency X 5% runoff X 10 acres = 1.8 lbs ai

b. Drift: (from site during application) 6.0 lbs ai/acre X 5% (drift) = 0.3 lbs ai

c.	Total	Loa	ading	= I	Runoff +	Drift
=	1.8	+	0.3	=	2.1 lbs a	i

- 3. <u>Aerial Drift Calculation</u> Drift: (from site during application)
  6.0 lbs ai/acre X 5% (drift) = 0.3 lbs ai
- 4. Direct Application 6.0 lbs ai/acre

### **Application Rate - 13.5 lbs ai/acre**

- 1. <u>Unincorporated Ground Application</u> 13.5 lbs ai/acre X 5% runoff X 10 acres = 6.75 lbs ai
- 2. <u>Direct Application</u> 13.5 lbs ai/acre

EEC Calculation for Aquatic Plant Exposure

# Application Rate - 1.125 lbs ai/acre (Agricultural Rights of Way)

1. <u>Unincorporated Ground Application</u> a. Indirect Application

1.125 lbs ai/acre X 5% runoff X 10 acres = 0.56 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 734 ppb X 0.56 lbs = 411.04 ppb

b. Direct Application

1.125 lbs ai/acre

Therefore: EEC = 1.125 lbs at X 734 ppb = 825.75 ppb

### **Application Rate - 1.5 lbs ai/acre (Alfalfa)**

- 1. <u>Unincorporated Ground Application</u> a. Indirect Application
  - 1.5 lbs ai/acre X 5% runoff X 10 acres = 0.75 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 feet deep is 61 ppb

Therefore: EEC = 61 ppb X 0.75 lbs = 45.75 ppb

- 2. <u>Aerial Application</u> a. Indirect Application
  - i. Runoff: (from site after application)

1.5 lbs ai/acre X 60% efficiency X 5% runoff X 10 acres = 0.45 lbs ai

ii. Drift: (from site during application)

1.5 lbs ai/acre X 5% (drift) = 0.075 lbs ai

iii. Total Loading = Runoff + Drift

= 0.45 + 0.075 = 0.53 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 feet deep is 61 ppb.

Therefore: EEC = 61 ppb X 0.53 lbs ai = 32.33 ppb

### **Application Rate - 6 lbs ai/acre (Forestry)**

1. Unincorporated Ground Application a. Indirect Application 6.0 lbs ai/acre X 5% runoff X 10 acres = 3 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 734 ppb X 3 lbs ai = 2202 ppb

b. Direct Application 6.0 lbs ai/acre

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 6.0 lbs at X 734 ppb = 4404 ppb

2. Aerial Application

a. Indirect Application

Runoff: (from site after application)
bs ai/acre X 60% efficiency X 5% runoff X 10 acres = 1.8 lbs ai
Drift: (from site during application)
0 lbs ai/acre X 5% (drift) = 0.3 lbs ai
Total Loading = Runoff + Drift
1.8 + 0.3 = 2.1 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 734 ppb X 2.1 lbs ai = 1541.2 ppb

b. Direct Application 6.0 Ibs ai/acre X 60% efficiency = 3.6 lbs ai/acre

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 734 ppb X 3.6 lbs ai = 2642.4 ppb

### Application Rate - 13.5 lbs ai/acre (Non-Agricultural Areas)

1. <u>Unincorporated Ground Application</u> a. <u>Indirect Application</u> 13.5 lbs ai/acre X 5% runoff X 10 acres = 6.75 lbs ai

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb

Therefore: EEC = 734 ppb X 6.75 lbs = 4954.8 ppb

b. Direct Application 13.5 lbs ai/acre

EEC of 1 lb ai direct application to 1 acre water body 6 inches deep is 734 ppb.

Therefore: EEC = 13.5 lbs ai X 734 ppb = 9909 ppb

**Risk to Endangered Species** 

Hexazinone exceeds the endangered species LOCs for both aquatic and terrestrial plants at all use rates. The risk quotients range from 4.6 to 2142.8.

No concern exists for endangered aquatic animals. Hexazinone exceeds the endangered species level of concern, using typical residues, for grass and insect eating mammals at use rates of 3.6 lbs ai/acre or greater. Using the maximum application rate for the granular formulation, which is 12 lbs ai/acre, and assuming no soil incorporation results in a risk quotient of 0.3 which exceeds the acute avian LOC for endangered birds.

At the present time EPA is working with the Fish and Wildlife Service and other Federal and State agencies to develop a program to avoid jeopardizing the continued existence of the identified species by the use of pesticides. When this program goes into effect endangered species precautionary labeling will be required.

# 3. Data Requirements

**Ecological Effects:** 

- 123-1(a) Seed Germination/Seedling Emergence (cucumber, onion, pea)
- 123-1(b) Vegetative Vigor (cucumber)

**Environmental Fate:** 

- 163-1 Leaching/Adsorption/Desorption
- 164-2 Aquatic Field Dissipation (not required if all aquatic uses are removed from hexazinone product labels)
- 166-1 Prospective Groundwater Monitoring Study
- 201-1 Droplet Size Spectrum
- 202-1 Drift Field Evaluation-

### 4. Summary of LOC Exceedance and Risk Characterization

#### a. Ecological Effects

Hexazinone exceeds the levels of concern for both endangered and non-endangered aquatic and terrestrial plants. The risk quotients range from 4.6 to 2142.8 depending on the application rate.

Contamination of aquatic sites within or adjacent to treated areas could be of ecological significance and may be exacerbated by the persistence and mobility of the chemical. Aquatic plants are an important component of the ecosystem. Algae are the link between solar radiation, aquatic animals and humans which are dependent on the oxygen produced by algae during photosynthesis. Algae are responsible for maintaining the quality of the aquatic habitat for fish, while at the same time providing food for fish either directly or indirectly. Thus, effects to aquatic plants expected from the use of hexazinone may alter aquatic ecosystems. The severity of these effects is dependent upon the frequency of the exposure to hexazinone and the nature of the receiving body. For example, the conifer release may be representative of a situation in which the pesticide is used only once in several years and the receiving body is a stream. In contrast, sugarcane fields may be treated once per year and drain into a shallow marsh. A much greater effect would be expected to occur from the latter use.

Hexazinone exceeds levels of concern for both endangered and non-endangered small mammals at several of the higher application rates. Using typical residues as the EEC estimates, the risk quotients range from < 0.1 to 0.6. Using the maximum application rate for the granular formulation, which is 4 lbs ai/acre, and assuming no soil incorporation results in a risk quotient of 0.1 which is the acute avian LOC for endangered birds.

Risk mitigation measures for ecological effects are discussed in Parts IV and V of this document.

### b. Ground Water

Hexazinone exceeds the following Levels of Concern for ground water:

**Ground Water Quality:** Hexazinone exhibits many of the properties and characteristics associated with chemicals that have been detected in ground water. Considering the mode of activation of the chemical; i.e., rainfall within two weeks of an application, there is a strong possibility of movement to ground water, especially in vulnerable areas. For these reasons, hexazinone use is likely to have a significant impact on ground-water quality. Hexazinone has been detected in ground water in Hawaii (0.06-0.72 ppb), Florida (0.12-2.90 ppb), Maine (0.2-29 ppb), and North Carolina (0.74-34 ppb), although well below the Health Advisory Level.

Based on this information, the Agency is requiring a ground water advisory and other risk mitigation measures that are discussed in Parts IV and V of this document.

The ecological effects assessment indicates that hexazinone presents a concern to terrestrial and aquatic plants. In areas where irrigation water is contaminated with hexazinone, or where ground water discharges to surface water, hexazinone residues in ground water could pose a threat to plants.

# IV. RISK MANAGEMENT AND REREGISTRATION DECISION

### A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing hexazinone active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing hexazinone. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of hexazinone, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of hexazinone and to determine that hexazinone can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing hexazinone as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix B. Although the Agency has found that all uses of hexazinone are eligible for

reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing hexazinone, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

### 1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient hexazinone, the Agency has sufficient information on the health effects of hexazinone and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing hexazinone for all uses are eligible for reregistration.

The Agency has determined that hexazinone products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Tolerances for alfalfa green forage, alfalfa hay, grass hay, meat/meat byproducts and milk could not be reassessed, however enough data were available to conduct a risk assessment. The Agency believes that existing tolerances are protective until data are available for reassessment.

# 2. Eligible and Ineligible Uses

The Agency has determined that all uses of hexazinone are eligible for reregistration.

## **B.** Regulatory Position

The following is a summary of the regulatory positions and rationales for hexazinone. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

## 1. Tolerance Reassessment

## TOLERANCE REASSESSMENT SUMMARY

The combined limit of quantitation for hexazinone residues by the method in PAM, Vol. II, is 0.55 ppm. The highest limit of quantitation for an individual hexazinone metabolite is 0.2 ppm, for metabolite C. The tolerance level for non-detectable residues will be 0.2 ppm. Metabolite F should be included in the tolerance expression if detected by the current analytical method. If not detected, it will be accounted for during the risk assessment.

# Tolerances Listed Under 40 CFR §180.396:

The tolerances listed in 40 CFR §180.396 are for the combined residues of hexazinone and its metabolites (calculated as hexazinone) in or on plant and animal commodities. Sufficient data are available to ascertain the adequacy of the established tolerance listed in 40 CFR for blueberries, pineapple, and sugarcane, provided all labels are amended to impose appropriate PHIs, and provided the sugarcane tolerance is changed to a tolerance with a regional registration in a separate subsection of 40 CFR 180.396. Data show that hexazinone concentrates in certain processed fractions of alfalfa, pineapple, and sugarcane. The Agency has determined that establishing food and feed additive tolerances for these commodities is appropriate and consistent with the Delaney Clause of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance for residues on grass hay is pending under PP 1F3967.

As there are no Codex tolerances for residues of hexazinone and its metabolites in plant and animal commodities, there is no question with respect to Codex/U.S. tolerance compatibility.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition	
Tolerances listed under 180.396				
Alfalfa green forage	2.0	<b>Reserved</b> <sup>1</sup>	Alfalfa, forage	
Alfalfa hay	8.0	Reserved <sup>1</sup>	Alfalfa, hay	
Blueberries	0.2	<b>0</b> .2 <sup>2</sup>		
Cattle, fat	0.1	Reserved <sup>1</sup>		
Cattle, mbyp	0.1			
Cattle, meat	0.1			
Eggs	0.1	Revoke <sup>3</sup>		
Goats, fat	0.1	Reserved <sup>1</sup>		
Goats, mbyp	0.1			
Goats, meat	0.1			
Grasses, pasture	10	Combine into one tolerance at 10 ppm	Grass, forage	
Grasses, range	10			
Grass, hay	30 (pending)	<b>Reserved</b> <sup>1</sup>		
Hogs, fat	0.1	Reserved <sup>1</sup>		
Hogs, mbyp	0.1			
Hogs, meat	0.1			
Horses, fat	0.1			
Horses, mbyp	0.1			

# TOLERANCE REASSESSMENT SUMMARY

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Horses, meat	0.1		
Milk	0.1		
Pineapple (whole fruit)	0.5	$0.2^{2}$	Pineapples
Pineapple, fodder	5.0	<b>Revoke</b> <sup>4</sup>	
Pineapple, forage	5.0	<b>Revoke</b> <sup>4</sup>	
Poultry, fat	0.1	Revoke <sup>3</sup>	
Poultry, mbyp	0.1		
Poultry, meat	0.1		
Sheep, fat	0.1		
Sheep, mbyp	0.1	<b>Reserved</b> <sup>1</sup>	
Sheep, meat	0.1		
Sugarcane	0.2	0.2 <sup>2, 5</sup>	

1. Data on hexazinone are inadequate to reassess tolerances.

2. Tolerances for non-detectable residues in plant commodities will be set at 0.2 ppm, the limit of quantitation for metabolite C (blueberries, sugarcane, pineapple).

3. The maximum residue expected in poultry tissues would be 0.005 ppm, an order of magnitude below the limit of detection for hexazinone metabolites. Tolerances for hexazinone in poultry commodities are not required and the existing tolerances for these commodities should be revoked.

4. Not a regulated raw agricultural commodity (RAC).

5. Residue data were not provided for Florida, the major growing site in the U.S. for sugarcane. Revoke tolerance and reestablish as a tolerance with regional registration placed in a separate section of 40 CFR 180.396.

The Agency cannot conclude that hexazinone has been found to induce cancer within the meaning of the Delaney clause and therefore food and feed additive regulations are not barred by the Delaney clause of the Federal Food Drug and Cosmetic Act. Currently there are no existing food or feed additive tolerances for hexazinone. Food/feed additive tolerances must be established for sugarcane molasses, alfalfa meal, and pineapple processing residue.

Both food and feed additive tolerance petitions have been submitted for sugarcane molasses and bagasse (FAP #4H5683). The proposed food and feed additive tolerances of 0.5 ppm on sugarcane molasses are appropriate. The proposed tolerance of 0.5 ppm on sugarcane bagasse is not needed because sugarcane bagasse is no longer considered a major livestock feed; this proposal should be withdrawn.

Residue data were not submitted and are not required on alfalfa meal, but residues can be translated from alfalfa hay to meal because of similar dry matter content (90% in hay, 91% in meal). Accordingly, a food additive tolerance of 8.0 ppm for alfalfa meal is required.

Residues of metabolite B have been shown to concentrate in bran (pineapple processing residue), but the concentration factor could not be determined because residues of parent and metabolites A through F were nondetectable on the harvested fruit. Data have been generated on pineapple processing residue; once these data have been evaluated, a feed additive tolerance for pineapple processing residue will be required.

# 2. Restricted Use Classification

Hexazinone is not currently classified for restricted use and no change in its classification is being imposed by this document. However, hexazinone may be considered for restricted use for ground water concerns once the Restricted Use Rule is finalized.

### 3. **Reference Dose**

The RfD is 0.05 mg/kg body weight/day, based on a No Observable Effect Level (NOEL) of 5.0 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was based on a one year feeding study in dogs (MRID 42162301) which demonstrated liver effects in both males and females at 38 mg/kg bwt/day (OPP RfD Peer Review Committee on February 11, 1993). The ARC for the overall U.S. population from all tolerances is  $3.5 \times 10^{-3}$  mg/kg bwt/day or 7% of the RfD. The subgroup most highly exposed, non-nursing infants (< 1 yr) has an ARC from all uses of 2.0 x  $10^{-2}$  mg/kg bwt/day, representing 40% of the RfD. The children (1-6 yrs) subgroup has an ARC from all tolerances of  $1.0 \times 10^{-2}$  mg/kg bwt/day, or 20% of the RfD. Anticipated residues were used for all commodities. However, a source of overestimation exists in that 100 percent crop treated was assumed for all commodities.

# 4. Cancer Classification

Hexazinone was classified as to its carcinogenic potential as a "Group D" chemical by the OPP Carcinogenicity Peer Review Committee on July 27, 1994.

## 5. Risk Mitigation

**Groundwater Concerns:** Due to groundwater concerns, the following mitigation steps are required:

• Hexazinone has been detected in ground water. Therefore, **all product labels must carry a groundwater advisory.** The label language for this advisory can be found in Part V of this document.

- Registrants must report **any domestic hexazinone ground water detections at any levels** to the Agency.
- Because of particular ground water concerns in Maine, the Agency is requiring that duPont prepare a report of the ongoing research in that state in regard to ground water detections. The details of this requirement are contained in Part V of this document.
- DuPont is also required to submit educational materials that are currently being developed to the Agency. These materials should be in specific regard to product stewardship and address the potential of ground water contamination from the use of hexazinone.

In addition to these measures, the Agency is requiring that a prospective ground water monitoring study be conducted for hexazinone to determine the potential of this chemical to leach to ground water. Site selection will be done in consultation with the Agency.

**Surface Water Concerns:** Due to surface water concerns, the following mitigation step is required:

• DuPont, the technical manufacturer of hexazinone, is in the process of consolidating precautionary label language in regard to surface water contamination for all of their hexazinone products. After the Agency has reviewed and approved these label amendments, all registrants will be required to amend their hexazinone labels in the same way.

**Risk to Non-Target Terrestrial and Aquatic Plants and Small Mammals**: Due to the risk to non-target plants, the following mitigation step is required:

• Reduction of the maximum application rate from 13.5 lb ai/acre to 8 lb ai/acre.

# 6. Spray Drift Label Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labeling statements. This future labeling may be required for all hexazinone products that may be applied aerially to agricultural crops.

# 7. Endangered Species Statement

Hexazinone exceeds the level of concern at all use rates for endangered aquatic and terrestrial plants that may be exposed. The risk quotients range from 4.6 to 2142.8.

Hexazinone exceeds levels of concern for endangered small mammals at use rates of 3.6 lbs ai/acre and up. Using typical residues as the EEC estimates, the risk quotients range from < 0.1 to 0.6. Using the maximum application rate for the granular formulation, which is 4 lbs ai/acre, and assuming no soil incorporation results in a risk quotient of 0.1 which is the acute avian LOC for endangered birds.

At the present time EPA is working with the Fish and Wildlife Service and other Federal and State agencies to develop a program to avoid jeopardizing the continued existence of the identified species by the use of pesticides. When this program goes into effect endangered species precautionary labeling will be required.

# 8. Labeling Rationale

### a. Compliance with Worker Protection Standard (WPS)

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the WPS (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person. **Post-Application Restrictions** 

**WPS Entry Restrictions:** Some registered uses of hexazinone are within the scope of the WPS.

**Restricted Entry Interval:** Under the WPS, interim restricted entry intervals (REI) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing hexazinone as an active ingredient, **the Agency is establishing a 48-hour REI** for each use of the product that is within the scope of the WPS. The basis for this requirement is that hexazinone is categorized as toxicity category I (severe) for eye irritation potential. The WPS REI in effect until now was 24 hours. The Agency notes that the WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces and it believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with hexazinone.

**Early-Entry PPE:** The WPS establishes very specific restrictions on entry by workers to areas that remain under a REI if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a REI are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways:

- 1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.
- 2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since hexazinone is classified as category IV for skin irritation potential and for acute dermal toxicity and EPA has no special concerns about other adverse effects, the PPE required for early entry is the minimum early entry PPE permitted under the WPS: coveralls, chemical-resistant gloves, shoes, and socks. Since hexazinone is classified as category I for eye irritation potential, protective eyewear is also required.

**Non-WPS Entry Restrictions:** Some registered uses of hexazinone are outside the scope of the WPS. The Agency is establishing the following entry restriction for all non-WPS occupational uses of hexazinone end-use products (except pellet formulations): "Do not enter or allow others to enter the treated area until sprays have dried." The basis for this requirement is that hexazinone is categorized as toxicity category I (severe) for eye irritation potential.

## **Personal Protective Equipment (PPE) Requirements**

**Handler PPE:** For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If the Agency has no special concerns regarding other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or certain adverse effects, such as allergic effects or other effects (cancer, developmental toxicity, reproductive effects, etc):

- the Agency may establish in the RED minimum or "baseline" handler PPE requirements for that active ingredient that pertain to all or most occupational end-use products containing that active ingredient.
- these minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product, and
- the more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are no special toxicological concerns about hexazinone that warrant the establishment of active-ingredient-based PPE requirements for pesticide handlers.

# V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

# A. Manufacturing-Use Products

## 1. Additional Generic Data Requirements

The generic data base supporting the reregistration of hexazinone for the above eligible uses has been reviewed and determined to be substantially complete. The following generic data will be required on a confirmatory basis:

- 123-1(a) Seed Germination/Seedling Emergence (cucumber, onion, pea)
- 123-1(b) Vegetative Vigor (cucumber)
- 163-1 Leaching, Adsorption/Desorption
- 164-2 Aquatic Field Dissipation (not required if all aquatic uses are removed from hexazinone product labels)
- 165-1 Confined Rotational Crops
- 166-1 Prospective Groundwater Monitoring Study
- 201-1 Droplet Size Spectrum
- 202-1 Drift Field Evaluation
- 171-4d Residue Analytical Method Ruminant
- 171-4e Storage Stability (Alfalfa, Metabolite C for Grass)
- 171-4j Magnitude of the Residue in Meat/Milk
- 171-4k Magnitude of the Residue in Grass Hay and Alfalfa Seed Screenings

## 2. Labeling Requirements for Manufacturing-Use Products

There are no labeling requirements for manufacturing-use products.

### **B.** End-Use Products

## 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

## 2. Labeling Requirements for End-Use Products

Due to risk mitigation measures imposed, several label requirements have been imposed. Please refer to section V(C) for details.

## a. Worker Protection Standard (WPS)

The RED evaluation of the REI established by the WPS concluded that **the REI should be changed to 48 hours**. The WPS REI in effect until now was 24 hours. The Agency found no reason to retain the 24-hour interim REI placed on hexazinone products by PR Notice 93-7. The new 48-hour REI must be inserted into the standardized REI statement required by PR Notice 93-7.

The PPE for early entry under the 48-hour REI for hexazinone is coveralls, chemical resistant gloves, shoes plus socks, and protective eyewear. These PPE must be inserted into the early entry PPE statement required by PR Notice 93-7.

## b. Ground Water Labeling

• All product labels must carry the following advisory: "This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

# c. Surface Water Labeling

• DuPont, the technical manufacturer of hexazinone, is in the process of consolidating label language relating to surface and ground water for all of their hexazinone products. After the Agency has reviewed and approved these label amendments, all hexazinone labels must carry this labeling.

# 3. Other Ground Water Requirements

- The Agency is requiring that registrants report **any domestic hexazinone ground water detections at any levels** to the Agency.
- The Agency is requiring that duPont prepare a report of the ongoing research in Maine in regard to ground water detections in blueberry use areas and submit it to the Agency. This report must be submitted within one year from receipt of this RED document. DuPont must do a one year follow-up to the original report as well.
- The Agency is also requiring that duPont submit an analytical method **or** immunoassay for detection of hexazinone in ground water. This must be submitted within one year from receipt of this RED document.
- DuPont is required to submit educational materials that are currently being developed to the Agency. These materials should be in specific regard to product stewardship and address the potential of ground water contamination from use of hexazinone. This information must be submitted within one year from receipt of this RED document.

# 4. Risk To Non-Target Plants and Small Mammals

Due to the risk to non-target plants and small mammals, the following mitigation step is required:

• Reduction of the maximum application rate from 13.5 lb ai/acre to 8 lb ai/acre.

# C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; <u>Federal Register</u>, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell hexazinone products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

# **VI. APPENDICES**

# **APPENDIX A.** Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Form(s	) Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

#### FOOD/FEED USES

GRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGERO	WS		Use Gi	roup	: TE	RRESTRIAL	J FEED CROP									
pray., When needed., Boom sprayer.	EC	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	FL					C46, G01(37), G83(37)
	EC	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	LA					C46, G01(37), G83(37)
	EC	NA	1.125 lb A	*	NS	NS	NS	NS	NS	NS	AL					C46, G01(37), G83(37)
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS						C46, G01(60), H12(60)
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	LA					C46, G01(37), G83(37)
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	MS					C46, G01(37), G83(37)
FALFA			Use G	roup	: TE	RRESTRIAL	FEED CROP									
w volume spray (concentrate)., Dormant., .rcraft.	EC	NA	1.5 lb A	*	NS	1/1 yr	NS	NS	NS	NS		MT,	SD,	ND,	WY	C46, G01(30), G83(30)
	SC/S	NA	1.35 lb A 1.35 lb A 1.35 lb A	М	NS	1/1 yr	NS	NS	NS	NS		MT,	ND,	SD,	WY	C46, G01(30), G83(30)
w volume spray (concentrate)., Dormant., om sprayer.	EC	NA	1.5 lb A	*	NS	1/1 yr	NS	NS	NS	NS		MT,	SD,	ND,	WY	C46, G01(30), G83(30)
	SC/S	NA	1.35 lb A 1.35 lb A 1.35 lb A	М	NS	1/1 yr	NS	NS	NS	NS		МΤ,	ND,	SD,	WY	C46, G01(30), G83(30)
w volume spray (concentrate)., Late pring., Aircraft.	EC	NA	1.5 lb A	*		NS	NS	NS	NS	NS	001, 013					C46, G01(30), G83(30)
					fo		plication m									eographic areas cific application
	SC/S	NA	.9 lb A	*	NS	NS	NS	NS	NS	NS	001, 013	MT,	ND	SD,	WY	C46, G01(30), G83(30)

Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
less noted	unless noted Max. /crop /year otherwise)/A]			Codes
otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
	cycle			
	less noted	Rate (AI un- less notedRate (AI Tex. @ Max. Rate unless noted unless noted Max. /crop /year otherwise)/A]otherwise)otherwise)Dose cycle/crop /year	Rate (AI un- less notedRate (AI Tex. @ Max. Rate unless noted unless noted Max. /crop /year otherwise)/A]Interv Entry (days) Interv (days) Interv [day(s)otherwise)otherwise)Dose cycle/crop /year[day(s)	Rate (AI un-       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry Allowed       Disallowed         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv         otherwise)       otherwise) Dose cycle       /crop /year       [day(s)]

ALFALFA (con't)			Use	Grou	p: TH	ERRESTRI	IAL FEED CROP	(con'	t)							
Low volume spray (concentrate)., Late spring., Boom sprayer.	EC	NA	1.5 lb A	*			NS	NS and M	NS NS							C46, G01(30), G83(30) eographic areas
					fo		application m									cific application
	SC/S	NA	.9 lb A	*			NS	NS and M	NS NS		l, 013					C46, G01(30), G83(30) eographic areas
							application m			Juiceb	are the speet		uII	owab	10 9	cographic areas
Low volume spray (concentrate)., Seed crop., Aircraft.	EC	NA	1.5 lb A	*	NS	NS	NS	NS	NS NS	G CA		MT,	SD,	ND,	WY	C14, C46, G01(30), G83(30)
	SC/S	NA	1.35 lb A 1.35 lb A 1.35 lb A	M	I	NS	NS	NS	NS NS	G CA		ΜT,	ND,	SD,	WY	C14, C46, G01(30), G83(30)
Low volume spray (concentrate)., Seed crop., Boom sprayer.	EC	NA	1.5 lb A	*	NS	NS	NS	NS	NS NS	S CA		ΜT,	SD,	ND,	WY	C14, C46, G01(30), G83(30)
	SC/S	NA	1.35 lb A 1.35 lb A 1.35 lb A	Μ	[	NS	NS	NS	NS NS	G CA		ΜT,	ND,	SD,	WY	C14, C46, G01(30), G83(30)
Low volume spray (concentrate)., Spring., Aircraft.	EC	NA	1.5 lb A	*	NS	1/1 yr	e ns	NS	NS NS	IA MA NH PA	, DE, IL, IN, , KY, ME, MD, , MI, MN, MO, I, NJ, NY, OH, A, RI, VT, VA, 7, WI		SD,	ND,	WY	C46, G01(30), G83(30)
	SC/S	NA	1.35 lb A	*	NS	1/1 yr	e ns	NS	NS NS	IA MA NH PA	, DE, IL, IN, A, KY, ME, MD, A, MI, MN, MO, I, NJ, NY, OH, A, RI, VT, VA, 7, WI		ND,	SD,	WY	C46, G01(30), G83(30)
Low volume spray (concentrate)., Spring., Boom sprayer.	EC	NA	1.5 lb A	*	NS	1/1 yr	c NS	NS	NS NS	IA MA NH PA	, DE, IL, IN, , KY, ME, MD, A, MI, MN, MO, I, NJ, NY, OH, A, RI, VT, VA, 7, WI		SD,	ND,	WY	C46, G01(30), G83(30)

SITE Application Type, Application Form(s	) Min. Appl.	Max. Appl. Soil Max. #	Apps Max. Dose [(	(AI Min. Re	estr. Geograph	nic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless noted	d Interv En	ntry Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /	/year otherwise)/A	A] (days) In	nterv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /ye	ear [d	day(s)]		
			cycle				

ALFALFA (con't)		Use Group: TERRESTRIAL FEB	EED CROP (con't)	
	SC/S NA	1.35 lb A * NS 1/1 yr	NS NS NS NS CT, DE, IL, IN, MT, ND, SD, WY C46, G01(30), IA, KY, ME, MD, G83(30) MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI	
Low volume spray (concentrate)., Stubble., Aircraft.	EC NA	1.5 lb A * NS 1/1 yr	NS NS NS NS CT, DE, IL, IN, MT, SD, ND, WY C46, G01(30), IA, KY, ME, MD, G83(30) MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI	
	SC/S NA	1.35 lb A * NS 1/l yr	NS NS NS NS CT, DE, IL, IN, MT, ND, SD, WY C46, G01(30), IA, KY, ME, MD, G83(30) MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI	
Low volume spray (concentrate)., Stubble., Boom sprayer.	EC NA	1.5 lb A * NS 1/1 yr	NS NS NS NS CT, DE, IL, IN, MT, SD, ND, WY C46, G01(30), IA, KY, ME, MD, G83(30) MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI	
	SC/S NA	1.35 lb A * NS 1/l yr	NS NS NS NS CT, DE, IL, IN, MT, ND, SD, WY C46, G01(30), IA, KY, ME, MD, G83(30) MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI	
Low volume spray (concentrate)., Winter., Aircraft.	EC NA	1.5 lb A * NS 1/1 yr	NS NS NS NS MT, SD, ND, WY C46, G01(30), G83(30)	
	SC/S NA	1.35 lb A F NS 1/1 yr 1.35 lb A M 1.35 lb A C	NS NS NS NS MT, ND, SD, WY C46, G01(30), G83(30)	
Low volume spray (concentrate)., Winter., Boom sprayer.	EC NA	1.5 lb A * NS 1/1 yr	NS NS NS NS MT, SD, ND, WY C46, G01(30), G83(30)	

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

ALFALFA (con't) Use Group: TERRESTRIAL FEED CROP (con't)													
	SC/S	NA	1.35 lb A 1.35 lb A 1.35 lb A	М		1/1 yr	NS	NS	NS	NS		MT, ND, SD, WY	C46, G01(30), G83(30)
Spray., Delayed dormant., Sprayer.	EC	NA	1 lb A 1 lb A .75 lb A	М		1/1 yr	NS	NS	NS	NS	WY		C46
BLUEBERRY			Use G	rouj	p: TE	RRESTRIA	L FOOD CROP						
Ground spray., Dormant., Boom sprayer.	EC	NA	2 lb A	*	NS	NS	NS	NS	NS	NS	NC		C46, H01(50)
GRASS FORAGE/FODDER/HAY			Use G	rouj	p: TE	RRESTRIA	L FEED CROP						
Spray., When needed., Boom sprayer.	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS			C46, G01(60), H12(60)
PASTURES			Use G	rouj	p∶ TE	RRESTRIA	L FEED CROP						
Basal spray., When needed., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	.66 lb	NS	NS	NS			C46
Spray., When needed., Boom sprayer.	EC	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL		C46, G01(37), G83(37)
	EC	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	FL		C46, G01(37), G83(37)
	EC	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	LA		C46, G01(37), G83(37)
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	LA		C46, G01(37), G83(37)
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	MS		C46, G01(37), G83(37)
Tree injection treatment., Summer., Injection.	EC	NA	.001585 lb ft. interval	*	NS	NS	.66 lb	NS	NS	NS			C46
Tree injection treatment., Summer., Tree injection equipment.	EC	NA	.001585 lb ft. interval	*	NS	NS	.66 lb	NS	NS	NS			C46
PINEAPPLE			Use G	rouj	p: TE	RRESTRIA	- FOOD+FEED	CROP					
Broadcast., Postharvest., Sprayer.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS			C46

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

PINEAPPLE (con't)			Use G	coup	p: TE	RRESTRIAI	L FOOD+FEED	CROP	(con't)			
Broadcast., Postplant., Sprayer.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
Broadcast., Preplant., Aircraft.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
Broadcast., Preplant., Sprayer.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
Directed spray., Postemergence., Boom sprayer.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
Directed spray., Postemergence., Knapsack sprayer.	SC/S	NA	1.8 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
Spot treatment., When needed., Sprayer.	SC/S	NA	3.6 lb A	*	NS	NS	5.4 lb	NS	NS	NS		C46
RANGELAND			Use G	coup	p∶ TE	RRESTRIAI	L FEED CROP					
Basal spray., Late winter., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	2 lb	NS	NS	NS	TX	C46
	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	NM	C46
Basal spray., Spring., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	2 lb	NS	NS	NS	ТХ	C46
	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	NM	C46
Basal spray., When needed., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	.66 lb	NS	NS	NS		C46
Spot soil treatment., Late winter., By hand	. P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS .59	5 lb	NS	NS		
Spot soil treatment., Spring., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS .59	5 lb	NS	NS		
Tree injection treatment., Summer., Injection.	EC	NA	.001585 lb ft. interval	*	NS	NS	.66 lb	NS	NS	NS		C46
Tree injection treatment., Summer., Tree injection equipment.	EC	NA	.001585 lb ft. interval	*	NS	NS	.66 lb	NS	NS	NS		C46
SUGARCANE Use Group: TERRESTRIAL FOOD+FEED CROP												
Band treatment., Fall., Boom sprayer.	SC/S	NA	.9 lb A .45 lb A		NS	1/1 yr	NS 1.3	5 lb	NS	NS	LA	C46, GA4

SITE Application Type, Application For	rm(s) Min. Appl.	Max. Appl. Soil Max. #	Apps Max. Dose [(	AI Min. Restr	Geographic Limi	tations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless noted	l Interv Entry	Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica	<ul> <li>less noted</li> </ul>	unless noted Max. /crop	/year otherwise)/A	A] (days) Interv	7		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /ye	ear [day(s	5)]		
			cycle				

SUGARCANE (con't)		Use Group: TERRESTRIAL F	OOD+FEED CROP (con't)	
Band treatment., Spring., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .45 lb A C	NS 1.35 lb NS NS LA	C46, GA4
Broadcast., Dormant., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .675 lb A M .45 lb A C	NS NS NS TX	C46, GA4
Broadcast., Early postemergence., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .675 lb A M .45 lb A C	NS NS NS TX	C46, GA4
Broadcast., Fall., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .45 lb A C	NS 1.35 lb NS NS LA	C46, GA4
Broadcast., Preemergence., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .675 lb A M .45 lb A C	NS NS NS TX	C46, GA4
Broadcast., Spring., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .45 lb A C	NS 1.35 lb NS NS LA	C46, GA4
Broadcast., Stubble., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .675 lb A M .45 lb A C	NS NS NS NS TX	C46, GA4
Directed spray., Layby., Boom sprayer.	SC/S NA	.9 lb A F NS 1/1 yr .675 lb A M .45 lb A C	NS NS NS TX	C46, GA4
Directed spray., Postemergence., Boom sprayer.	SC/S NA	1.8 lb A O NS 1/1 yr .9 lb A C	NS NS NS FL	C46, GA4
Low volume spray (concentrate)., Postemergence., Boom sprayer.	SC/S NA	3.6 lb A F NS 1/1 yr 1.8 lb A M .9 lb A C	NS NS NS HI, PR	C46, GA4
Low volume spray (concentrate)., Preemergence., Aircraft.	SC/S NA	3.6 lb A F NS 1/1 yr 1.8 lb A M .9 lb A C	NS NS NS HI	C46, GA4
Low volume spray (concentrate)., Preemergence., Boom sprayer.	SC/S NA	3.6 lb A F NS 1/1 yr 1.8 lb A M .9 lb A C	NS NS NS NS FL, HI, PR	C46, GA4
Spot treatment., When needed., Knapsack sprayer.	SC/S NA	1.8 lb A * NS 1/1 yr	NS NS NS NS HI, PR	C46, GA4

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

#### NON-FOOD/NON-FEED

AGRICULTURAL FALLOW/IDLELAND			Use G	rour	p: TER	RESTRIA	AL NON-	-FOOD C	ROP				
Bark cut treatment., April., Sprayer.	EC	NA	UC	*	NS	NS		NS	NS	NS	NS	FL	C46
Bark cut treatment., February., Sprayer.	EC	NA	UC	*	NS	NS		NS	NS	NS	NS	FL	C46
Bark cut treatment., June., Sprayer.	EC	NA	UC	*	NS	NS		NS	NS	NS	NS	FL	C46
Bark cut treatment., March., Sprayer.	EC	NA	UC	*	NS	NS		NS	NS	NS	NS	FL	C46
Bark cut treatment., May., Sprayer.	EC	NA	UC	*	NS	NS		NS	NS	NS	NS	FL	C46
Basal spray., April., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS		NS	NS	NS	NS	FL	C46
Basal spray., February., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS		NS	NS	NS	NS	FL	C46
Basal spray., June., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS		NS	NS	NS	NS	FL	C46
Basal spray., March., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS		NS	NS	NS	NS	FL	C46
Basal spray., May., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., April., Aircraft.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., April., Sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., February., Aircraft.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., February., Sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., June., Aircraft.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., June., Sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., March., Aircraft.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., March., Sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., May., Aircraft.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Broadcast., May., Sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46
Soil treatment (specialized)., April., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS		NS	NS	NS	NS	FL	C46

SITE Application Type, Application Form(s	) Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

NON-FOOD/NON-FEED (con't)

AGRICULTURAL FALLOW/IDLELAND (con't)			Use G	rou	p: :	FERR	ESTRIAL NO	N-FOOD CR	ROP (c	con't)			
Soil treatment (specialized)., February., Hand held sprayer.	EC	NA	6 lb A	*	N	S	NS	NS	NS	NS	NS	FL	C46
Soil treatment (specialized)., June., Hand held sprayer.	EC	NA	6 lb A	*	N	S	NS	NS	NS	NS	NS	FL	C46
Soil treatment (specialized)., March., Hand held sprayer.	EC	NA	6 lb A	*	N	S	NS	NS	NS	NS	NS	FL	C46
Soil treatment (specialized)., May., Hand held sprayer.	EC	NA	6 lb A	*	NS	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., April., Injection.	EC	NA	5.284E-04 lb in. DBH	*	NS	5	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., April., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., February., Injection.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., February., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., June., Injection.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., June., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., March., Injection.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., March., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	N	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., May., Injection.	EC	NA	5.284E-04 lb in. DBH	*	NS	S	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., May., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	S	NS	NS	NS	NS	NS	FL	C46

CHRISTMAS TREE PLANTATIONS Use Group: TERRESTRIAL NON-FOOD CROP

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(	AI Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A	] (days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /ye	ar [day(s	)]	
		cycle			

CHRISTMAS TREE PLANTATIONS (con't)		Use Group: TERRESTRIAL NON-FOOD CROP (con't)
Band treatment., Spring., Sprayer.	EC NA	2 lb A F NS NS NS NS NS NS NS NS 013 CT, DE, ME, MD, C46, G01(30) 1.75 lb A M 1.25 lb A C Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this
		application method. Dosage is given at the broadcast rate; for band treatment, reduce dosage proportionately.
	SC/S NA	1.8 lb A F NS NS NS NS NS NS 013       CT, DE, ME, MD, C46, G01(30)         1.575 lb A M       NH, NJ, NY, NC,         1.125 lb A C       PA, RI, TX, VT,         VA, WV       VA
		Geo.013: See above
Broadcast., Fall., Aircraft.	SC/S NA	1.8 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Fall., Sprayer.	SC/S NA	1.8 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Spring., Aircraft.	SC/S NA	1.8 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Spring., Sprayer.	EC NA	2 lb A F NS NS NS NS NS NS NS CT, DE, ME, MD, C46, G01(30)         1.75 lb A M         1.25 lb A C         PA, RI, TX, VT, VA, WV
	SC/S NA	1.8 lb A F NS NS NS NS NS NS 013       CT, DE, ME, MD, C46, G01(30)         1.575 lb A M       NH, NJ, NY, NC,         1.125 lb A C       PA, RI, TX, VT,         VA, WV       VA
		Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this application method. This application method may be used in areas west of the Rocky Mountains with dosages of 2 pounds per acre in 20 gallons of water.
Directed spray., Spring., Sprayer.	EC NA	2 lb A F NS NS NS NS NS NS NS       CT, DE, ME, MD, C46, G01(30)         1.75 lb A M       NH, NJ, NY, NC,         1.25 lb A C       PA, RI, TX, VT,         VA, WV       VA

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

CHRISTMAS TREE PLANTATIONS (con't)			lise G	rour	TERE	FSTRI	AL NON-FOOD	CROP	(con't)				
CIRCIDINAD IREE FERMINITOND (COIL C)			030 0	LOUL	<b>.</b> 1500	1001101	LAL NON FOOD	CITOL					
Directed spray., When needed., Sprayer.	SC/S	NA	1.8 lb A 1.575 lb A 1.125 lb A	М	NS	NS	NS	NS	NS	NS	013	CT, DE, ME, MD NH, NJ, NY, NC PA, RI, TX, VT VA, WV	,
					appl	icati	on method. 7	'his ap	plicat	ion met		lowable geograph in areas west of ns of water.	
Spray., Fall., Aircraft.	EC	NA	2 lb A 1.75 lb A 1.25 lb A	М	Geo.C		NS West of the c area for t		Mounta			is the specific a	C46, G01(30) allowable
Spray., Fall., Ground.	EC	NA	2 lb A 1.75 lb A 1.25 lb A	М		NS 013:	NS See above	NS	NS	NS	013		C46, G01(30)
Spray., Spring., Aircraft.	EC	NA	2 lb A 1.75 lb A 1.25 lb A	М	Geo.C			NS Rocky		NS ins is	013 the specific al	lowable geograph	C46, G01(30) ic area for this
Spray., Spring., Ground.	EC	NA	2 lb A 1.75 lb A 1.25 lb A	М	NS Geo.(	NS 013:	NS See above	NS	NS	NS	013		C46, G01(30)
CONIFER RELEASE			Use G	rour	FORE	ESTRY							
Band treatment., Fall., Boom sprayer.	EC	NA	3 lb A 2 lb A 1.25 lb A	М	NS	NS	NS	NS	NS	NS	МТ		C46
Band treatment., Fall., Ground.	EC	NA	3 lb A	*	Geo. geog	raphi		his ap	Mounta	ion met	hod. Dosage is g	is the specific a given at the broa	
	SC/S	NA	2.7 lb A	*		NS 013:	NS See above	NS	NS	NS	013		C46, G01(30)
Band treatment., Late winter., Ground.	EC	NA	3 lb A	*	Geo. geog:	raphi		his ap	Mounta	ion met	hod. Dosage is g	is the specific a given at the broa	
	SC/S	NA	2.7 lb A	*		NS 013:	NS See above	NS	NS	NS	013		C46, G01(30)

SITE Application Type, Application	Form(s)	Min. Appl.	Max. Appl.	Soil Ma	ax. # Ap	ps Max. Dos	se [(AI	Min.	Restr.	Geographic	Limitations	Use
Timing, Application Equipment -		Rate (AI un-	Rate (AI	Tex. @	Max. Ra	te unless n	oted	Interv	Entry	Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Eff:			unless noted	Max. /c	crop /ye	ear otherwis	se)/A]	(days)	Interv			Codes
cy Influencing Factor (Antimicrobial on	ly)	otherwise)	otherwise)	Dose cy	zcle	/crop	/year		[day(s)]			
						cycle						

CONIFER RELEASE (con't)		Use Group: FORESTRY (con't)
Band treatment., Postplant., Ground.	EC NA	3 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method. Dosage is given at the broadcast rate; for band treatment, reduce dosage proportionately.
	g na	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above
	SC/S NA	2.7 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Band treatment., Preplant., Ground.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
	g na	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above
	SC/S NA	2.7 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Band treatment., Spring., Boom sprayer.	EC NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
Band treatment., Spring., Ground.	EC NA	3 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt and snowbelt areas is the specific allowable geographic area for this application method. Dosage is given at the broadcast rate; for band treatment, reduce dosage proportionately.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt and snowbelt areas are the specific allowable geographic area for this application method. Dosage is given at the broadcast rate; for band treatment, reduce dosage proportionately.
Basal spray., Early summer., Hand held sprayer.	EC NA	4 lb A F NS NS NS NS NS NS C46, G01(30) 4 lb A M 1.5 lb A C
Basal spray., Late winter., Hand held sprayer.	EC NA	4 lb A F NS NS NS NS NS NS C46, G01(30) 4 lb A M 1.5 lb A C
Basal spray., Preharvest., Hand held sprayer.	EC NA	4 lb A F NS NS NS NS NS NS NS C46, G01(30) 4 lb A M 1.5 lb A C

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

CONIFER RELEASE (con't)		Use Group: FORESTRY (con't)
Basal spray., When needed., Hand held sprayer.	EC NA	.002114 lb in. * NS NS NS NS NS NS NS C46, G01(30) DBH
Broadcast., Early summer., Aircraft.	P/T NA	3 lb A F NS NS NS NS NS NS 013 2.5 lb A M Geo.013: East of the Rocky Mountains in areas with greater than 20 inches of annual 1.5 lb A C rainfall is the specific allowable geographic area for this site on label.
Broadcast., Early summer., Ground.	P/T NA	3 lb A F NS NS NS NS NS 013 2.5 lb A M Geo.013: See above 1.5 lb A C
Broadcast., Fall., Aircraft.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in snowbelt areas is the specific allowable geographic area for this application method.
	EC NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains and east of the Cascades are the specific allowable geographic areas for this application method.
	g na	3 lb A * NS NS NS NS NS NS 013 C46, G01(60), H12(60) Geo.013: West of the Rocky Mountains in the Snowbelt region is the specific allowable geographic area.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in snowbelt areas is the specific allowable geographic area for this application method.
Broadcast., Fall., Boom sprayer.	EC NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
Broadcast., Fall., Granule applicator.	g na	3 lb A * NS NS NS NS NS NS NS 013 Geo.013: West of the Rocky Mountains in the Snowbelt region is the specific allowable geographic area. A backpack equipped with a granular applicator is the specific type of application method equipment.
Broadcast., Fall., Ground.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in snowbelt areas is the specific allowable geographic area for this application method.

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps	s Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate	e unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year	r otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /year	[day(s)	]	
			cycle			

\_\_\_\_

#### USES ELIGIBLE FOR REREGISTRATION

CONIFER RELEASE (con't)		Use Group: FORESTRY (con't)
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains and east of the Cascades are the specific allowable geographic areas for this application method.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in snowbelt areas is the specific allowable geographic area for this application method.
Broadcast., Late winter., Aircraft.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt areas is the specific allowable geographic area for this application method.
	g na	3 lb A * NS NS NS NS NS NS 013 C46, G01(60), Geo.013: See above H12(60)
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Late winter., Granule applicator.	g na	3 lb A * NS NS NS NS NS NS NS 013 Geo.013: West of the Rocky Mountains in the Rainbelt region is the specific allowable geographic area. A backpack equipped with a granular applicator is the specific type of application method equipment.
Broadcast., Late winter., Ground.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt areas is the specific allowable geographic area for this application method.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Postplant., Aircraft.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
	g na	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Postplant., Ground.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
	g na	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

CONIFER RELEASE (con't)		Use Group: FORESTRY (con't)
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Posttransplant., Aircraft.	g na	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
roadcast., Posttransplant., Ground.	g na	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Preplant., Aircraft.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
	g na	4 lb A F NS NS NS NS NS NS 013 G01(30) 3.5 lb A M Geo.013: East and west of the Rocky Mountains is the specific allowable geographic area 3 lb A C for this application method. Maximum dosage for areas west of the Rocky Mountains is 20 pounds per acre.
	g na	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Preplant., Ground.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
	g NA	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above
	SC/S NA	2.7 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: See above
Broadcast., Pretransplant., Aircraft.	g na	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.

SITE Application Type, Application Form(s	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

CONIFER RELEASE (con't)		Use Group: FORESTRY (con't)
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Pretransplant., Ground.	g na	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	g na	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Spring., Aircraft.	EC NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt and snowbelt areas is the specific allowable geographic area for this application method.
	EC NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
	g na	3 lb A F NS NS NS NS NS NS NS G01(30) 2.2 lb A M 1.5 lb A C
	g na	3 lb A F NS NS NS NS NS NS NS 013 2.25 lb A M 1.5 lb A C Geo.013: East of the Rocky Mountains in areas with greater than 20 inches of annual rainfall are the specific allowable geographic areas for this application method. Product may be applied at a rate of 4 pounds per acre west of the Rocky Mountains.
	g na	3 lb A F NS NS NS NS NS NS NS 013, 014 G01(30) 2.25 lb A M Geo.013: East of the Rocky Mountains in areas with greater than 20 inches of annual 1.5 lb A C rainfall, and east and west of the Cascades are the specific allowable geographic areas for this application method. Maximum dosage for east and west of the Cascades is 12 pounds per acre.
	P/T NA	3 lb A F NS NS NS NS NS NS 013 2.5 lb A M Geo.013: East of the Rocky Mountains in areas with greater than 20 inches of annual 1.5 lb A C rainfall is the specific allowable geographic area for this site on label.
	SC/S NA	2.7 lb A * NS NS NS NS NS NS NS 013 C46, G01(30) Geo.013: West of the Rocky Mountains in rainbelt and snowbelt areas are the specific allowable geographic area for this application method.
Broadcast., Spring., Boom sprayer.	EC NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

CONIFER RELEASE (con't)			Use Group: FORESTRY (con't)	
Broadcast., Spring., Granule applicator.	G	NA	rainfall are the s may be applied at	S NS NS NS 013 C46, G01(60), H12(60) the Rocky Mountains in areas with greater than 20 inches of annual gecific allowable geographic areas for this application method. Product a rate of 4 pounds per acre west of the Rocky Mountains. A backpack annular applicator is the specific type of application method equipment.
Broadcast., Spring., Ground.	EC	NA		S NS NS NS 013 C46, G01(30) the Rocky Mountains in rainbelt and snowbelt areas is the specific hic area for this application method.
	G	NA	1.5 lb A C rainfall, and east	S NS NS NS 013, 014 G01(30) the Rocky Mountains in areas with greater than 20 inches of annual and west of the Cascades are the specific allowable geographic areas for method. Maximum dosage for east and west of the Cascades is 12 pounds per
	G	NA		S NS NS NS 014, 013 G01(30) the Rocky Mountains and east and west of the Cascades are the specific ic areas for this application method.
	P/T	NA		S NS NS NS 013 the Rocky Mountains in areas with greater than 20 inches of annual ecific allowable geographic area for this site on label.
	SC/S	NA	2.7 lb A * NS NS N Geo.013: West of allowable geograph	S NS NS NS 013 C46, G01(30) the Rocky Mountains in rainbelt and snowbelt areas are the specific hic area for this application method.
Directed spray., Late winter., Ground.	EC	NA		S NS NS NS 013 C46, G01(30) the Rocky Mountains in rainbelt areas is the specific allowable or this application method.
Directed spray., Spring., Ground.	EC	NA	3 lb A * NS NS N Geo.013: See abov	
Ground spray., Early spring., Sprayer.	SC/S	NA	3.6 lb A * NS NS N	S NS NS NS 008 C46, G01(30)
Ground spray., Early summer., Sprayer.	SC/S	NA	3.6 lb A * NS NS N	S NS NS NS 008, 016 C46, G01(30)
Ground spray., Late spring., Sprayer.	SC/S	NA	3.6 lb A * NS NS N	S NS NS NS 016 C46, G01(30)
Soil treatment., Early summer., By hand.	P/T	NA	3.770 lb A * NS NS N	S NS NS NS G01(30)
Soil treatment., Late winter., By hand.	P/T	NA	3.770 lb A * NS NS N	S NS NS NS GO1(30)

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min Restr	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted		(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)		
· · · · · · · · · · · · · · · · · · ·		cycle			

CONIFER RELEASE (con't) Use Group: FORESTRY (con't)													
Spot soil treatment., Early summer., By hand.	P/T	NA	.001984 lb A	*	NS	NS	NS	1	NS	NS	NS		G01(30)
Spot soil treatment., Late winter., By hand	. P/T	NA	.001984 lb A	*	NS	NS	NS	1	NS	NS	NS		G01(30)
Spray., Early spring., Aircraft.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	008	C46, G01(30)
	SC/S	NA	3.6 lb A	*	NS	NS	NS	1	NS	NS	NS	008	C46, G01(30)
Spray., Early spring., Ground.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	008	C46, G01(30)
Spray., Early summer., Aircraft.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	008, 016	C46, G01(30)
	SC/S	NA	3.6 lb A	*	NS	NS	NS	1	NS	NS	NS	008, 016	C46, G01(30)
Spray., Early summer., Ground.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	008, 016	C46, G01(30)
Spray., Late spring., Aircraft.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	016	C46, G01(30)
	SC/S	NA	3.6 lb A	*	NS	NS	NS	1	NS	NS	NS	016	C46, G01(30)
Spray., Late spring., Ground.	EC	NA	4 lb A	*	NS	NS	NS	1	NS	NS	NS	016	C46, G01(30)
Tree injection treatment., Summer., Injection.	EC	NA	1.321E-04 lb in. interval	*	NS	NS	NS	ĩ	NS	NS	NS		C46, G01(30)
Tree injection treatment., Summer., Tree injection equipment.	EC	NA	1.321E-04 lb in. interval	*	NS	NS	NS	ľ	NS	NS	NS		C46, G01(30)
DRAINAGE SYSTEMS			Use G	rou	p: AQU	JATIC NO	N-FOOD IN	DUSTRI	IAL				
Basal spray., Early summer., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	ĩ	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	ĩ	NS	NS	NS		C46
Basal spray., Fall., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	1	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	1	NS	NS	NS		C46
Basal spray., Late winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	ĩ	NS	NS	NS		C46

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-		Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

\_\_\_\_

#### USES ELIGIBLE FOR REREGISTRATION

DRAINAGE SYSTEMS (con't)		Use G	rour	AQ	UATIC NON-	FOOD INDU	STRIAL	(con't	= )		
	RTU N.	A 3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS	C46	
Basal spray., Winter., Hand held sprayer.	EC N	A .002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS	C46	
	RTU N.	A 3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS	C46	
Broadcast., Early summer., Aircraft.	G N.	A 5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Early summer., Ground.	G N.	A 5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Early summer., Sprayer.	SC/S N	A 7.2 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Broadcast., Fall., Aircraft.	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Fall., Ground.	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Late winter., Aircraft.	G N.	A 5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Late winter., Ground.	G N.	A 5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Late winter., Sprayer.	SC/S N	A 7.2 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Broadcast., Spring., Aircraft.	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Ground.	P/T N	A 8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Aircraft.	G N.	A 12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T N	A 12 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Boom sprayer.	RTU N.	A 12.45 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	SC/S N.	A 1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL, AR, FL, GA, C46 LA, MS, OK, NC, SC, TN, TX	

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. #	Appg Max Dogo [(AT	Min Postr	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop	/year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /year	[day(s)	]	
			cycle			

DRAINAGE SYSTEMS (con't)			Use (	Grou	ıp: AQU	ATIC N	ON-FOOD INDUS	TRIAL	(con't	)		
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX C46	
Broadcast., When needed., Ground.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Broadcast., When needed., Hand held sprayer	. EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX C46	
Broadcast., When needed., Sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Broadcast., Winter., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Winter., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Directed spray., Early summer., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Directed spray., Fall., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Directed spray., Late winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Directed spray., When needed., Sprayer.	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX C46	
Directed spray., Winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Soil treatment (specialized)., Early summer., Hand held sprayer.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	C46	
Soil treatment (specialized)., Late winter. Hand held sprayer.	, EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	C46	

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

DRAINAGE SYSTEMS (con't)			Use G	roup	): A(	QUATIC NON-F	OOD INDU	JSTRIAL	(con't	.)		
Spot soil treatment., Early summer., By hand.	G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Fall., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Late winter., By hand.	G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Spring., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Winter., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spray., When needed., Boom sprayer.	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL	C46
FOREST PLANTINGS (REFORESTATION PROGRAMS) Use Group: FORESTRY												
Band treatment., Fall., Boom sprayer.	EC	NA	3 lb A 2 lb A 1.25 lb A	М	NS	NS	NS	NS	NS	NS	MT	C46
Band treatment., Postplant., Ground.	EC	NA	3 lb A	*	Ge ap		ethod. D	Rocky osage			013 the specific allowable ge the broadcast rate; for bas	
	G	NA	2 lb A	*		NS o.013: See	NS above	NS	NS	NS	013	G01(30)
Band treatment., Preplant., Boom sprayer.	EC	NA	3 lb A 2 lb A 1.25 lb A	М	NS	NS	NS	NS	NS	NS	MT	C46
Band treatment., Preplant., Ground.	EC	NA	3 lb A	*	Ge ap		ethod. D	Rocky osage			013 the specific allowable ge the broadcast rate; for bas	
	G	NA	2 lb A	*		NS o.013: See	NS above	NS	NS	NS	013	G01(30)
Band treatment., Spring., Boom sprayer.	EC	NA	3 lb A 2 lb A 1.25 lb A	М	NS	NS	NS	NS	NS	NS	МТ	C46

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

FOREST PLANTINGS (REFORESTATION PROGRAMS)	(con't)		Use Group	: FORESTRY	(con't)					
Basal spray., Early summer., Hand held sprayer.	EC	NA	6 lb A F 6 lb A M 3 lb A C	NS NS	NS	NS	NS	NS		C46
Basal spray., Late winter., Hand held sprayer.	EC	NA	6 lb A F 6 lb A M 3 lb A C	NS NS	NS	NS	NS	NS		C46
Basal spray., Preharvest., Hand held sprayer.	EC	NA	6 lb A F 6 lb A M 3 lb A C	NS NS	NS	NS	NS	NS		C46
Basal spray., When needed., Hand held sprayer.	EC	NA	.002114 lb in. * DBH	NS NS	NS	NS	NS	NS		C46
Broadcast., Early summer., Aircraft.	P/T	NA	3 1b A M					ns in a	013 areas with greater than 20 inch phic area for this site on labe	
Broadcast., Early summer., Ground.	P/T	NA	4 lb A F 3 lb A M 2 lb A C	NS NS Geo.013:	NS See above	NS	NS	NS	013	
Broadcast., Fall., Aircraft.	EC	NA	3 lb A *	Geo.013:	NS West of the ic area for t			ns in s	013 snowbelt areas is the specific od.	C46 allowable
	EC	NA	3 lb A F 2 lb A M 1.25 lb A C	NS NS	NS	NS	NS	NS	MT	C46
	G	NA	3 lb A *	Geo.013:	NS West of the ic areas for			ns and	013 east of the Cascades are the s hod.	G01(30) specific allowable
	G	NA	3 lb A *			NS Rocky 1	NS Mountai		013 the Snowbelt region is the spec	C46, G01(60), H12(60) ific allowable
Broadcast., Fall., Boom sprayer.	EC	NA	3 lb A F 2 lb A M 1.25 lb A C	NS NS	NS	NS	NS	NS	MT	C46

Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
	cycle			
		Rate (AI un- less notedRate (AI Tex. @ Max. Rate unless noted unless noted Max. /crop /year otherwise)/A] otherwise)Obse cycle/crop /year	Rate (AI un-       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv         otherwise)       otherwise) Dose cycle       /crop /year       [day(s)]	Rate (AI un-       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry       Allowed       Disallowed         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv       otherwise)       Dose cycle       /crop /year       [day(s)]

FOREST PLANTINGS (REFORESTATION PROGRAMS)	(con't)	)	Use Group: FORESTRY (con't)
Broadcast., Fall., Granule applicator.	G	NA	3 lb A * NS NS NS NS NS NS NS 013 C46, G01(60), H12(60) Geo.013: West of the Rocky Mountains in the Snowbelt region is the specific allowable geographic area. A backpack equipped with a granular applicator is the specific type of application method equipment.
Broadcast., Fall., Ground.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: West of the Rocky Mountains in snowbelt areas is the specific allowable geographic area for this application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains and east of the Cascades are the specific allowable geographic areas for this application method.
Broadcast., Late winter., Aircraft.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: West of the Rocky Mountains in rainbelt areas is the specific allowable geographic area for this application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 C46, G01(60), Geo.013: See above H12(60)
Broadcast., Late winter., Granule applicator.	G	NA	3 lb A * NS NS NS NS NS NS NS 013 C46, G01(60), H12(60) Geo.013: West of the Rocky Mountains in the Rainbelt region is the specific allowable geographic area. A backpack equipped with a granular applicator is the specific type of application method equipment.
Broadcast., Late winter., Ground.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: West of the Rocky Mountains in rainbelt areas is the specific allowable geographic area for this application method.
Broadcast., Postplant., Aircraft.	G	NA	2 lb A * NS NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Postplant., Ground.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: See above
	G	NA	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: See above
Broadcast., Posttransplant., Aircraft.	EC	NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C

SITE Application Type, Application Form(	s) Min. Appl.	Max. Appl. Soil Max. # A	Apps Max. Dose [(A:	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max. R	Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /y	year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /year	[day(s)	]	
			cycle			

FOREST PLANTINGS (REFORESTATION PROGRAMS) (	con't)		Use Group: FORESTRY (con't)
	G	NA	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Posttransplant., Boom sprayer.	EC	NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
Broadcast., Posttransplant., Ground.	G	NA	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Preplant., Aircraft.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: See above
	EC	NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
	G	NA	4 lb A F NS NS NS NS NS NS 013 G01(30) 3.5 lb A M Geo.013: East and west of the Rocky Mountains is the specific allowable geographic area 3 lb A C for this application method. Maximum dosage for areas west of the Rocky Mountains is 20 pounds per acre.
	G	NA	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Preplant., Boom sprayer.	EC	NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
Broadcast., Preplant., Ground.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. #	Apps Max, Dose [(A	T Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /	/vear otherwise)/Al	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /yea	· · · ·		
	· · · · · · ,		cycle		-	

FOREST PLANTINGS (REFORESTATION PROGRAMS	) (con't)		Use Group: FORESTRY (con't)
	G	NA	4 lb A F NS NS NS NS NS NS 013 G01(30) 3.5 lb A M Geo.013: East and west of the Rocky Mountains is the specific allowable geographic area 3 lb A C for this application method. Maximum dosage for areas west of the Rocky Mountains is 20 pounds per acre.
	G	NA	2 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Pretransplant., Aircraft.	G	NA	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Pretransplant., Ground.	G	NA	1.25 lb A F NS NS NS NS NS NS 013 G01(30) 1 lb A M Geo.013: East of the Rocky Mountains is the specific allowable geographic area for this .75 lb A C application method.
	G	NA	3 lb A * NS NS NS NS NS NS 013 G01(30) Geo.013: West of the Rocky Mountains is the specific allowable geographic area for this application method.
Broadcast., Spring., Aircraft.	EC	NA	3 lb A * NS NS NS NS NS NS 013 C46 Geo.013: West of the Rocky Mountains in rainbelt areas is the specific allowable geographic area for this application method.
	EC	NA	3 lb A F NS NS NS NS NS MT C46 2 lb A M 1.25 lb A C
	G	NA	3 lb A F NS NS NS NS NS NS NS G01(30) 2.2 lb A M 1.5 lb A C
	G	NA	<pre>6 lb A F NS NS NS NS NS NS NS 013 C46, G01(60), 3.998 lb A M H12(60) 3 lb A C Geo.013: Areas east of the Rocky Mountains with greater than 20 inches of annual rainfall are the specific allowable geographic areas on label. Product may be applied at a rate of 4 pounds per acre west of the Rocky Mountains.</pre>

SITE Application Type, Application For	n(s) Min. Appl.	Max. Appl. Soil Max.	# Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-			Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop	/year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle	/crop /year	[day(s)	]	
			cycle			

	(con't)		Use Gi	roup	: FORESTR	Y (con't)					
	G	NA	4.5 lb A	ਸ	NS NS	NS	NS	NS	NS	013, 014	G01(30)
											than 20 inches of annual
											c allowable geographic areas for
											of the Cascades is 12 pounds per
					acre.				j-		
	P/T	NA	4 lb A	F	NS NS	NS	NS	NS	NS	013	
	F / 1	INA									than 20 inches of annual
										aphic area for this	
			2 10 11	C	raintari	ib the speer	IIC UII	owabie	geogr	iphic area for chib	bite on inder.
coadcast., Spring., Boom sprayer.	EC	NA	3 lb A		NS NS	NS	NS	NS	NS	MT	C46
			2 lb A								
			1.25 lb A	С							
roadcast., Spring., Granule applicator.	G	NA	6 lb A	F	NS NS	NS	NS	NS	NS	013	C46, G01(60),
, <u>1</u> 5, 1 1 1			3.998 lb A	М							H12(60)
			3 lb A	С							than 20 inches of annual
					rainfall	are the spec	cific a	llowab	le geog	raphic areas for th	is application method. Product
											locky Mountains. A backpack
					equipped	l with a granu	lar ap	plicato	or is t	he specific type of	application method equipment.
Broadcast., Spring., Ground.	G	NA	4.5 lb A	F	NS NS	NS	NS	NS	NS	013, 014	G01(30)
	0	1421									than 20 inches of annual
					rainfall						
						, and east an	d west	of the	Casca	les are the specifi	c allowable geographic areas for
						, and east an	d west	of the	Casca	les are the specifi	
	ā		3 lb A	С	this app acre.	, and east an Dlication meth	d west nod. Ma	of the ximum c	Casca dosage	des are the specifi for east and west o	c allowable geographic areas for of the Cascades is 12 pounds per
	G	NA	3 lb A 3 lb A	C F	this app acre. NS NS	, and east an Dlication meth NS	d west nod. Ma NS	of the ximum o NS	Cascad dosage NS	des are the specifi for east and west o 014, 013	c allowable geographic areas for f the Cascades is 12 pounds per G01(30)
	G	NA	3 lb A 3 lb A 2.2 lb A	C F M	this app acre. NS NS Geo.013:	, and east an Dlication meth NS East of the	d west hod. Ma NS Rocky	of the ximum o NS Mounta	Casca dosage NS ins and	des are the specifi for east and west of 014, 013 d east and west of	c allowable geographic areas for of the Cascades is 12 pounds per
	G	NA	3 lb A 3 lb A 2.2 lb A	C F M	this app acre. NS NS Geo.013:	, and east an Dlication meth NS East of the	d west hod. Ma NS Rocky	of the ximum o NS Mounta	Casca dosage NS ins and	des are the specifi for east and west o 014, 013	c allowable geographic areas for f the Cascades is 12 pounds per G01(30)
		NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A	C F M C F	this app acre. NS NS Geo.013: allowabl NS NS	, and east an Dication meth NS East of the e geographic NS	d west nod. Mai NS Rocky areas f NS	of the ximum o NS Mounta or thi NS	Cascad dosage NS ins and s appl: NS	des are the specifi for east and west of 014, 013 d east and west of ication method. 013	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific
			3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A	C F M C F M	this app acre. NS NS Geo.013: allowabl NS NS Geo.013:	, and east an olication meth NS East of the e geographic NS East of the	d west nod. Ma NS Rocky areas f NS Rocky	of the ximum of NS Mounta for thi NS Mounta	Cascad dosage NS ins and s appl: NS ins in	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater	c allowable geographic areas for of the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual
			3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A	C F M C F M	this app acre. NS NS Geo.013: allowabl NS NS Geo.013:	, and east an olication meth NS East of the e geographic NS East of the	d west nod. Ma NS Rocky areas f NS Rocky	of the ximum of NS Mounta for thi NS Mounta	Cascad dosage NS ins and s appl: NS ins in	des are the specifi for east and west of 014, 013 d east and west of ication method. 013	c allowable geographic areas for of the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual
irected spray . Late winter . Ground	P/T	NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A	C FMC FMC	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: rainfall	, and east an lication meth NS East of the e geographic NS East of the is the speci	d west nod. Ma Rocky areas f NS Rocky fic all	of the ximum of NS Mounta or thi NS Mounta owable	Cascad losage NS ins and s appl: NS ins in geogra	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label.
irected spray., Late winter., Ground.			3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A	C FMC FMC	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: rainfall NS NS	, and east an lication meth NS East of the e geographic NS East of the is the speci NS	d west nod. Ma Rocky areas f NS Rocky fic all	of the ximum of NS Mounta or thi NS Mounta .owable NS	Cascad losage NS ins and s appl: NS ins in geogra	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this 013	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label. C46, GO1(30)
irected spray., Late winter., Ground.	P/T	NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A	C FMC FMC	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: rainfall NS NS Geo.013:	, and east an lication meth NS East of the e geographic NS East of the is the speci NS West of the	d west nod. Ma Rocky areas f NS Rocky fic all NS Rocky	of the ximum of NS Mounta for thi NS Mounta owable NS Mounta	Cascad losage NS ins and s appl: NS ins in geogra NS ins in	des are the specifi for east and west of d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label.
irected spray., Late winter., Ground.	P/T	NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A	C FMC FMC	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: rainfall NS NS Geo.013:	, and east an lication meth NS East of the e geographic NS East of the is the speci NS	d west nod. Ma Rocky areas f NS Rocky fic all NS Rocky	of the ximum of NS Mounta for thi NS Mounta owable NS Mounta	Cascad losage NS ins and s appl: NS ins in geogra NS ins in	des are the specifi for east and west of d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label. C46, GO1(30)
irected spray., Late winter., Ground. Firected spray., Spring., Ground.	P/T	NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A	С	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: geograph NS NS	, and east an plication meth NS East of the e geographic NS East of the is the speci NS West of the hic area for the NS	d west nod. Ma NS Rocky areas f NS Rocky fic all NS Rocky this ap	of the ximum of NS Mounta owable NS Mounta plicat: NS	Cascad NS ins and s appl: NS ins in geogra NS ins in ion met NS	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is hod. 013	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label. C46, GO1(30) the specific allowable C46, GO1(30)
	P/T EC	NA NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A 3 lb A	С	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: geograph NS NS Geo.013: geograph	, and east an NS East of the e geographic NS East of the is the speci NS West of the NS West of the	d west nod. Ma NS Rocky areas f NS Rocky fic all NS Rocky this ap NS	of the ximum of NS Mounta or thi NS Mounta plicat: NS Mounta	Cascad losage NS ins and s appl: NS ins in geogra NS ins in ion met NS ins in	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is hod. 013 rainbelt and snowb	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label. C46, GO1(30) the specific allowable
	P/T EC	NA NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A 3 lb A	С	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: geograph NS NS Geo.013: geograph	, and east an NS East of the e geographic NS East of the is the speci NS West of the NS West of the	d west nod. Ma NS Rocky areas f NS Rocky fic all NS Rocky this ap NS	of the ximum of NS Mounta or thi NS Mounta plicat: NS Mounta	Cascad losage NS ins and s appl: NS ins in geogra NS ins in ion met NS ins in	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is hod. 013	c allowable geographic areas for f the Cascades is 12 pounds per GO1(30) the Cascades are the specific than 20 inches of annual site on label. C46, GO1(30) the specific allowable C46, GO1(30)
irected spray., Spring., Ground.	P/T EC EC	NA NA NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A 3 lb A 3 lb A	C FMC FMC *	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: rainfall NS NS Geo.013: geograph NS NS Geo.013: allowabl	, and east an NS East of the e geographic NS East of the is the speci NS West of the hic area for t NS West of the e geographic	d west nod. Ma NS Rocky areas f NS Rocky fic all NS Rocky this ap NS Rocky area f	of the ximum of NS Mounta ovable NS Mounta plicat: NS Mounta or this	Cascad losage NS ins and s appl: NS ins in geogra NS ins in ion met NS ins in	des are the specifi for east and west of 014, 013 d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is hod. 013 rainbelt and snowb cation method.	c allowable geographic areas for f the Cascades is 12 pounds per G01(30) the Cascades are the specific than 20 inches of annual site on label. C46, G01(30) the specific allowable C46, G01(30) elt areas is the specific
	P/T EC EC	NA NA NA	3 lb A 3 lb A 2.2 lb A 1.5 lb A 4 lb A 3 lb A 2 lb A 3 lb A	C FMC FMC *	this app acre. NS NS Geo.013: allowabl NS NS Geo.013: geograph NS NS Geo.013: allowabl NS NS	, and east an NS East of the e geographic NS East of the is the speci NS West of the hic area for t NS West of the e geographic NS	d west nod. Ma NS Rocky areas f NS Rocky this ap NS Rocky this ap NS Rocky area f	of the ximum of NS Mounta or thi NS Mounta plicat: NS Mounta pr this NS	Cascad losage NS ins and s appl: NS ins in geogra NS ins in s appli NS	des are the specifi for east and west of d east and west of ication method. 013 areas with greater aphic area for this 013 rainbelt areas is hod. 013 rainbelt and snowb cation method. 013	c allowable geographic areas for f the Cascades is 12 pounds per G01(30) the Cascades are the specific than 20 inches of annual site on label. C46, G01(30) the specific allowable C46, G01(30)

Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
	cycle			
)		Rate (AI un- less noted unless noted Max. /crop /year otherwise)/A] otherwise) otherwise) Dose cycle /crop /year	Rate (AI un- less noted unless noted Max. /crop /year otherwise)/A]       Interv Entry (days) Interv otherwise)         Otherwise)       Otherwise)       Dose cycle       /crop /year       [day(s)	Rate (AI un- less noted       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry       Allowed       Disallowed         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv       otherwise)       Dose cycle       /crop /year       [day(s)]

FOREST PLANTINGS (REFORESTATION PROGRAMS) (	con't)		Use G	rou	p: FOF	RESTRY (con	't)					
Ground spray., Early summer., Sprayer.	SC/S	NA	5.4 lb A	*		NS .013: See a	NS above	NS	NS	NS	013	C46
Ground spray., Late spring., Boom sprayer.	SC/S	NA	5.4 lb A	*		NS .013: See a	NS above	NS	NS	NS	013	C46
Ground spray., Late spring., Sprayer.	SC/S	NA	5.4 lb A	*		NS .013: See a	NS above	NS	NS	NS	013	C46
Ground spray., When needed., Boom sprayer.	SC/S	NA	5.4 lb A	*	NS	NS	NS	NS	NS	NS	ME, MI, MN, NH, NY, VT, WI	C46
Ground spray., When needed., Sprayer.	SC/S	NA	5.4 lb A	*	NS	NS	NS	NS	NS	NS	ME, MI, MN, NH, NY, VT, WI	C46
Soil treatment., Early summer., By hand.	P/T	NA	5.754 lb A	*	NS	NS	NS	NS	NS	NS		G01(30)
Soil treatment., Late winter., By hand.	P/T	NA	5.754 lb A	*	NS	NS	NS	NS	NS	NS		G01(30)
Soil treatment., Preharvest., By hand.	P/T	NA	5.754 lb A	*	NS	NS	NS	NS	NS	NS		G01(30)
Spot soil treatment., Early summer., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		G01(30)
Spot soil treatment., Late winter., By hand	. P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		G01(30)
Spot soil treatment., Preharvest., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		G01(30)
Spray., Delayed dormant., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	ME, MI, MN, NH, NY, VT, WI	C46
Spray., Delayed dormant., Boom sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	ME, MI, MN, NH, NY, VT, WI	C46
Spray., Early summer., Aircraft.	EC	NA	6 lb A	*	Geo	NS .013: East lication me		NS ocky i	NS Mountai	NS ns is	013 the specific allowable geograph:	C46 ic area for this
	SC/S	NA	5.4 lb A	*		NS .013: See a	NS above	NS	NS	NS	013	C46
Spray., Early summer., Boom sprayer.	EC	NA	6 lb A	*		NS .013: See a	NS above	NS	NS	NS	013	C46

SITE Application Type, Application For	rm(s) 1	Min. Appl.	Max. Appl.	Soil M	4ax. #	Apps Max.	. Dose [(AI	Min.	Restr.	Geographic Li	mitations	Use
Timing, Application Equipment –	1	Rate (AI un-	Rate (AI	Tex. @	🤉 Max.	Rate unle	ess noted	Interv	Entry	Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	-	less noted	unless noted i	Max. /	crop .	/year othe	erwise)/A]	(days)	Interv			Codes
cy Influencing Factor (Antimicrobial only)		otherwise)	otherwise)	Dose c	cycle	/cro	op /year		[day(s)]			
						CYC	le					

FOREST PLANTINGS (REFORESTATION PROGRAMS)	(con't)		Use G	rouj	p: FOI	RESTRY	(con't)					
Spray., Late spring., Aircraft.	EC	NA	6 lb A	*		NS .013:	NS See above	NS	NS	NS	013	C46
	SC/S	NA	5.4 lb A	*		NS .013:	NS See above	NS	NS	NS	013	C46
Spray., Late spring., Boom sprayer.	EC	NA	6 lb A	*		NS .013:	NS See above	NS	NS	NS	013	C46
Spray., When needed., Aircraft.	SC/S	NA	5.4 lb A	*	NS	NS	NS	NS	NS	NS	ME, MI, MN, NH, NY, VT, WI	C46
Tree injection treatment., Summer., Injection.	EC	NA	1.321E-04 lb in. interval	*	NS	NS	NS	NS	NS	NS		C46
Tree injection treatment., Summer., Tree injection equipment.	EC	NA	1.321E-04 lb in. interval	*	NS	NS	NS	NS	NS	NS		C46
FOREST TREES (ALL OR UNSPECIFIED)			Use G	rouj	p: FO	RESTRY						
Soil treatment., Early summer., By hand.	P/T	NA	5.754 lb A	*	NS	NS	NS	NS	NS	NS		G01(30)
Soil treatment., Late winter., By hand.	P/T	NA	5.754 lb A	*	NS	NS	NS	NS	NS	NS		G01(30)
Spot soil treatment., Early summer., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		G01(30)
Spot soil treatment., Late winter., By hand	l. P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		G01(30)
Tree injection treatment., When needed., Tree injection equipment.	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS		
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMIS	SES		Use G	rou	o: OU	TDOOR	RESIDENTIAL					
Tree injection treatment., When needed., Tree injection equipment.	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS		
INDUSTRIAL AREAS (OUTDOOR)			Use G	rou	p∶ TEI	RRESTR	IAL NON-FOOD C	ROP				
Basal spray., Early summer., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46

SITE Application Type, Application Fo	rm(s) Mi	in. Appl.	Max. Appl.	Soil	Max. #	Apps 1	Max. Dos	e l(AI	Min.	Restr.	Geographic Li	mitations	Use
Timing, Application Equipment -	Ra	ate (AI un-	Rate (AI	Tex.	@ Max.	Rate	unless n	oted	Interv	Entry	Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica	- le	ess noted	unless noted	Max.	/crop	/year	otherwis	e)/A]	(days)	Interv			Codes
cy Influencing Factor (Antimicrobial only)	ot	herwise)	otherwise)	Dose	cycle		/crop	/year		[day(s)]			
							cycle						

INDUSTRIAL AREAS (OUTDOOR) (con't)			Use G	roup	: TEF	RESTRIA	L NON-FOOD (	CROP (	con't)		
Basal spray., Fall., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS	C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS	C46
Basal spray., Late winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS	C46
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS	C46
Basal spray., When needed., Hand held sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL C46
Basal spray., When needed., Power sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL C46
Basal spray., Winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS	C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS	C46
Broadcast., Early summer., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS	
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Early summer., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS	
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Early summer., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	C46
Broadcast., Fall., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Fall., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Late winter., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS	
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Late winter., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS	
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS	
Broadcast., Late winter., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	C46

) Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Rate (AI un-			Allowed Disallowed	Limitations
less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
otherwise)	otherwise) Dose cycle /crop /year	[day(s	)]	
	cycle			
		Rate (AI un- less noted unless noted Max. Rate unless noted otherwise) otherwise) Dose cycle /crop /year	Rate (AI un-       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv         otherwise)       otherwise) Dose cycle       /crop /year       [day(s)]	Rate (AI un-       Rate (AI Tex. @ Max. Rate unless noted       Interv Entry Allowed       Disallowed         less noted       unless noted Max. /crop /year otherwise)/A]       (days) Interv       Disallowed         otherwise)       otherwise)       Dose cycle       /crop /year       [day(s)]

INDUSTRIAL AREAS (OUTDOOR) (con't)			Use (	Grouj	p: TE	RRESTRIAL	NON-FOOD C	CROP (	con't)			
Broadcast., Not on label., By hand.	P/T	NA	6.945 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Aircraft.	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Boom sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL, AR, FL, GA, LA, MS, OK, NC, SC, TN, TX	C46
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	ТХ	C46
Broadcast., When needed., Granule applicator.	G	NA	11.25 lb A	*	NS	NS	NS	NS	NS	NS		C46, G01(60 H12(60)
Broadcast., When needed., Ground.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., When needed., Hand held sprayer.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX	C46
Broadcast., When needed., Sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., Winter., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Winter., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Directed spray., Early summer., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

NON-FOOD/NON-FEED (con't)

INDUSTRIAL AREAS (OUTDOOR) (con't)			Use G	rour	o: TH	RRESTRIAL	NON-FOOD	CROP (	con't)			
Directed spray., Fall., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		
Directed spray., Late winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C
Directed spray., When needed., Sprayer.	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX	C4
Directed spray., Winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46
Soil treatment (specialized)., Early summer., Hand held sprayer.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
Soil treatment (specialized)., Late winter. Hand held sprayer.	, EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
Spot soil treatment., Early summer., By hand.	G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Fall., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Late winter., By hand	. G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Not on label., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Spring., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Winter., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spray., When needed., Boom sprayer.	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL	C46
Tree injection treatment., When needed., Tree injection equipment.	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS		

NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS Use Group: TERRESTRIAL NON-FOOD CROP

SITE Application Type, Application	Form(s)	Min. Appl.	Max. Appl. Soil Max. #	Apps Max. Do:	se [(AI	Min. Restr.	Geographi	c Limitations	Use	
Timing, Application Equipment -		Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless :	noted	Interv Entry	Allowed	Disallowed	Limitations	
Surface Type (Antimicrobial only) & E	ffica-	less noted	unless noted Max. /crop /	year otherwi	se)/A]	(days) Interv			Codes	
cy Influencing Factor (Antimicrobial	only)	otherwise)	otherwise) Dose cycle	/crop	/year	[day(s)	]			
				cycle						

NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEL	GEROWS	(con't)	Use G	rou	: TE	RRESTRIAI	NON-FOOD C	ROP (	con't)			
Basal spray., Early summer., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., Fall., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., Late winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., When needed., Hand held sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., When needed., Power sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., Winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., Early summer., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Early summer., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Early summer., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., Fall., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Fall., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Late winter., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDO	GEROWS	(con't)	Use G	roup	: TE	RRESTRIAL	NON-FOOD C	CROP (	con't)			
Broadcast., Late winter., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Late winter., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., Not on label., By hand.	P/T	NA	6.945 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Aircraft.	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Boom sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL, AR, FL, GA, LA, MS, OK, NC, SC, TN, TX	C46
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX	C46
Broadcast., When needed., Granule applicator.	G	NA	11.25 lb A	*	NS	NS	NS	NS	NS	NS		C46, G01(60), H12(60)
Broadcast., When needed., Ground.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., When needed., Hand held sprayer	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX	C46
Broadcast., When needed., Sprayer.	RTU	NA	12.45 lb A			NS	NS	NS	NS	NS		C46
Broadcast., Winter., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s	)]	
		cycle			

NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDO	GEROWS	(con't)	Use G	rouj	p: TE	RRESTRIA	L NON-FOOD C	ROP (	con't)			
Broadcast., Winter., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Directed spray., Early summer., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46
Directed spray., Fall., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46
Directed spray., Late winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46
Directed spray., When needed., Sprayer.	SC/S	NA	13.5 lb A	*	NS	NS	NS	NS	NS	NS	TX	C46
Directed spray., Winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46
Soil treatment (specialized)., Early summer., Hand held sprayer.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
Soil treatment (specialized)., Late winter., Hand held sprayer.	, EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
Spot soil treatment., Early summer., By hand.	G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Fall., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Late winter., By hand.	. G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Not on label., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Spring., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Winter., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spray., When needed., Boom sprayer.	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL	C46

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HED	GEROWS	(con't)	Use G	rouj	p: TE	RRESTRIA	L NON-FOOD (	CROP (	con't)			
Tree injection treatment., When needed., Tree injection equipment.	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS		
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS			Use G	rouj	p: TE	RRESTRIA	L NON-FOOD (	CROP				
Bark cut treatment., April., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	FL	C46
Bark cut treatment., February., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	FL	C46
Bark cut treatment., June., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	FL	C46
Bark cut treatment., March., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	FL	C46
Bark cut treatment., May., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., April., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., Early summer., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., Fall., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., February., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., June., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., Late winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	3.000E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46
Basal spray., March., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Basal spray., May., Hand held sprayer.	EC	NA	.002114 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46

SITE Application Type, Application	Form(s)	Min. Appl.	Max. Appl. Soil Max. #	Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -		Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Ef	fica-	less noted	unless noted Max. /crop	/year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial o	only)	otherwise)	otherwise) Dose cycle		[day(s)	]	
				cycle			

NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)													
Basal spray., When needed., Hand held sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Basal spray., When needed., Power sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Basal spray., Winter., Hand held sprayer.	EC	NA	.002114 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS		C46	
	RTU	NA	3.113E-04 lb sq.ft	*	NS	NS	NS	NS	NS	NS		C46	
Broadcast., April., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., April., Sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., Early summer., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., Early summer., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., Early summer., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Broadcast., Fall., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., Fall., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., February., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., February., Sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., June., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., June., Sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Broadcast., Late winter., Aircraft.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., Late winter., Ground.	G	NA	5 lb A	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS			
Broadcast., Late winter., Sprayer.	SC/S	NA	7.2 lb A	*	NS	NS	NS	NS	NS	NS		C46	

SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. D	ose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment -	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless	noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherw	ise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop	/year	[day(s)]	]	
		cycle				

NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)												
Broadcast., March., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Broadcast., March., Sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Broadcast., May., Aircraft.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Broadcast., May., Sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
Broadcast., Not on label., By hand.	P/T	NA	6.945 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Spring., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Aircraft.	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., When needed., Boom sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL, AR, FL, GA, LA, MS, OK, NC, SC, TN, TX	C46
Broadcast., When needed., Ground.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	G	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	P/T	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., When needed., Hand held sprayer	. EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
	SC/S	NA	10.8 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., When needed., Sprayer.	RTU	NA	12.45 lb A	*	NS	NS	NS	NS	NS	NS		C46
Broadcast., Winter., Aircraft.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Broadcast., Winter., Ground.	P/T	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		
Directed spray., Early summer., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46

				a 11 al 11 al	
SITE Application Type, Application Form(s)	Min. Appl.	Max. Appl. Soil Max. # Apps Max. Dose [(AI	Min. Restr.	Geographic Limitations	Use
Timing, Application Equipment –	Rate (AI un-	Rate (AI Tex. @ Max. Rate unless noted	Interv Entry	Allowed Disallowed	Limitations
Surface Type (Antimicrobial only) & Effica-	less noted	unless noted Max. /crop /year otherwise)/A]	(days) Interv		Codes
cy Influencing Factor (Antimicrobial only)	otherwise)	otherwise) Dose cycle /crop /year	[day(s)	]	
		cycle			

NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)													
Directed spray., Fall., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Directed spray., Late winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Directed spray., Winter., Sprayer.	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	NS		C46	
	RTU	NA	8.3 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Soil treatment (specialized)., April., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Soil treatment (specialized)., Early summer., Hand held sprayer.	EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Soil treatment (specialized)., February., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Soil treatment (specialized)., June., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Soil treatment (specialized)., Late winter. Hand held sprayer.	, EC	NA	12 lb A	*	NS	NS	NS	NS	NS	NS		C46	
Soil treatment (specialized)., March., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Soil treatment (specialized)., May., Hand held sprayer.	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46	
Spot soil treatment., Early summer., By hand.	G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS			
Spot soil treatment., Fall., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS			
Spot soil treatment., Late winter., By hand	. G	NA	.004688 lb in. DBH	*	NS	NS	NS	NS	NS	NS			
	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS			
Spot soil treatment., Not on label., By hand.	P/T	NA	.001984 lb in. of stem dia	*	NS	NS	NS	NS	NS	NS			

SITE Application Type, Application	Form(s)	Min. Appl.	Max. Appl. Soil Max. #	Apps Max. Dos	se [(AI	Min. Restr.	Geographic Li	mitations	Use
Timing, Application Equipment -		Rate (AI un-	Rate (AI Tex. @ Max.	Rate unless r	noted	Interv Entry	Allowed	Disallowed	Limitations
Surface Type (Antimicrobial only) & Ef	fica-	less noted	unless noted Max. /crop	/year otherwis	se)/A]	(days) Interv			Codes
cy Influencing Factor (Antimicrobial o	only)	otherwise)	otherwise) Dose cycle	/crop	/year	[day(s)	]		
				cycle					

NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)												
Spot soil treatment., Spring., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spot soil treatment., Winter., By hand.	P/T	NA	.00475 lb in. DBH	*	NS	NS	NS	NS	NS	NS		
Spray., When needed., Boom sprayer.	SC/S	NA	1.125 lb A	*	NS	1/1 yr	NS	NS	NS	NS	AL	C46
Tree injection treatment., April., Injection.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., April., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., February., Injection.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., February., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., June., Injection.	. EC	NA	5.284E-04 lb in. DBH		NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., June., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., March., Injection.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., March., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., May., Injection.	EC	NA	5.284E-04 lb in. DBH		NS	NS	NS	NS	NS	NS	FL	C46
Tree injection treatment., May., Tree injection equipment.	EC	NA	5.284E-04 lb in. DBH	*	NS	NS	NS	NS	NS	NS	FL	C46
RECREATIONAL AREAS			Use G	rou	p: TE	RRESTRIAL	NON-FOOD C	CROP				
Tree injection treatment., When needed., Tree injection equipment.	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS		

#### LEGEND

HEADER ABBREVIATIONS Min. Appl. Rate (AI unless : Minimum dose for a single application to a single site. System calculated. Microbial claims only. noted otherwise) Max. Appl. Rate (AI unless : Maximum dose for a single application to a single site. System calculated. noted otherwise) Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only). Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr" Max. Dose [(AI unless : Maximum dose applied to a site over a single crop cycle or year. System calculated. noted otherwise)/A] Min. Interv (days) : Minimum Interval between Applications (days) Restr. Entry Interv (days) : Restricted Entry Interval (days) SOIL TEXTURE FOR MAX APP. RATE \* : Non-specific C : Coarse М : Medium F : Fine 0 : Others FORMULATION CODES EC : EMULSIFIABLE CONCENTRATE G : GRANULAR P/T : PELLETED/TABLETED : LIOUID-READY TO USE RTU SC/S : SOLUBLE CONCENTRATE/SOLID ABBREVIATIONS AN : As Needed NA : Not Applicable NS : Not Specified (on label) : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, UC briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablets, tag, tape, towelette, tray, unit, --APPLICATION RATE DCNC : Dosage Can Not be Calculated No Calc : No Calculation can be made W : PPM calculated by weight v : PPM Calculated by volume : Hundred Weight cwt nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234" USE LIMITATIONS CODES C14 : Grown for seed only. C46 : Do not apply through any type of irrigation system. G01 : \_\_\_\_ day(s) pregrazing interval. GA4 : Do not feed treated forage to livestock. H01 : \_\_\_\_ day(s) preharvest interval. \* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION. GEOGRAPHIC CODES 001 : Northeast 008 : Southern States 013 : Other 014 : OR West of the Cascade Mountains 016 : Northern States AL : Alabama AR : Arkansas CA : California CT : Connecticut DE : Delaware FL : Florida GA : Georgia HI : Hawaii IA : Iowa IL : Illinois IN : Indiana

- KY : Kentucky LA : Louisiana
- MA : Massachussets

- MD : Maryland ME : Maine MI : Michigan MN : Minnesota MO : Missouri MS : Mississippi MT : Montana NC : North Carolina ND : North Dakota NH : New Hampshire
- NJ : New Jersey
- NM : New Mexico NY : New York
- OH : Ohio
- OK : Oklahoma
- PA : Pennsylvania PR : Puerto Rico
- RI : Rhode Island
- SC : South Carolina SD : South Dakota
- TN : Tennessee
- TX : Texas VA : Virginia VT : Vermont

- WI : Wisconsin
- WV : West Virginia WY : Wyoming

# APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

### **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Hexazinone covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Hexazinone in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. <u>Data Requirement</u> (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. <u>Use Pattern</u> (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

- A Terrestrial food
- B Terrestrial feed
- C Terrestrial non-food
- D Aquatic food
- E Aquatic non-food outdoor
- F Aquatic non-food industrial
- G Aquatic non-food residential
- H Greenhouse food
- I Greenhouse non-food
- J Forestry
- K Residential
- L Indoor food
- M Indoor non-food
- N Indoor medical
- O Indoor residential

3. <u>Bibliographic citation</u> (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography\appendix for a complete citation of the study.

# **APPENDIX B**

REQUIRI	EMENT	USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	All	41172501, 42345701
61-2A	Starting Materials & Manufacturing Process	All	41172501, 42345701
61-2B	Formation of Impurities	All	41172501, 42345701
62-1	Preliminary Analysis	All	41309001, 42345702
62-2	Certification of limits	All	41309001, 42345702
62-3	Analytical Method	All	41309001, 42345702
63-2	Color	All	41203201
63-3	Physical State	All	41203201
63-4	Odor	All	41203201
63-5	Melting Point	All	41203201, 42292801
63-6	Boiling Point	N/A	
63-7	Density	All	41203201, 42292801
63-8	Solubility	All	41203201, 42292801
63-9	Vapor Pressure	All	41203201, 42741801
63-10	<b>Dissociation Constant</b>	All	41203201, 42292801
63-11	Octanol/Water Partition	All	41203201, 42292801
63-12	рН	All	00118509, 41203201, 42292801
63-13	Stability	All	41203201, 42292801

REQUIRE	CMENT	USE PATTERN	CITATION(S)
63-14	<b>Oxidizing/Reducing Action</b>	All	41203201, 42292801
63-15	Flammability	N/A	
63-16	Explodability	All	41203201, 42292801
63-17	Storage stability	All	41203201, 42292801
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion characteristics	All	41203201, 42292801
ECOLO	GICAL EFFECTS		
71-1A	Acute Avian Oral - Quail/Duck	A, B, C, J	00073988
71-2A	Avian Dietary - Quail	A, B, C, J	00072663, 00107878
71-2 <b>B</b>	Avian Dietary - Duck	A, B, C, J	00104981
71-4A	Avian Reproduction - Quail	A, B, C, J	41764901, 41938001
71-4 <b>B</b>	<b>Avian Reproduction - Duck</b>	A, B, C, J	41764902
72-1A	Fish Toxicity Bluegill	A, B, C, J	00076959, 00104980
72-1B	Fish Toxicity Bluegill - TEP	J	41235001
72-1C	Fish Toxicity Rainbow Trout	A, B, C, J	00104980
72-1D	Fish Toxicity Rainbow Trout- TEP	J	41235002
72-2A	Invertebrate Toxicity	A, B, C, J	00116269
72-2 <b>B</b>	Invertebrate Toxicity - TEP	J	41235003
72-3A	Estuarine/Marine Toxicity - Fish	A, B, C, J	Waived

REQUIRE	MENT	USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	A, B, C, J	00047164
72-3C	Estuarine/Marine Toxicity - Shrimp	A, B, C, J	00047164
72-4A	Early Life Stage Fish	A, B, C, J	41406001
72-4B	Life Cycle Invertebrate	A, B, C, J	00078041, 41406002
123-1A	Seed Germination/Seedling Emergence	A, B, C, J	43162501
123-1B	Vegetative Vigor	A, B, C, J	43162501
123-2	Aquatic Plant Growth	A, B, C, J	41287001, 43225101, 43225102, 43302701
141-1	Honey Bee Acute Contact	A, B, C, J	41216502
TOXICO	LOGY		
81-1	Acute Oral Toxicity - Rat	A, B	41235004
81-2	Acute Dermal Toxicity - Rabbit/Rat	A, B	00104974
81-3	Acute Inhalation Toxicity - Rat	A, B	41756701
81-4	Primary Eye Irritation - Rabbit	A, B	00106003
81-5	Primary Dermal Irritation - Rabbit	A, B	00106004
81-6	Dermal Sensitization - Guinea Pig	A, B	41235005
82-1A	90-Day Feeding - Rodent	A, B	00104977
82-1B	90-Day Feeding - Non-rodent	A, B	00114484
82-2	21-Day Dermal - Rabbit/Rat	A, B	41309005
83-1B	Chronic Toxicity - Non-Rodent	A, B	42162301
83-2B	Oncogenicity - Mouse	A, B	00079203, 41359301, 42509301

REQUIRE	MENT	USE PATTERN	CITATION(S)
83-3A	Developmental Toxicity - Rat	A, B	40397501
83-3B	Developmental Toxicity - Rabbit	A, B	00028863
83-4	2-Generation Reproduction - Rat	A, B	42066501
83-5	Chronic Feeding/Carcinogenicity Rat	A, B	00108638
84-2A	Gene Mutation (Ames Test)	A, B	00098982, 00076956
84-2B	Structural Chromosomal Aberration	A, B	00130709, 00131355
84-4	Other Genotoxic Effects	A, B	00130708
85-1	General Metabolism	А, В	00247874
ENVIRC	NMENTAL FATE		
161-1	Hydrolysis	A, B, C, J	00064260, 41587301
161-2	Photodegradation - Water	A, B, C, J	41300801
161-3	Photodegradation - Soil	А, В	41300802
162-1	Aerobic Soil Metabolism	A, B, C, J	41807401, 42635001
162-3	Anaerobic Aquatic Metabolism	A, B	41807402, 42657301
162-4	Aerobic Aquatic Metabolism	Ε	41811801
163-1	Leaching/Adsorption/Desorption	A, B, C, J	00064262, 41528101 (DATA GAP; Due 4/3/95)
164-1	<b>Terrestrial Field Dissipation</b>	A, B, C	42377901, 42379201
164-2	Aquatic Field Dissipation	Ε	DATA GAP (Waived if all aquatic uses are dropped)
164-3	Forest Field Dissipation	J	00072664, 42336401

REQUIRE	MENT	USE PATTERN	CITATION(S)
165-1	<b>Confined Rotational Crop</b>	A, B	41008401, 42824001 (DATA GAP; Due 5/31/95)
165-2	Field Rotational Crop	A, B	RESERVED
165-3	Accumulation - Irrigated Crop	Ε	RESERVED (Waived if all aquatic uses are dropped)
165-4	<b>Bioaccumulation in Fish</b>	A, B, C, J	00078032, 00064265
166-1	<b>Ground Water - Small Prospective</b>		DATA GAP
201-1	Droplet Size Spectrum		DATA GAP; Due 12/31/94
202-1	Drift Field Evaluation		DATA GAP; Due 12/31/94
RESIDU	E CHEMISTRY		
171-4A	Nature of Residue - Plants		00078047, 00104846, 00126127
171-4 <b>B</b>	Nature of Residue - Livestock		$\begin{array}{c} 00104843,\ 41524801,\ 42187901,\ 42219301\\ 42248901,\ 42690601 \end{array}$
171-4C	Residue Analytical Method - Plants		00038868, 00101574, 00126127, 41572101 41572102, 41572103, 41572104, 41572105 41572106, 41964101, 41964102, 42987201 43025401
171-4D	Residue Analytical Method - Animal		00038868, 00101574, 00126127, 41572101 41572102, 41572103, 41572104, 41572105 41572106, 41964101, 41964102, 43074201
171-4E	Storage Stability		42276001, 42322701, 42418001, 42423001 42492101, 42535601, 42867501 (DATA GAP for Alfalfa and Metabolite C for Grass)

REQUIRE	EMENT	USE PATTERN	CITATION(S)
171-4J	Magnitude of Residues - Meat/Milk		DATA GAP; Due 5/31/95
171-4K	Crop Field Trials		
	Berries Group		
	- Blueberries		00101574, 41964101, 41964102
	Grass Forage, Fodder, and Hay Group		
	- Grasses, Pasture, and Rangeland		00138226, 41898301, 42419101 <b>(DATA</b> GAP for hay)

REQUIREMENT		USE PATTERN	CITATION(S)
	Non-Grass Animal Feeds (forage, fodder, straw, and hay) Group		
	- Alfalfa		00118050, 43074401, 43074402 (DATA GAP for alfalfa seed screenings)
	Miscellaneous Commodities		
	- Pineapple		00126127, 42535601
	- Sugarcane		$00028733,\ 00114039,\ 42322701$
171-4L	Processed Food		
	- Alfalfa		Feed additive tolerance of 8.0 ppm required for alfalfa meal
	- Sugarcane		Feed additive tolerance required for molasses 42276001, 42417901
	- Pineapple		Feed additive tolerance required for pineapple processing residue 42492101

# APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Hexazinone

# **GUIDE TO APPENDIX C**

- 1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
- 2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
- 3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
- 4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

# MRID

- 00028733 E.I. du Pont de Nemours & Company (1976) Determination of Hexazinone Metabolite C. Undated method. (Unpublished study received Jan 21, 1980 under 352-378; CDL:099225-A)
- 00028863 Serota, D.G.; Wolfe, G.W.; Cole, S.S.; et al. (1980) Teratology Study in Rabbits: H-12932: Project No. 201-522. Final rept. (Unpublished study including project no. 201-521, received Mar 14, 1980 under 352-378; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099298-A)
- 00038868 Holt, R.F. (1980) Determination of Hexazinone and Metabolite Residues Using Nitrogen Selective Gas Chromatography. Undated method. (Unpublished study received Jul 1, 1980 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099514-E)
- 00047164 Heitmuller, T. (1976) Acute Toxicity of H-9877 to Embryos of Eastern Oysters (Crassostrea virginica), to Grass Shrimp (Palaemonetes pugio), and to Fiddler Crabs (Uca pugila tor). (Unpublished study received Jul 25, 1979 under 352378; prepared by EG&G Bionomics, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099674-B)
- 00064260 Rhodes, R.C. (1974) Studies with Velpar Weed Killer in Water. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 110699-E)
- 00064262 Rhodes, R.C. (1974?) Mobility and Adsorption Studies with Velpar Weed Killer on Soils. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:110699-G)
- 00064265 Rhodes, R.C. (1974?) Four Week Residue Studies with Velpar Weed Killer and Bluegill Sunfish. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:110699-J)

## MRID

- 00072663 Dudeck, S.H.; Bristol, K.L. (1980) Avian Dietary Toxicity (LC50) Study in Bobwhite Quail: Project No. 201-547. Final rept. (Unpublished study received Jan 23, 1981 under 352-387; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:244106-A)
- 00072664 Neary, D.G.; Douglass, J.E.; Bush, P.B.; et al. (1980) Movement of Hexazinone in Forest Watersheds after a Hand Application of Velpar Gridball Pellets for Site Preparation. Progress rept., Nov 1980. By U.S. Forest Service, Southeastern Experiment Station, Coweeta Hydrologic Laboratory and Univ. of Georgia, Extension Poultry Science Dept. and Institute of Ecology. ?: USFS, SE. (FS-SE-1651-26(1); available from: U.S. Government Printing Office; published study; CDL:244106-B)
- 00073988 Fink, R.; Beavers, J.B.; Brown, R. (1978) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 112-121. (Unpublished study received May 23, 1978 under 352-387; prepared by Wildlife International, Ltd., and Washington College, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:233989-A)
- 00076956 Krahn, D.F.; McCooey, K.T. (1981) Chinese Hamster Ovary Cell Assay for Mutagenicity: Haskell Laboratory Report No. 56-81. (Unpublished study received May 20, 1981 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245117-A)
- 00076959 Schneider, P.W., Jr. (1976) 96-hour LC50 to Bluegill Sunfish: Haskell Laboratory No. 408-76. (Unpublished study received May 20, 1981 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245117-D)
- 00078047 Rhodes, R.C. (1975) Letter sent to 324 File dated Aug 12, 1975: Uptake and metabolism studies with 14C-DPX-3674 on sugarcane in the greenhouse. (Unpublished study received Mar 22, 1976 under 352-EX-91; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:095980-E)
- 00079203 Goldenthal, E.I.; Trumball, R.R. (1981) Two-year Feeding Study in Mice: IRDC No. 125-026. (Unpublished study received Jul 30, 1981 under 352-378; prepared by International Research and Development Corp., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245676-A; 245677)

## MRID

- 00101574 Interregional Research Project No. 4 (1982) Residue Studies of Hexazinone on Blueberries and Methomyl on Sugarcane. (Compilation; unpublished study received May 17, 1982 under 2E2687; CDL:070861-A)
- 00104846 Rapisarda, C. (19??) Metabolism of 14C-labeled Hexazinone in Alfalfa: Doc. No. HME 12-79. (Unpublished study received May 24, 1979 under 9G2214; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:098309-D)
- 00104974 Morrow, R. (1973) Skin Absorption Toxicity ALD and Skin Irritancy Test: Haskell Laboratory Report No. 503-73. (Unpublished study received Dec 5, 1973 under 352-EX-85; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-F)
- 00104980 Sleight, B. (1973) Acute Toxicity of H-7759, MR-581 to Bluegill (Lepomis macrochirus), Rainbow Trout (Salmo gairdneri) and Fathead Minnow (Pimephales promelas). (Unpublished study received Dec 5, 1973 under 352-EX-85; prepared by Bionomics, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-L)
- 00104981 Fletcher, D. (1973) Report to...: 8-day Dietary LC50 Study with H-7759; MR-581 in Mallard Ducklings: IBT No. 651-03194. (Unpublished study received Dec 5, 1973 under 352-EX-85; prepared by Industrial Bio-Test Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-N)
- 00106003 Dashiell, O.; Henry, J. (1982) Eye Irritation Test in Rabbits-EPA Pesticide Registration INA-3674-122: Haskell Laboratory Report No. 251-82. (Unpublished study received Jul 7, 1982 under 352-399; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:247801-A)
- 00106004 Dashiell, O.; Hinckle, L. (1982) Skin Irritation Test on Rabbits for EPA Pesticide Registration: Haskell Laboratory Report No. 203-82. (Unpublished study received Jul 7, 1982 under 352399; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:247802-A)

# MRID

- 00107878 Fletcher, D. (1973) Report to E.I. du Pont de Nemours & Company: 8 day Dietary LC50 Study with H-7759; MR-581 in Bobwhite Quail: IBT No. 651-03199. (Unpublished study received Dec 5, 1973 under 352-EX-85; prepared by Industrial Bio-Test Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-M)
- 00108638 Kaplan, A.; Frazier, C.; Adams, L.; et al. (1977) Long-term Feeding Study in Rats with ... (INA-3674): Haskell Laboratory Report No. 353-77. (Unpublished study received Aug 29, 1978 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:097323-C)
- 00114039 E.I. du Pont de Nemours & Co., Inc. (1978) Investigations Made with Respect to Residue Chemistry: Velpar. (Compilation; unpublished study received Aug 29, 1978 under 352-378; CDL: 097321-E)
- 00114484 Sherman, H.; Dale, N.; Adams, L.; et al. (1973) Three-month Feeding Study in Dogs with Sym Triazine-2,4(1H,3H)-dione, 3-cyclohexyl1-methyl-6dimethylamino-INA-3674: Haskell Laboratory Report No. 408-73. (Unpublished study received Apr 3, 1980 under 352378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:140051-A)
- 00116269 Schneider, P. (1976) 48-hour LC50 to Daphnia magna: Haskell Laboratory Report No. 262-76. (Unpublished study received Dec 30, 1977; under 352-387; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:232556-A; 235401)
- 00118050 E.I. du Pont de Nemours & Co., Inc. (1982) Data Supporting Amendment of Velpar Weed Killer Use on Alfalfa and Adding Velpar L Weed Killer Use on Alfalfa. (Unpublished study received Nov 15, 1982 under 352-378; CDL:248831-A)
- 00118509 E.I. du Pont de Nemours & Co., Inc. (1982) Product Chemistry: Hexazinone. (Compilation; unpublished study received Dec 17, 1982 under 352-399; CDL:071264-A)
- 00126127 E.I. du Pont de Nemours & Co., Inc. (1983) Results of Tests on the Amount of Residue Remaining on Treated Crop: Hexazinone. (Compilation; unpublished study received Feb 28, 1983 under 352-378; CDL:071438-A)

# MRID

- 00130708 Ford, L. (1983) Unscheduled DNA Synthesis/Rat Hepatocytes in vitro: INA-3674-112: Haskell Lab Report No. 766-82. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251041-A)
- 00130709 Vlachos, D.; Martenis, J.; Horst, A. (1982) In vitro Assay for Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Haskell Lab Report No. 768-82. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251042-A)
- 00131355 Farrow, M.; Cortina, T.; Zito, M.; et al. (1982) In vivo Bone Marrow Cytogenetic Assay In Rats: HLA Project No. 201-573. Final rept. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251043-A)
- 00138226 E.I. du Pont de Nemours & Co., Inc. (1984) Residue Chemistry Data Supporting the Use of Velpar L Weed Killer for Control of Undesirable Woody Plants in Rangeland. (Compilation; unpublished study received Apr 4, 1984 under 352-392; CDL:252954-A)
- 40397501 Mullin, L. (1987) Teratogenicity Study of INA-3674 in Rats: Haskell Laboratory Report No. 748-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 186 p.
- 41008401 Rapisarda, C. (1980) Rotational Crop Studies with Carbon 14-Labeledhexazinone: Proj. ID AMR-26-80. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 25 p.
- 41172501 Adams, C. (1989) Velpar (Hexazinone): Product Identity and Composition: Project ID A3674.E. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 50 p.
- 41203201 Silveira, E. (1989) Hexazinone: Physical and Chemical Characteristics: Laboratory Project ID A3674.D. Unpublished study prepared by E.I. du Pone de Nemours and Co., Inc. 60 p.
- 41216502 Hoxter, K.; Thompson, M.; Jaber, M. (1989) An Acute Contact Toxicity with the Honey Bee: Project ID 112-217. Unpublished study prepared by Wildlife International Ltd. 15 p.

## MRID

- 41235001 Hutton, D. (1989) Static Acute 96-Hour LC50 of IN A3674-208 to Bluegill Sunfish (Lepomis macrochirus): Project ID 462-89. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 17 p.
- 41235002 Hutton, D. (1989) Static Acute 96-Hour LC50 of IN A3674-208 to Rainbow Trout (Salmo gairdneri): Project ID 463-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. 18 p.
- 41235003 Hutton, D. (1989) Static Acute 48-Hour EC50 of IN A3674-208 to Daphnia magna: Project ID 452-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. 17 p.
- 41235004 Hutton, J. (1989) Acute Oral Toxicity Study with IN A3674-207 in Male and Female Rats: Project ID 347-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. 34 p.
- 41235005 Pharmakon Research International, Inc. (1989) Closed Patch Repeated Insult Dermal Sensitization Study (Buehler Method) with IN A3674 -207 in Guinea Pigs: Project ID 446-89. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 35 p.
- 41287001 Forbis, A. (1989) Acute Toxicity of Hexazinone to Selenastrum capricornutum Printz: Lab Project Number 38069; AMR-1446-89. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 31 p.
- 41300801 Hawkins, D.; Elsom, L.; Gray, S. (1989) The Photodegradation of Carbon-14-hexazinone in water: HRC Report No. HRC/DPT 196/ 891351; Du Pont Doc. No. AMR-1412-89. Unpublished study prepared by Huntingdon Research Centre, Ltd., Dept. of Chemical Metabolism and Radiosynthesis. 55 p.
- 41300802 Hawkins, D.; Elsom, L.; Gray, S. (1989) The Photodegradation of Carbon-14-hexazinone on Soil: HRC Report No. HRC/DPT 197/ 891455; Du Pont Document No. AMR-1413-89. Unpublished study prepared by Huntingdon Research Centre Ltd., Dept. of Chemical Metabolism and Radiosynthesis. 63 p.

## MRID

- 41309001 Silveira, E. (1989) Technical Hexazinone: Analysis and Certification of Product Ingredients: Lab Project Number: A3674/F. Unpublished study prepared by E. I. du Pont de Nemours and Co. 122 p.
- 41309005 Malek, D. (1989) Repeated Dose Dermal Toxicity: 21-Day Study with DPX-A3674-207 (Hexazinone) in Rabbits: Lab Project Number: 8705/001 : 673/89. Unpublished study prepared by du Pont de Nemours and Co. 206 p.
- 41359301 Goldenthal, E. (1989) Supplement 1 to: Two-Year Feeding Study in Mice with Hexazinone: Lab Project Number: HLO/141/81. Unpublished study prepared by International Research and Development Corp. 41 p.
- 41406001 Pierson, K. (1990) Effects of IN A3674-207 on the Embryos and Larvae of Fathead Minnows (Pimephales promelas): Lab Project Number HLR 656-89: MR-8705-001. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 221 p.
- 41406002 Pierson, K. (1990) Chronic Toxicity of IN A3674-207 to Daphnia magna: Lab Project Number: HLR 68-90: MR-8705-001. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 198 p.
- 41524801 Hawkins, W.; Elsom, L.; Gray, S., et al. (1990) The Metabolism of Carbon 14-Hexazinone in Laying Hens: Lab Project Number: 203/ 90454: AMR-1517-89. Unpublished study prepared by Huntingdon Research Centre, Ltd. 80 p.
- 41528101 Priester, T.; Sheftic, G. (1990) Batch Equilibrium (Adsorption/Desorption) of Carbon 14Hexazinone and Soil Thin-Layer Chromatography Studies of Carbon 14Hexazinone and Its Major Soil Degrades: Lab Project Number: AMR-1421-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. 85 p.
- 41572101 Fomenko, J. (1990) Testing of DPX-A3674 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1489-89: DP001-01. Unpublished study prepared by Spectralytix. 67 p.
- 41572102 Fomenko, J. (1990) Testing of IN-T3937 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1490-89: DP001-02. Unpublished study prepared by Sprectalytix Inc. 57 p.

## MRID

- 41572103 Fomenko, J. (1990) Testing of IN-A3928 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1491-89: DP001-03. Unpublished study prepared by Spectralytix, Inc. 67 p.
- 41572104 Fomenko, J. (1990) Testing of IN-T3935 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1492-89: DP001-04. Unpublished study prepared by Spectralytix Inc. 57 p.
- 41572105 Fomenko, J. (1990) Testing of IN-B2838 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1493-89: DP001-05. Unpublished study prepared by Spectralytix Inc. 67 p.
- 41572106 Fomenko, J. (1990) Testing of IN-B3936 through FDA Multi-Residue Protocols A-E: Lab Project Number: AMR-1494-89: DP001-06. Unpublished study prepared by Spectralytix Inc. 67 p.
- 41587301 Chrzanowski, R. (1990) Hydrolysis of carbon 14 Hexazinone in pH 5, 7 and 9 Buffer Solutions: Lab Project Number: AMR 1643-90. Unpublished study prepared by E. I. Du Pont de Nemours and Co., Ag Products Dept. 51 p.
- 41756701 Shapiro, R. (1990) Acute Inhalation-Limit Test: Hexazinone, Batch # GG1-15: Lab Project Number: T-452. Unpublished study prepared by Product Safety Labs. 24 p.
- 41764901 Beavers, J.; Campbell, S.; Smith, G.; (1991) H 17,705: A One Generation Reproduction Study With the Northern Bobwhite (Colinus virginianus): Lab Project Number: 112-225: 772-90. Unpublished Study prepared by Wildlife International Ltd. 168 p.
- 41764902 Beavers, J.; Campbell, S.; Smith, G.; (1991) H 17,705: A One Generation Reproduction Study With the Mallard (Anus platyrhynchos) Lab Project Number: 112-226: 773-90. Unpublished study prepared by Wildlife International Ltd. 167 p.
- 41807401 Hawkins, D.; Elsom, L.; Kane, T.; et al. (1990) The Metabolism of carbon 14-Hexazinone in a California Type Soil Under Aerobic Conditions: Lab Project Number: HRC/DPT 194/901364: AMR-1329-88. Unpublished study prepared by Huntingdon Research Centre Ltd. 68 p.

## **MRID**

- 41807402 Hawkins, D.; Elson, L.; Kane, T.; et al. (1990) The Anaerobic Aquatic Metabolism of carbon 14-Hexazinone: Lab Project Number: AMR-1328-88: HRC/DPT 193/901475. Unpublished study prepared by Huntingdon Research Centre Ltd. 80 p.
- 41811801 Chrzanowski, R. (1991) Aerobic Aquatic Metabolism of Carbonylcarbon 14 Hexazinone in Madera, California Field Water and Sediment: Lab Project Number: AMR 1690-90. Unpublished study prepared by E.I. du Pont de Nemours and Co. 64 p.
- 41898301 Bollin, E. (1991) Magnitude of Residues of Velpar Herbicide in Pasture and Range Grasses: Lab Project Number: AMR-1429-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. 241 p.
- 41938001 Beavers, J.; Campbell, S.; Smith, G.; et al. (1991) Supplement to H 17,705: A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos): Lab Project Number: 112-226: HLO-773-90. Unpublished study prepared by Wildlife International Ltd. 9 p.
- 41964101 Bollin, E.; Hay, R. (1991) Magnitude of Residues of Velpar and Velpar L Herbicide in Lowbush Blueberries: Lab Project Number: AMR1431-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. 46 p.
- 41964102 Bollin, E.; Hay, R. (1991) Magnitude of Residues of Velpar and Velpar L Herbicide in Highbush Blueberries: Lab Project Number: AMR-1434-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. 46 p.
- 42066501 Mebus, C. (1991) Reproductive and Fertility Effects with IN A3674207 Multigeneration Reproduction Study in Rats: Lab Project Number: 404-91: 8873-001. Unpublished study prepared by E.I. du Pont Nemours and Co., Haskell Lab. 1218 p.
- 42162301 Dalgard, D. (1991) Chronic Toxicity Study in Dogs with DPXA3674-207 (Hexazinone): Lab Project Number: 8754-001: 201905: HLO 164-91. Unpublished study prepared by E. I. du Pont de Nemours and Co. 526 p.
- 42187901 Hawkins, D.; Elsom, L.; Dighton, M.; et al. (1992) The Metabolism of carbon 14-Hexazinone in the Goat: Lab Project Number: 245/91718: AMR-1906-90. Unpublished study prepared by Huntingdon Research Centre Ltd. 105 p.

## MRID

- 42219301 Hawkins, D.; Elsom, L.; Dighton, M.; (1992) The Metabolism of carbon 14-Hexazinone in Laying Hens: The Freezer Storage Stability of Tissues, Eggs and Excreta from Laying Hens Dosed with carbon 14-Hexazinone: Supplement to: Lab Project Number: HRC/203/90454; AMR-1517-89. Unpublished study prepared by Huntingdon Research Centre Ltd. 33 p.
- 42248901 Hawkins, D.; Elsom, L.; Dighton, M. (1992) The Metabolism of Carbon-14 Hexazinone in the Goat, Supplement 1: The Freezer Storage Stability of Carbon-14 Residues in Tissues and Milk from a Lactating Goat Dosed with Carbon 14 Hexazinone: Lab Project Number: HRC/DPT 245/91718: AMR-1906-90. Unpublished study prepared by Huntingdon Research Centre. 36 p.
- 42276001 Powley, C.; Tomic, D. (1992) Magnitude of the Residue of Velpar Herbicide in Sugarcane and its Processed Fractions: Lab Project Number: AMR 1473-89: 35-5300: 14-5308. Unpublished study prepared by Dupont and Hawaiian Sugar Planters Association. 151 p.
- 42292801 Silveira, E. (1992) Hexazinone: Physical and Chemical Characteristics: A Supplement: Lab Project Number: A3674.D. Unpublished study prepared by E.I. du Pont de Nemours & Co., Inc. 13 p.
- 42322701 Powley, C.; Tomic, D. (1992) Magnitude of Residues of Velpar Herbicide in Sugarcane: Lab Project Number: AMR 1472-89: 14-5308. Unpublished study prepared by E.I. DuPont de Nemours and Co. and Hawaiian Sugar Planters Assoc. 180 p.
- 42336401 Michael, J. (1992) Fate of Hexazinone After Application for Pine Planting Site Preparation: Lab Project Number: 1786-90. Unpublished study prepared by Auburn University. 700 p.
- 42345701 Adams, C. (1989) Velpar (Hexazinone): Product Identity and Composition: Supplement to: Lab Project Number: A3674. E. Unpublished study prepared by E. I. du Pont de Nemours & Co. 178 p.
- 42345702 Silveira, E. (1992) Technical Hexazinone Analysis and Certification of Product Ingredients: Supplement to: Lab Project Number: A3674.F. Unpublished study prepared by E. I. du Pont de Nemours and Co. 72 p.

## MRID

- 42377901 Bollin, E. (1992) Field Soil Dissipation of Hexazinone Herbicide: Lab Project Number: AMR 1474-89: 9045258: 9140414. Unpublished study prepared by E. I. du Pont de Nemours and Comp., Harris Environemntal Tech., Inc. and Enviro Test Laboratories. 419 p.
- 42379201 Bollin, E. (1992) Dissipation of Hexazinone in California Soil Following Application of Velpar L Herbicide: Lab Project Number: AMR 1923-91: 9100226: 91-P1368. Unpublished study prepared by E. I. du Pont de Nemours and Comp., Harris Environmental Technologies, Inc., Enviro-Test Laboratories. 272 p.
- 42417901 Mulcahey, L. (1992) Magnitude of the Residues of Velpar Herbicide in Sugarcane and its Processed Fractions (Supplemental): Lab Project Number: AMR 1473-89 (SUPP 1): 35-5300: 14-5308. Unpublished study prepared by E. I. DuPont de Nemours and Co. in coop with the Hawaiian Sugar Planters' Assoc. 40 p.
- 42418001 Klemens, A.; Tomic, D. (1992) Freezer Storage Stability of Hexazinone and Metabolites in Pasture and Range Grasses. Lab Project Number: AMR 1582-90: A022.005. Unpublished study prepared by E. I. DuPont de Nemours and Co. in coop with Huntingdon Analytical Services. 54 p.
- 42419101 Mulcahey, L. (1992) Magnitude of Residues of Velpar Herbicide in Pasture and Range Grasses: A Supplement: Lab Project Number: AMR 1429-89: 1022.004: 91012. Unpublished study prepared by E.I. du Pont de Nemours and Co. 89 p.
- 42423001 Klemens, A.; Devine, P. (1992) Freezer Storage Stability of Velpar Herbicide and Metabolites on Blueberries: Lab Project Number: AMR 1911-90. Unpublished study prepared by E. I. DuPont de Nemours and Co. 47 p.
- 42492101 Powley, C.; Tomic, D. (1992) Magnitude of Residues of Velpar Herbicide in the Processed Fractions of Pineapples: Lab Project Number: AMR 1471-89: MP 90-03.01: 36-5309. Unpublished study prepared by E.I. du Pont de Nemours & Co. 114 p.
- 42509301 Slone, T. (1992) Two-year Feeding Study in Mice with Hexazinone: Supplement No. 1: Lab Project Number: 9463-001: HLO 414-81. Unpublished study prepared by E. I. du Pont de Nemours & Co. 56 p.

## MRID

- 42535601 Powley, C.; Tomic, D. (1992) Magnitude of Residues of Velpar Herbicide in Pineapples: Lab Project Number: AMR 1570-89: 36-5309. Unpublished study prepared by E.I. du Pont de Nemours and Co.; Hawaiian Sugar Planters' Association. 81 p.
- 42635001 Hawkins, D.; Elsom, L.; Kane, T.; et al. (1993) The Metabolism of (carbon 14)-Hexazinone in a California Type Soil under Aerobic Conditions: Supplement 1: Lab Project Number: HRC/DPT 194/901364. Unpublished study prepared by Huntingdon Research Centre Ltd. 17 p.
- 42657301 Hawkins, D.; Elsom, L.; Kane, T.; et al. (1993) The Anaerobic Aquatic Metabolism of (carbon 14)-Hexazinone: Supplement 1: Analysis of 2 Additional Non-Sterile Anaerobic Water-Sediment Systems after 365 Days Incubation and Structural Assignment of Metabolite 2: Lab Project Number: HRC/DPT 193/901475: AMR-1328-88. Unpublished study prepared by Huntingdon Research Centre Ltd. 20 p.
- 42690601 Hawkins, D.; Elsom, L.; Kitmitto, A. (1993) The Metabolism of (carbon 14)-Hexazinone in Laying Hens: Supplement 2 (Comparison of (carbon 14)-Hexazinone Metabolites in Excreta, Tissues and Eggs of Hens with Reference Compounds Metabolites A-1, C-1 and E-1): Lab Project Number: HRC/DPT 203/90454: AMR-1517-89. Unpublished study prepared by Huntingdon Research Centre Ltd. 32 p.
- 42741801 Morrissey, M. (1993) Series 63 Vapor Pressure Determination of Hexazinone Pure Active Ingredient: Final Report: Lab Project Number: HWI 6324-109: AMR 2632-93. Unpublished study prepared by Hazleton Wisconsin, Inc. 42 p.
- 42824001 Rapisarda, C. (1993) Rotational Crop Studies with (carbon 14)-Labeled Hexazinone: Supplement No. 1: Lab Project Number: AMR 26-80. Unpublished study prepared by E. I. du Pont de Nemours and Co. 11 p.
- 42867501 Klemens, A.; Devine, P. (1993) Freezer Storage Stability of Hexazinone and Metabolites in Pasture and Range Grasses: Supplement No. 1: Lab Project Number: AMR 1582-90: A022.005. Unpublished study prepared by E. I. du Pont de Nemours and Co. and Huntingdon Analytical Services. 72 p.

## MRID

- 42987201 Powley, C.; Zhou, M.; DeBernard, P. (1993) Method for the Determination of Hexazinone in Sugarcane and Processed Fractions: Lab Project Number: AMR 2654-93. Unpublished study prepared by DuPont Agricultural Products. 30 p.
- 43025401 Bruns, G. (1993) Independent Laboratory Validation of the Analytical Enforcement Method for the Determination of Hexazinone in Sugarcane, Molasses, and Bagasse by Gas Chromatography: Lab Project Number: DUP69/REP: AMR/2804/93. Unpublished study prepared by Enviro-Test Labs. 34 p.
- 43074201 Hawkins, D.; Elsom, L.; Dighton, M.; et al. (1993) A Comparison of (carbon 14)-Hexazinone Metabolites in Hen Tissues and Eggs and Goat Tissues and Milk Synthesised Metabolite Standards: Lab Project Number: 294/932331: DPT/294/932331: HRC/DPT/294/932331. Unpublished study prepared by Huntingdon Research Centre Ltd. 110 p.
- 43074401 Djanegara, T.; Devine, P. (1993) Magnitude of Residues of Hexazinone in Alfalfa Forage, Hay, and Seed Grown in the Western United States Following Application of Velpar Herbicide: Lab Project Number: AMR 1924-91: 92013. Unpublished study prepared by E.I. du Pont de Nemours & Co. and Spectralytix, Inc. 330 p.
- 43074402 Djanegara, T.; Devine, P. (1993) Magnitude of Residues of Hexazinone in Alfalfa Forage and Hay Grown in the Eastern United States Following Application of Velpar Herbicide: Lab Project Number: AMR 2010-91: 92025. Unpublished study prepared by E.I. du Pont de Nemours & Co. and Spectralytix, Inc. 316 p.
- 43162501 McKelvey, R.; Heldreth, K. (1994) Influence of Hexazinone on Seed Germination, Seedling Emergence, and Vegetative Vigor of Several Terrestrial Plants: Lab Project Number: AMR 2678-93: AMR 2736-93. Unpublished study prepared by DuPont Agricultural Products. 351 p.
- 43225101 Kannuck, R.; Sloman, T. (1994) Hexazinone (DPX-A3674): Influence on Growth and Reproduction of Lemna gibba G3: Lab Project Number: AMR 2874-93: MR 9785-001. Unpublished study prepared by Stine-Haskell Research Center, DuPont Agricultural Products. 41 p.

## MRID

- 43225102 Baer, K. (1994) Hexazinone (DPX-A3674): Influence on Growth and Reproduction of Skeletonema costatum: Lab Project Number: 241-94: AMR 2884-93: MR 8785. Unpublished study prepared by Stine-Haskell Research Center, DuPont Agricultural Products. 38 p.
- 43302701 Thompson, S. (1994) Hexazinone (DPX-A3674): Influence on Growth and Reproduction of Two Select Algal Species: Lab Project Number: AMR 3011-94: 335-94: 9785. Unpublished study prepared by Wildlife International Ltd. and E.I. du Pont de Nemours & Co. 75 p.

# **APPENDIX D. List of Available Related Documents**

The following is a list of available documents related to Hexazinone. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Hexazinone and are included in the EPA's Office of Pesticide Programs Public Docket.

- 1. Health and Environmental Effects Science Chapters
- 2. Detailed Label Usage Information System (LUIS) Report
- 3. Hexazinone RED Fact Sheet
- 4. PR Notice 86-5 (included in this appendix)
- 5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

# APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

#### PR NOTICE 86-5

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

# Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

#### I. <u>Purpose</u>

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

#### II. <u>Applicability</u>

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

#### III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

#### IV. <u>Background</u>

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

#### V. <u>Relationship of this Notice to Other OPP Policy and Guidance</u>

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any <u>data</u> submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data <u>submitted</u> with an application.

#### VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

#### - INDEX-

A.	Organization of the Submittal Package		Example Page 17
в.	Transmittal Document		11
С.	Individual Studies	. 4	
	C. 1 Special Considerations for Identifying Studies .	. 5	
D.	Organization of each Study Volume	. 6	17
	D. 1 Study Title Page	. 7	12

	D. 2 Statement of Data Confidentiality Claims
	(based on FIFRA §10(d)(1)) 8
	D. 3 Confidential Attachment
	D. 4 Supplemental Statement of Data Confidentiality Claims (other than those based on FIFRA §10(d)(1)) 8
	D. 5 Good Laboratory Practice Compliance Statement 9
Ε.	Reference to Previously Submitted Data 9
F.	Physical Format Requirements & Number of Copies 9
G.	Special Requirements for Submitting Data to the Docket 10

13 15

14 16

#### A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to <u>one</u> study, they should be included as an appendix to that study.

- If such materials relate to <u>more than one</u> study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

#### B. <u>Transmittal Document</u>

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP),  $\S3(c)(2)(B)$  data call-in,  $\S6(a)(2)$  submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition <u>and</u> an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

#### C. <u>Individual Studies</u>

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

 Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies. When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

#### C.1 <u>Special Considerations for Identifying Studies</u>

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. <u>Safety Studies</u>. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. <u>Product Chemistry Studies</u>. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline <u>series</u> (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA S10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. <u>Residue Chemistry Studies</u>. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single crop, all such trials should be reported as a single study.

#### D. <u>Organization of Each Study Volume</u>

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

<u>When Required</u>	<u>Example</u>	
Always	Page 12	
One of the two alternative forms of this statement is always required	Page 13	
If study reports laboratory work subject to GLP require- ments	Page 16	
For certain toxicology studies (When flagging requirements are finalized.)		
Always - with an English language translation if required.		
At submitter's option		
If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)		
If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15	
Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (	Page 14 C)	
	Always One of the two alternative forms of this statement is always required If study reports laboratory work subject to GLP require- ments For certain toxicology studies flagging requirements are find Always - with an English lange translation if required. At submitter's option If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	

#### D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. <u>Study title</u>. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. <u>Data requirement addressed</u>. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. <u>Author(s)</u>. Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. <u>Study Date</u>. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. <u>Performing Laboratory Identification</u>. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. <u>Supplemental Submissions</u>. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. <u>Facts of Publication</u>. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA [0(d)(1)(A), (B), or (C)]. Use the appropriate alternative form of the statement either to assert a claim of [0(d)(1)] data confidentiality ([158.33(b)]) or to waive such a claim ([158.33(c)]). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

#### D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. <u>Supplemental</u> Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study <u>other than</u> described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

#### E. <u>Reference to Previously Submitted Data</u>

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should <u>not</u> be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

#### F. <u>Physical Format Requirements</u>

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

<u>Number of Copies Required</u> - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln <u>three</u> complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

#### G. <u>Special Requirements for Submitting Data to the Docket</u>

Data submittal packages associated with a Registration Standard or Special Review must be provided in <u>four</u> copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material contains no information claimed as confidential".

#### V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman Acting Director, Registration Division

Attachment 1.	Sample Transmittal Document
Attachment 2.	Sample Title Page for a Newly Submitted Study Statements of Data Confidentiality Claims
Attachment 3.	Statements of Data Confidentiality Claims
Attachment 4.	Supplemental Statement of Data Confidentiality
	Claims
Attachment 5.	Samples of Confidential Attachments
Attachment 6.	Sample Good Laboratory Practice Statements
Attachment 7.	Format Diagrams for Submittal Packages and Studies

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT\*

1. <u>Name and address of submitter</u> (or all joint submitters\*\*)

*Smith Chemical Corporation 1234 West Smith Street Cincipnati OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington Ky 56789
Cincinnati, OH 98765		Covington, KY 56789

\*Smith Chemical Corp will act as sole agent for all submitters.

2. <u>Regulatory action in support of which this package is</u> <u>submitted</u>

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

- 3. <u>Transmittal date</u>
- 4. <u>List of submitted studies</u>
  - Vol 1. Administrative materials forms, previous correspondence with Project Managers, and so forth.
  - Vol 2. Title of first study in the submittal (Guideline No.)
  - Vol n Title of nth study in the submittal (Guideline No.)
  - \* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

\* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company	Official: _		
		Name	Signature
Company	Name		
Company	Contact:		
		Name	Phone

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

<u>Author</u>

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories 940 West Bay Drive Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X (X is the total number of pages in the study)

#### STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).
Company \_\_\_\_\_\_
Company Agent: \_\_\_\_\_ Typed Name \_\_\_\_ Date: \_\_\_\_\_
Title \_\_\_\_\_ Signature \_\_\_\_\_

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.				
Company:				
Company Agent: _	Typed Name	Date:		
	Title	Signature		

#### STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

#### SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

### EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

<u>Example 1.</u> (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1       This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.         DELETED WORDS OR PHRASE:       Ethylene Glycol				
PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE	
6	14	Identity of Inert Ingredient	§10(d)(C)	
28	25		"	
100	19		"	

Example 2. (Confidential paragraph(s) that have been deleted from the study)

<u>CROSS REFERENCE NUMBER 5</u> This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.					0
DELETED PAR	AGRAPH	(S):			
(					)
(	Reprodu	ce the del	leted paragraph(s) here		)
(					)
PAGE	LINES	REASO	N FOR THE DELETION	FI	FRA REFERENCE
20.	2-17	Descript	tion of the quality control process	<u>§1</u>	0(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7       This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.         DELETED PAGES(S): are attached immediately behind this page					
PAGES 35-41.	REASON FOR THE DELETION Description of product manufacturing process	FIFRA REFERENCE §10(d)(1)(A)			

## ATTACHMENT 6.

## SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets	the requirements for 40 CFR Part 160
Submitter _	
Sponsor _	

## Example 2.

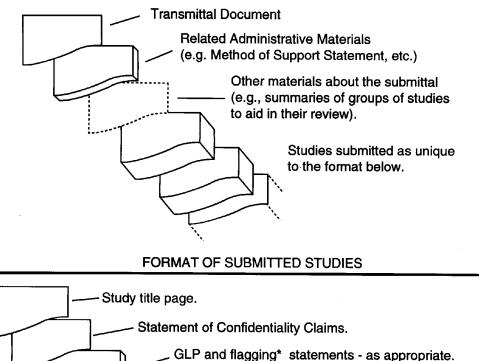
This study does not meet the requirements of 40 CFR differs in the following ways:	Part 160,	and
1		
2		
3		
Submitter		
Sponsor		
Study Director		

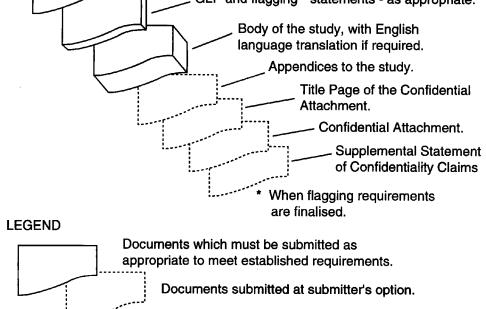
## Example 3.

The submitter of this study was neither the sponsor of this study no conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.	r
Submitter	

### ATTACHMENT 7.

#### FORMAT OF THE SUBMITTAL PACKAGE





PR Notice 91-2

WIND STARS. TO BE CHURDNER

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### **PR NOTICE** 91-2

#### NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

#### III. REQUIREMENTS

As described below under Unit V. " COMPLIANCE SCHEDULE," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

# After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

#### IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

#### V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

- (2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.
- (3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

### VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/ Anne E. Lindsay, Director Registration Division (H-7505C)

# APPENDIX F. Combined Generic and Product Specific Data Call-In

# GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

# **CERTIFIED MAIL**

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

- 1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or
- 2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the <u>Requirements</u> Status and Registrant's Response Form, (see section III-B); or
- 3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I-Why You are Receiving this NoticeSection II-Data Required by this NoticeSection III-Compliance with Requirements of this NoticeSection IV-Consequences of Failure to Comply with this NoticeSection V-Registrants' Obligation to Report Possible Unreasonable Adverse EffectsSection VI-Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet

- 2 Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
- 3 Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
- 4 <u>EPA Grouping of End-Use Products for Meeting Acute Toxicology Data</u> Requirements for Reregistration
- 5 EPA Acceptance Criteria
- 6 List of Registrants Receiving This Notice
- 7 Cost Share and Data Compensation Forms

# SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

# SECTION II. DATA REQUIRED BY THIS NOTICE

# II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

# II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the <u>Requirements Status and Registrant's Response Forms</u> (Attachment 3) within the timeframes provided.

### **II-C. TESTING PROTOCOL**

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

### II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

### **III-A. SCHEDULE FOR RESPONDING TO THE AGENCY**

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

### **III-B. OPTIONS FOR RESPONDING TO THE AGENCY**

**1. Generic Data Requirements** 

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

### a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific

Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

### b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

### c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

### d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

### e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

# 2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

# a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

#### b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

#### **Request for Product Specific Data Waivers.** c.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

# **III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE**

#### 1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

- (1)I will generate and submit data within the specified timeframe (Developing Data)
- (2)I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- I have made offers to cost-share (Offers to Cost Share)
- (3) (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study) (5)
- I am citing an existing study that EPA has classified as acceptable or an existing (6) study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

# **Option 1. Developing Data**

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40

CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's <u>Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.</u>

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the <u>Requirements Status and Registrant's Response Form</u> are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

### Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

### Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(ii) and must not qualify this offer. The other registrant is Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

### **Option 4. Submitting an Existing Study**

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, <u>all of the</u> following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been

transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

- b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

### Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

### **Option 6. Citing Existing Studies**

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, <u>Certification with Respect to Data</u> Compensation Requirements.

### 2. Product Specific Data

If you acknowledge on the product specific <u>Data Call-In Response Form</u> that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the <u>Requirements Status and Registrant's Response Form</u> related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the <u>Requirements Status and Registrant's Response Form</u>. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified time-frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data

jointly (Cost Sharing)

- I have made offers to cost-share (Offers to Cost Share)
- (3) (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study) I am submitting or citing data to upgrade a study classified by EPA as partially
- (5)acceptable and upgradeable (Upgrading a Study) I am citing an existing study that EPA has classified as acceptable or an existing
- (6) study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The <u>registration number</u> of the product for which data <u>will</u> be submitted <u>must</u> be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development -- The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

# **III-D REQUESTS FOR DATA WAIVERS**

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

#### Low Volume/Minor Use Waiver a.

Option 8 under item 9 on the <u>Requirements</u> <u>Status and Registrant's Response</u> Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the

pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

### b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised <u>Requirements Status and Registrant's Response Form</u> indicating the option chosen.

### 2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the <u>only</u> opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

# SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

# IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

- 1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
- 2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
- 3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
- 4. Failure to submit on the required schedule acceptable data as required by this Notice.
- 5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
- 6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
- 7. Withdrawal of an offer to share in the cost of developing required data.
- 8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a <u>Requirements Status and Registrant's</u> Response Form.

ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

# IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

# IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received <u>after</u> the 90 day response period required by this Notice will not result in the agency granting <u>any</u> additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, <u>unless</u> you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

#### **SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS**

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registrant are registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

#### **INQUIRIES AND RESPONSES TO THIS NOTICE SECTION VI.**

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2) and completed <u>Requirements</u> Status and <u>Registrant's Response Forms</u> (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director Special Review and **Reregistration Division** 

# Attachments

The Attachments to this Notice are:

- Data Call-In Chemical Status Sheet 1 -
- 2 -Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
- 3 -Generic Data Call-In and Product Specific Data Call-In Requirements Status
- and Registrant's Response Forms with Instructions EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration EPA Acceptance Criteria 4 -
- 5 -
- 6 -
- List of Registrants Receiving This Notice Confidential Statement of Formula, Cost Share and Data Compensation Forms 7 -

**Attachment 1. Chemical Status Sheets** 

# Hexazinone DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Hexazinone.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Hexazinone. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Hexazinone Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

# DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Hexazinone are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Hexazinone are needed. These data are needed to fully complete the reregistration of all eligible Hexazinone products.

## INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Andrew Ertman at (703) 308-8063.

All responses to this Notice for the generic data requirements should be submitted to:

Andrew Ertman, Chemical Review Manager Reregistration Branch Special Review and Registration Division (H7508W) Office of Pesticide Programs U.S. Environmental Protection Agency Washington, D.C. 20460 RE: Hexazinone

# HEXAZINONE DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Hexazinone.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Hexazinone. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Hexazinone Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Hexazinone are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Hexazinone are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Hexazinone products.

# INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Hexazinone, please contact Andrew Ertman at (703) 308-8063.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) 305-8590.

All responses to this Notice for the Product Specific data requirements should be submitted to:

C.P. Moran Chemical Review Manager Team 81 Product Reregistration Branch Special Review and Reregistration Branch 7508W Office of Pesticide Programs U.S. Environmental Protection Agency Washington, D.C. 20460

**RE:** Hexazinone

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

### Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

### **INTRODUCTION**

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form. BOTH "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has pre-printed these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been pre-printed on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

### INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS Generic and Product Specific Data Call-In

Item 1.ON BOTH FORMS: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In In response forms. You do not need to complete any item on the <u>Requirements Status and</u> Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

# INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS Generic and Product Specific Data Call-In

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the <u>Requirements Status and Registrant's Response</u> Form that indicates how you will satisfy those requirements.

# NOTE: Item 6a and 6b are not applicable for Product Specific Data.

Item 7a.**ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b.For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

# FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

### NOTE: Item 7a and 7b are not applicable for Generic Data.

### INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9.**ON BOTH FORMS:** Enter the date of signature.

Item 10.**ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11.ON BOTH FORMS: Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

### Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

### INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form. Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has pre-printed these forms to include certain information unique to this chemical. <u>DO NOT</u> use these forms for any other active ingredient.

Items 1 through 8 have been pre-printed on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" Generic and Product Specific Data Call-In

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

- Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.
- Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the <u>Requirements Status and Registrant's</u> Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" Generic and Product Specific Data Call-In

- Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:
  - A Terrestrial food
  - B Terrestrial feed
  - C Terrestrial non-food

- Aquatic food
- Aquatic non-food outdoor
- D E F Aquatic non-food industrial
- G H Aquatic non-food residential Greenhouse food
- I Greenhouse non-food crop
- J Forestry
- Κ Residential
- L Indoor food
- Indoor non-food Μ
- Indoor medical Ν
- 0 Indoor residential
- Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active
	Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient Pure Active Ingredient and Metabolites
PAI/PAIRA	Dure Active Ingredient or Dure Active
r Al/r AlkA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant
	Metabolites
TEP	Typical End-Use Product
TEP%	Typical End-Use Product, Percent Active Ingredient
	Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and
	Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active
	Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active
	Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use
	Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
21-	See: guideline comment

This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5. Item 8.

> **ON THE GENERIC DATA FORM:** The time frame runs from the date of your receipt of the Data Call-In notice.

**ON THE PRODUCT SPECIFIC DATA FORM:** The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the

date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

- Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.
  - Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.
  - Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

**However, for Product Specific Data**, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

**However, for Product Specific Data,** I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

- Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
- Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

**However, for Product Specific Data,** I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

#### FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that <u>apply</u> only to the "Requirements Status and Registrant's Response Form" for generic data.

- Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.
- Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
- Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

# **FOR PRODUCT SPECIFIC DATA:** The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

- Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.
- Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.
- Item 11. **ON BOTH FORMS:** Enter the date of signature.
- Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

# EPA'S DECISION ON BATCHING PRODUCTS CONTAINING HEXAZINONE FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient hexazinone, the Agency considered batching products. This process involves grouping similar products for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Acute toxicity data on individual products has frequently been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is cited, the registrant must clearly identify the material tested by its EPA registration number. If more than one Confidential Statement of Formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response", asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response", lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 3), or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch from citing his/her studies and offering to cost share (Option 3) those studies.

		Table 1: Hexazinone Batching	
Batch No.	EPA Reg. No.	% of Hexazinone	Formulation Type
1	352-421	1.0	liquid
	352-422	1.25	liquid
2	352-392	25.0	liquid
	FL86000900	25.0	liquid
	MT82001200	25.0	liquid
	NC83001200	25.0	liquid
	NM82002300	25.0	liquid
	TX83000200	25.0	liquid
	WY92000100	25.0	liquid
3	352-378	90.0	wettable powder
	62802-1	90.0	wettable powder in plugs
	FL80001800	90.0	wettable powder
	TX80002000	90.0	wettable powder

Table I lists the registered products, their active ingredient(s) and formulation type included in the batches identified for hexazinone.

Table II lists the registered products which could not be batched. For the purposes of acute toxicity batching, these products were not considered similar, or their similarity could not be determined with the information available. The registrants of these products are responsible for meeting the acute toxicity data requirements specified in the data matrix for end-use products.

	Table II: Non-Batched Hexazinone Registrations	
EPA Reg. No.	% of Hexazinone & other Active Ingredients	Formulation Type
228-220	1.25	liquid
352-450	75.0	granular
352-399	98.7	technical
7234-76	10.0	pellet
33560-21	10.0	granular
33560-41	75.0	pellet
33560-45	25.0	granular
62802-2	72.0	tablet

Attachment 1. EPA Acceptance Criteria

#### SUBDIVISION D

Guideline

Study Title

Series 61Product Identity and CompositionSeries 62Analysis and Certification of Product IngredientSeries 63Physical and Chemical Characteristics
--

#### **61 Product Identity and Composition**

#### ACCEPTANCE CRITERIA

- 1.\_\_\_\_ Name of technical material tested (include product name and trade name, if appropriate).
- 2.\_\_\_\_ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.
- Name and upper certified limit for each impurity or each group of impurities present at  $\geq 0.1\%$  by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at < 0.1%. 3.\_\_\_\_
- Purpose of each active ingredient and each intentionally-added inert. 4.
- Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active 5.\_\_\_\_ ingredient and, if available, for each intentionally-added inert.
- Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code 6.\_\_\_\_ numbers for each active ingredient.
- 7.\_\_\_
- 8.\_
- Description of manufacturing process.
   Statement of whether batch or continuous process.
   Relative amounts of beginning materials and order in which they are added.
   Description of equipment.
   Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
   Statement of whether process involves intended chemical reactions.
   Flow chart with chemical equations for each intended chemical reaction.
   Duration of each step of process.
   Description of purification procedures.
   Description of measures taken to assure quality of final product.
- Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at  $\geq 0.1\%$  or was found at  $\geq 0.1\%$  by product analyses and (2) certain toxicologically significant impurities (see #3). 9.\_

#### **62** Analysis and Certification of Product Ingredients

#### ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and

- Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 1.
- Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at  $\geq 0.1\%$ . Degree of accountability or closure  $\geq$  ca 98%. Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]. Complete and detailed description of each step in analytical method used to analyze above samples. Statement of precision and accuracy of analytical method used to analyze above samples. Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient. Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined. Upper certified limit proposed for each impurity present at  $\geq 0.1\%$  and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined. Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described. Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy. 3.

- 8.
- 10.

#### **63 Physical and Chemical Characteristics**

#### ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Does your study meet the following acceptance criteria? 63-2 Color Verbal description of coloration (or lack of it) Any intentional coloration also reported in terms of Munsell color system 63-3 Physical State Verbal description of physical state provided using terms such as "solid, granular, volatile liquid" Based on visual inspection at about 20-25° C 63-4 Odor Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds" Observed at room temperature 63-5 Melting\_Point Reported in °C Any observed decomposition reported \_\_\_\_ 63-6 Boiling Point Reported in °C Pressure under which B.P. measured reported Any observed decomposition reported 63-7 Density, Bulk Density, Specific Gravity Measured at about 20-25° C Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft<sup>3</sup> or lbs/gallon.] 63-8 Solubility Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide Measured at about 20-25° C Reported in g/100 ml (other units like ppm acceptable if sparingly soluble) 63-9 Vapor Pressure Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° Experimental procedure described Reported in mm Hg (torr) or other conventional units 63-10 Dissociation Constant Experimental method described Temperature of measurement specified (preferably about 20-25°C) 63-11 Octanol/water Partition Coefficient \_\_\_\_\_ Measured at about 20-25° C \_\_\_\_\_ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350) Data supporting reported value provided 63-12 pH Measured at about 20-25  $^\circ$  C Measured following dilution or dispersion in distilled water 63-13 Stability Sensitivity to metal ions and metal determined Stability at normal and elevated temperatures Sensitivity to sunlight determined

212

#### SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

#### 81-1 Acute Oral Toxicity in the Rat

#### ACCEPTANCE CRITERIA

- 3
- 4.
- 5
- 6
- Identify material tested (technical, end-use product, etc). At least 5 young adult rats/sex/group. Dosing, single oral may be administered over 24 hrs. Vehicle control if other than water. Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg). Individual observations at least once a day. Observation period to last at least 14 days, or until all test animals appear normal whichever is longer. Individual body weights. Gross necropsy on all animals. 7
- 8 ĝ
- 10.

#### 81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

#### ACCEPTANCE CRITERIA

ingestion.

Does your study meet the following acceptance criteria?

- 2.3 <del>ار</del> ا
- **4**
- k
- 5. 6. 7.
- 8.9
- Identify material tested (technical, end-use product, etc). At least 5 animals/sex/group. Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm. Dosing duration at least 24 hours. Vehicle control, only if toxicity of vehicle is unknown. Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg). Application site at least 10% of body surface area. Application site covered with a porous nonirritating cover to retain test material and to prevent Individual observations at least 14 days. Individual body weights. Gross necropsy on all animals. 10
- 12 13

14.

Criteria marked with an \* are supplemental and may not be required for every study. 215

#### 81-3 Acute Inhalation Toxicity in the Rat

#### ACCEPTANCE CRITERIA

- Identify material tested (technical, end-use product, etc). Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less). At least 5 young adult rats/sex/group. Dosing, at least 4 hours by inhalation. Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content. Chamber temperature, 22° C (+ 2°), relative humidity 40-60%. Monitor rate of air flow. Monitor actual concentrations of test material in breathing zone. Monitor aerodynamic particle size for aerosols. Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance). Individual observation period to last at least 14 days. Individual body weights. Gross necropsy on all animals.  $\hat{2}$

#### 81-4 Primary Eye Irritation in the Rabbit

#### ACCEPTANCE CRITERIA

- 2

- Identify material tested (technical, end-use product, etc). Study not required if material is corrosive, causes severe dermal irritation or has a pH of  $\leq 2$  or  $\geq 11.5$ . 6 adult rabbits. Dosing, instillation into the conjunctival sac of one eye per animal. Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance. Solid or granular test material ground to a fine dust. Eyes not washed for at least 24 hours. Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter). Individual daily observations.
- 9.\*

#### 81-5 Primary Dermal Irritation Study

#### ACCEPTANCE CRITERIA

- Identify material tested (technical, end-use product, etc). Study not required if material is corrosive or has a pH of  $\leq 2$  or  $\geq 11.5$ . 6 adult animals. Dosing, single dermal. Dosing duration 4 hours. Application site shaved or clipped at least 24 hours prior to dosing. Application site approximately 6 cm<sup>2</sup>. Application site covered with a gauze patch held in place with nonirritating tape. Material removed, washed with water, without trauma to application site. Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter). Individual daily observations. 11.\*

#### 81-6 Dermal Sensitization in the Guinea Pig

#### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

- 2.
- 3.

- Identify material tested (technical, end-use product, etc). Study not required if material is corrosive or has a pH of < 2 or > 11.5. One of the following methods is utilized: Freund's complete adjuvant test Guinea pig maximization test Split adjuvant technique Buehler test Open epicutaneous test Mauer optimization test Footpad technique in guinea pig. Complete description of test. Reference for test. Test followed essentially as described in reference document. Positive control included (may provide historical data conducted within the last 6 months). 5. 6. 7.

Criteria marked with an \* are supplemental and may not be required for every study. 219

Attachment 2. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 3. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidenti	al Business Info.	Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)	National Security	v Information (E.C	0.12065)	Form Approved	1. OMB No. 207	Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94	Expires 2/28/94
<b>ŞEPA</b>		United States Environmental Protection Agency Office of Pesticide Programs (TS-767) Washington, DC 20480 Confidential Statement of Formula	gency Formula	A. Basic Formulation		6. age	ō	See Instruc	See Instructions on Back
1. Name and Ado	ess of Appli	1. Name and Address of Applicant/Registrant <i>(Include ZIP Code)</i>		2. Name and Address of Producer (Include ZIP Code)	ss of Producer (	Include ZIP Code)			
3. Product Name				4. Registration No./File Symbol		5. EPA Product Mgr/Team No.	eam No.	6. Country Where Formulated	Formulated
				7. Pounds/Gal or Bulk Density		8. pH		9. Flash Point/Flame Extension	ne Extension
EPA USE ONLY		10. Components in Formulation /List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)	11. Supplier N	11. Supplier Name & Address	12. EPA Reg. No.	ļ	Component nulation t b.% by Weigl	13. Each Component         14. Certified Limits           16. Formulation         % by Weight           a. Amount         b. % by Weight	15. Purpose in Formulation
16. Typed Name	16. Typed Name of Approving Official					17. Total Weight	ight 100%	-	
18. Signature of	18. Signature of Approving Official		19. Title			20.1	20. Phone No. (Include Area Code)	le Area Code) 21. Date	te
EPA Form 857(	EPA Form 8570-4 (Rev. 12-90)	Previous editions are obsolete.	If you can photocopy t	If you can photocopy this, please submit an additional copy. White -	dditional copy. V		EPA File Copy (original)	Yellow -	Applicant copy

## Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

- b. If any block is not applicable, mark it N/A.
- The CSF must be signed, dated and the telephone number of the responsible party must be provided. c.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- For all active ingredients, the EPA Registration Numbers for the currently registered source products g. must be reported under column 12.
- The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for h. the trade names must be reported.
- For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms). i.
- j.
- k. All the items under column 13.b. must total 100 percent.
- All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form. 1.
- The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 m. instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that n. specific formulation.

#### United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

#### Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

<u> </u>

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

111111月11日,1111月月日,在内以口内内内的东西在4月1日,4月1		
United States Environmental Prote Washington, DC 2046	ction Agency <b>F</b> e	rm Approved
CERTIFICATION WITH RES	PECT TO	IB No. 2070-0107 2070-0057 proval Expires 3-31-9
Public reporting burden for this collection of information is estimated to av time for reviewing instructions, searching existing data sources, gathering completing and reviewing the collection of information. Send comments r aspect of this collection of information, including suggestions for reducing Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W. of Management and Budget, Paperwork Reduction Project (2070-0106),	and maintaining the ( regarding the burden ) this burden, to Chief Washington, DC 20	data needed, and estimate or any other , Information Policy 460: and to the Office
Please fill in blanks below.		
Company Name	Compan	y Number
Product Name	EPA Re	g. No.
Certify that:		
. That for each study cited in support of registration or reregistration under study, I am the original data submitter, or I have obtained the written per have notified in writing the company(ies) that submitted data I have cited	mission of the original	data submitter or L
compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation re compensation due, if any. The companies I have notified are: (check o	3(c)(2)(D) of FIFRA; a quirement of FIFRA a	(a) Pay and (b) Commence
<ul> <li>Compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation recompensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o due) due) due to the compensation due to the compensatio</li></ul>	3(c)(2)(D) of FIFRA; quirement of FIFRA; ne) of this form or attach egistrants' Response	(a) Pay and (b) Commence and the amount of ed Form,"
<ul> <li>Compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation recompensation due, if any. The companies I have notified are: (check o sheets, or indicated on the attached "Requirements Status and Recompleters, or indicated on the attached "Requirements Status and Recompleters, or indicated on the attached "Requirements Status and Recompleters, or indicated on the attached "Requirements Status and Recompleters, or indicated on under FIFRA.</li> </ul>	3(c)(2)(D) of FIFRA; quirement of FIFRA; ne) of this form or attach egistrants' Response	(a) Pay and (b) Commence and the amount of ed Form,"
<ul> <li>Compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation recompensation due, if any. The companies I have notified are: (check or sheets, or indicated on the submitted the studies listed on the back sheets, or indicated on the attached "Requirements Status and Recompliant in the previously complied with section 3(c)(1)(D) of FIFRA for the registration or reregistration under FIFRA.</li> </ul>	3(c)(2)(D) of FIFRA; quirement of FIFRA; ne) of this form or attach egistrants' Response studies I have cited in	(a) Pay and (b) Commence and the amount of ed Form,"
<ul> <li>Compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation recompensation due, if any. The companies I have notified are: (check o sheets, or indicated on the submitted the studies listed on the back sheets, or indicated on the attached "Requirements Status and Recompliant in the previously complied with section 3(c)(1)(D) of FIFRA for the registration or reregistration under FIFRA.</li> </ul>	3(c)(2)(D) of FIFRA; quirement of FIFRA; ne) of this form or attach egistrants' Response studies I have cited in	(a) Pay and (b) Commence and the amount of ed Form,"
Compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation re compensation due, if any. The companies I have notified are: (check o sheets, or indicated on the attached "Requirements Status and Re That I have previously complied with section 3(c)(1)(D) of FIFRA for the registration or reregistration under FIFRA.	3(c)(2)(D) of FIFRA; a quirement of FIFRA a ne) of this form or attach egistrants' Response studies I have cited in Date	<ul> <li>(a) Pay</li> <li>(b) Commence</li> <li>and the amount of</li> <li>ed</li> <li>Form,"</li> <li>a support of</li> <li>b regard to the</li> </ul>
<ul> <li>compensation for those data in accordance with sections 3(c)(1)(D) and negotiation to determine which data are subject to the compensation re compensation due, if any. The companies I have notified are: (check o compensation due, if any. The companies I have notified are: (check o sheets, or indicated on the attached "Requirements Status and Re . That I have previously complied with section 3(c)(1)(D) of FIFRA for the</li> </ul>	3(c)(2)(D) of FIFRA; a quirement of FIFRA a ne) of this form or attach egistrants' Response studies I have cited in Date	<ul> <li>(a) Pay</li> <li>(b) Commence</li> <li>and the amount of</li> <li>ed</li> <li>Form,"</li> <li>a support of</li> <li>b recard to the</li> </ul>

EPA Form \$570-31 (4-90)

# **APPENDIX G. FACT SHEET**

Prevention, Pesticides And Toxic Substances (7508W) EPA-738-F-94-019 September 1994

# SEPA R.E.D. FACTS

# <u>Hexazinone</u>

# Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be <u>re</u>registered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0266, hexazinone.

**Use Profile** Hexazinone is a herbicide used to control a broad spectrum of weeds including undesirable woody plants in alfalfa, rangeland and pasture, woodland, pineapples, sugarcane and blueberries. It is also used on ornamental plants, forest trees and other non-crop areas. Hexazinone is registered for pre-emergent, post-emergence, layby, directed spray and basal soil applications. It is used as a non-selective herbicide in non-cropland areas and as a selective herbicide in reforestation practices.

Hexazinone products are formulated as granulars, pellets/tablets, emulsifiable concentrates, ready-to-use liquids, soluble concentrates/solids and a technical grade active ingredient. Products are applied using aerial or ground equipment or by hand, or using a hand-held, boom, knapsack or power sprayer.

Use practice limitations prohibit application of hexazinone through any type of irrigation system. The pesticide also cannot be applied within 30 to 60 days before grazing, harvest or feeding.

# Regulatory History <sup>mag</sup>

Hexazinone is the common name for 3-cyclohexyl-6-(dimethylamino)-1methyl-1,3,5 triazine-2,4(1H,3H)-dione. Hexazinone was first registered as a pesticide in the U.S. in 1975 for general weed control in non-cropland areas. Use in the culture of Christmas and forest trees was added in 1977, and uses on sugarcane and alfalfa were conditionally registered in 1980 and 1981, respectively.

EPA issued one Registration Standard for hexazinone in February 1982 (NTIS #PB87-110292), and a second in September 1988 (NTIS #PB89-126080). These documents summarized available data supporting the registration of hexazinone products, and required additional product chemistry, residue chemistry, toxicology, ecological effects and environmental fate data.

EPA's Office of Drinking Water issued a drinking water Health Advisory (HA) for hexazinone in August 1988. A lifetime HA was established at 200 ppb for an adult consuming 2 liters of water per day. For a 10 kg child, a one-and ten-day HA was determined to be 2 mg/L.

Currently, 20 end-use pesticide products and one technical grade, manufacturing use product containing hexazinone are registered.

#### Human Health Toxicity Assessment Health

Hexazinone is classified as a Group D carcinogen--a chemical that is not classifiable as to human carcinogenicity. Animal data presented to EPA is equivocal--it is not entirely negative, but not convincingly positive. The Agency has concluded that the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect. Since hexazinone has not been found to induce cancer, food and feed additive regulations are not prohibited by the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Reference Dose (RfD) approach was used to assess human risk from exposure to hexazinone.

In acute toxicity studies using laboratory animals, hexazinone has been shown to be a severe eye irritant and has been placed in Toxicity Category I (the highest of four levels) for primary eye irritation. It is slightly toxic through the acute oral route (Toxicity Category III) and very mildly toxic through the acute dermal and acute inhalation routes (Toxicity Category IV). Hexazinone is only mildly toxic for skin irritation potential (Toxicity Category IV) and is not a skin sensitizer.

Some treatment-related effects were found in developmental toxicity studies using rats and rabbits, at the high dose levels. Similarly, some effects were noted in a reproductive toxicity study at the mid- and high dose levels. Hexazinone was positive in one mutagenicity study but negative in the remaining studies. There are no other acute or chronic toxicological endpoints of concern.

#### **Dietary Exposure**

People may be exposed to residues of hexazinone through their diet. EPA reassessed existing tolerances or maximum residue limits (please see 40 CFR 180.396) for blueberries, pineapple and sugarcane at the time of this RED. Tolerances for meat, meat byproducts and milk cannot be reassessed until a cattle feeding study is completed. However, sufficient data were available to conduct a risk assessment, and the Agency believes that the existing tolerances are protective until data are available for reassessment.

The Reference Dose (RfD) or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime is 0.05 mg/kg/day based upon

a No Observable Effect Level (NOEL) of 5 mg/kg/day in a one-year feeding study in dogs. EPA calculated that the Anticipated Residue Contribution (ARC) for the overall U.S. population from all hexazinone tolerances equals 7% of the RfD. The ARC for the subgroup most highly exposed, non-nursing infants age less than 1 year, represents 40% of the RfD, while the ARC for children age 1 to 6 years is 20% of the RfD. EPA's calculations overestimate exposure, however, by assuming 100% of crop treated for all commodities. Actual dietary risk from hexazinone is believed to be minimal. When current residue chemistry data gaps are filled, however, dietary exposure estimates for hexazinone could change.

Hexazinone concentrates in certain processed fractions of alfalfa, pineapple and sugarcane. EPA has determined that establishing food and feed additive tolerances for these commodities is appropriate and consistent with the Delaney Clause of the FFDCA, and that such tolerances must be established for alfalfa meal, pineapple processing residue and sugarcane molasses.

EPA's Office of Water has issued a lifetime Health Advisory (HA) which sets a maximum level of 0.21 mg/L, or 200 ppb allowable in drinking water. No international CODEX Maximum Residue Limits are established for hexazinone so compatibility with U.S. tolerances is not an issue.

#### **Occupational and Residential Exposure**

Based on current use patterns, workers may be exposed to hexazinone during and after applications in agricultural and other settings. In assessing handler and post-application exposure, Agency concerns are predominantly related to skin contact. Hexazinone is poorly absorbed through the skin, so little or no absorption is anticipated. Therefore, no changes in personal protective equipment (PPE) required by the Worker Protection Standard (WPS) are being imposed at this time. However, the Restricted Entry Interval (REI) is being changed from 24 to 48 hours because hexazinone is in Toxicity Category I for primary eye irritation.

There are no residential uses of hexazinone, so residential exposure is not expected.

#### Human Risk Assessment

Hexazinone generally is of relatively low acute toxicity but is a severe eye irritant (Toxicity Category I). It is not classifiable as to human carcinogenicity (Group D carcinogen) and does not cause other toxic effects of concern.

The dietary risk posed by hexazinone is expected to be minimal. Most tolerances were reassessed and other existing tolerances are considered protective until confirmatory data are available for reassessment. A lifetime Health Advisory sets a maximum level of exposure to hexazinone from drinking water.

Exposure to workers and other applicators generally is not expected to pose undue risks, due to hexazinone's overall low acute toxicity. However, based on toxicity concerns regarding primary eye irritation, a 48-hour rather than a 24-hour REI is required.

### Environmental Assessment

#### Environmental Fate

Based on laboratory data and confirmed by field and forestry data, hexazinone appears to be persistent and mobile in soil and aquatic environments. The degradates of hexazinone also are believed to be persistent and mobile. Hexazinone was reported in runoff water up to 6 months posttreatment in a forestry dissipation study. Therefore, field and laboratory data indicate that hexazinone may be of concern for both groundwater and surface water contamination.

Hexazinone has been detected in ground water (at levels well below the Health Advisory) in Hawaii, Florida, Maine and North Carolina. Hexazinone also can contaminate surface water by spray drift at application, and for several months post-application via runoff. It is not expected to accumulate in fish but does accumulate in crops grown on treated soil.

#### **Ecological Effects**

Hexazinone is practically non-toxic to birds on an acute oral and subacute dietary basis. It is practically non-toxic to freshwater fish and freshwater invertebrates in acute exposures. Hexazinone is practically nontoxic to mollusks, slightly toxic to crustaceans, and relatively non-toxic to honey bees.

#### **Ecological Effects Risk Assessment**

Exposure of non-target organisms to hexazinone can result from direct application, spray drift from treated areas, and runoff from treated areas. Such exposure would be chronic as well as acute.

Hexazinone exceeds the levels of concern (LOC) for terrestrial and aquatic plants, at all application rates, using aerial and ground equipment. Contamination of aquatic sites adjacent to treated areas could be of great ecological significance and may be exacerbated by the persistence and mobility of hexazinone.

Aquatic plants are an important component of the ecosystem. Algae are the link between solar radiation, aquatic animals and humans, which are dependent on the oxygen produced by algae during photosynthesis. Algae are responsible for maintaining the quality of the aquatic habitat for fish, while at the same time providing food for fish either directly or indirectly. Effects to aquatic plants expected from the use of hexazinone may alter aquatic ecosystems, the severity of which is dependent on the frequency of application and the nature of the receiving body of water.

Hexazinone also exceeds the LOC for small mammals at several of the higher application rates.

#### **Risk to Endangered Species**

Hexazinone exceeds the endangered species LOCs for grass- and insecteating mammals at use rates of 3.6 pounds active ingredient per acre (lb ai/acre) or greater. It also exceeds the LOCs for both aquatic and terrestrial plants at all use rates.

#### **Risk Mitigation Measures**

Hexazinone exceeds the levels of concern for both aquatic and terrestrial plants, and exceeds levels of concern for small mammals at several of the higher application rates. Hexazinone also is likely to have a significant impact on ground water quality. In areas where irrigation water is contaminated with hexazinone or where ground water discharges to surface water, hexazinone residues in water could pose a threat to plants. Therefore, the following risk mitigation measures are required:

• All hexazinone product labels must carry a ground water advisory;

• Registrants must report any domestic hexazinone ground water detections at any levels to EPA;

• The registrant must prepare a report summarizing ongoing research regarding ground water detections in the State of Maine;

• The registrant also must submit to EPA the educational materials under development regarding product stewardship and addressing the potential for ground water contamination from use of hexazinone;

• A prospective ground water monitoring study must be conducted to determine the potential for hexazinone to leach to ground water;

• To address surface water concerns, precautionary label language will be required;

• To address the risk to nontarget plants and small mammals, the maximum application rate must be reduced from 13.5 lb ai/acre to 8 lb ai/acre.

• To inform the user of best management practices to minimize spray drift, EPA is preparing labeling statements that may be required in the future for all aerially-applied hexazinone products;

• To address endangered aquatic and terrestrial plant species as well as endangered small mammal concerns, endangered species precautionary labeling will be required in the future;

• Hexazinone may be classified as a Restricted Use Pesticide for ground water concerns once the Agency's Ground Water Restricted Use Rule is finalized.

Additional Data Required The Agency is requiring additional generic data on hexazinone's residue chemistry, ecological effects and environmental fate. The following confirmatory generic studies are required: residue analytical methods (ruminant only), magnitude of the residue on grass hay and alfalfa seed screenings, magnitude of the residue in meat/milk, storage stability (alfalfa and Metabolite C for grass), rotational crops (sorghum and leafy vegetable), seed germination/seedling emergence (cucumber, onion, pea), vegetative vigor (cucumber), batch equilibrium, aquatic sediment dissipation, spray drift, and a prospective groundwater monitoring study.

> The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

## Product Labeling Changes Required

All hexazinone end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

**Worker Protection Standard (WPS)** - EPA has evaluated the 24-hour interim REI established by the WPS and concluded that it should be changed to 48 hours because hexazinone is in Toxicity Category I for primary eye irritation. The new 48-hour REI must be inserted into the standardized REI statement required by PR Notice 93-7.

The PPE for early entry under the 48-hour REI for hexazinone is coveralls, chemical resistant gloves, shoes plus socks, and protective eyewear. These PPE must be inserted into the early entry PPE statement required by PR Notice 93-7.

**Ground Water Labeling Advisory** - All products must carry the following advisory:

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

**Surface Water Labeling** - The technical manufacturer of hexazinone is in the process of consolidating label language relating to surface and ground water for all of their hexazinone products. After the Agency has reviewed and approved these label amendments, all hexazinone labels must carry this labeling.

#### **Other Ground Water Requirements**

- Registrants must report any domestic hexazinone ground water detections at any levels to the Agency.
- The registrant must prepare and submit a report summarizing the ongoing research in Maine regarding ground water detections in blueberry use areas. This report must be submitted within one year from receipt of the RED document. The registrant also must prepare a one year follow-up to the original report.

• The registrant also must submit an analytical method or immuno assay for detection of hexazinone in ground water, within one year after receipt of the RED document.

• The registrant is required to submit educational materials that are currently being developed to the Agency. These materials should be in specific regard to product stewardship and should address the potential for ground water contamination from use of hexazinone.

**Risk to Non-Target Plants and Small Mammals** - To mitigate the risk to non-target plants and small mammals, registrants must reduce the maximum application rate from 13.5 lb ai/acre to 8 lb ai/acre.

**Spray Drift Label Advisory** - The Agency is preparing spray drift labeling statements to inform users of management practices that would minimize spray drift from the target site. This future labeling may be required for all hexazinone products that may be applied aerially to agricultural crops.

**Endangered Species Statement** - EPA is working with the Fish and Wildlife Service and other Federal and State agencies to develop a program to avoid jeopardizing the continued existence of identified species by the use

Attachment 1. EPA Acceptance Criteria

of pesticides. When this program goes into effect, endangered species precautionary labeling will be required.

## Regulatory Conclusion

The use of currently registered products containing hexazinone in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Hexazinone products will be reregistered once the required product specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

# For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for hexazinone during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224, and also can be reached on the Internet via *FEDWORLD.GOV* and EPA's gopher server, *EARTH1.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the hexazinone RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the hexazinone RED, or reregistration of individual products containing hexazinone, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.