United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R95-019 August 1995

Reregistration Eligibility Decision (RED)

Picloram

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 Picloram which includes the active ingredients triisopropanolamine picloram, isooctyl picloram, and potassium picloram. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical case, 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 may also include requirements for additional data (generic) on the active ingredient(s) 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 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 Emily Mitchell at (703) 308-8583. Address any questions on required generic data to the Special Review and Reregistration Division representative, Venus Eagle at (703) 308-8045.

Sincerely yours,

Lois A. Rossi, 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"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--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 time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. 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. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance 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, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to 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; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. 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. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

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 PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
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

PICLORAM

LIST A

CASE 0096

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

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PICLORAM REREGISTRATION ELIGIBILITY DECISION TEAM

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James Saulmon	Biological Analysis Branch
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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
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
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	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
LC_{50}	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_{50}	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_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
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
NOEC	No effect concentration
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
OP	Organophosphate

GLOSSARY OF TERMS AND ABBREVIATIONS

OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose 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
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision document (RED) addresses the eligibility for reregistration of pesticide products containing picloram acid and its derivatives; specifically it includes triisopropanolamine picloram (TIPA-salt), isooctyl/ethylhexyl picloram (IOE) and potassium picloram (K-salt). Hereafter, in this document, the term "picloram" refers to picloram acid and these three derivatives.

Picloram is a systemic herbicide used to control deeply rooted herbaceous weeds and woody plants in rights-of-ways, forestry, rangelands, pastures and small grains. Picloram salts and ester are manufactured by an integrated system from picloram acid. Picloram acid has no end uses. TIPA-salt and K-salt have food/feed uses. The IOE of picloram is registered for non-food uses only. TIPA-salt and K-salt are currently applied pre or postemergence as a ground or aerial broadcast or spot treatment.

In March 1985, the Agency issued a Registration Standard for picloram. This document required additional data and imposed a maximum level of hexachlorobenzene (HCB) in the technical product of 200 ppm. It also required testing for nitrosoamines. The sole registrant of picloram has complied with these requirements; no nitrosoamines were detected in picloram products (< 1 ppm) and the level of HCB, an impurity that results from the manufacturing process, has been certified to be less than 100 ppm. The picloram Final Reregistration Standard and Tolerance Reassessment (FRSTR) was issued 5/18/88.

Supporting Rationales for Reregistration Decision

A reference dose (RfD) for picloram was calculated to be 0.20 mg/kg/day based on a NOEL of 20 mg/kg/day body-weight per day from a two-year rat chronic feeding study. An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability. The picloram chronic dietary exposure/risk estimates are extremely low. For the United States population as a whole, the Theoretical Maximum Residue Contribution (TMRC) is 0.9% of the RfD. For this same group, the Anticipated Residue Contribution (ARC) is 0.5% of the RfD. Because the dietary exposure/risk is so low, about 1/200th of the RfD, there are no concerns regarding chronic dietary exposure to picloram.

The Agency has classified picloram as a Group E carcinogen (evidence of non-carcinogenicity for humans). Even though picloram was shown to be non-carcinogenic, a cancer risk assessment was performed on the maximum HCB concentration since HCB has been classified by the Agency as a Group B_2 carcinogen. The refined, ARC dietary carcinogenicity risk estimates for the United States population as a whole for the impurity, HCB, is 7×10^{-7}, which is less than 1.0×10^{-6} point below which risk is generally considered to be negligible.

Picloram IOE bears structural similarity to di(2-ethylhexyl)phthalate (DEHP) in that both possess a 2-ethylhexyl moiety. DEHP and certain other substances containing the 2-ethylhexyl moiety have been found to be carcinogenic in rodents. The Agency performed a cancer risk assessment for workers and found that the risk associated with post-application exposure is not a major concern since exposure to workers is minimal due to the use patterns defined by the IOE labels and the cultural practices typically associated with a broad spectrum herbicide of this type. The Agency is requiring that the restricted reentry intervals (REI) of 12 hours for all end use products containing picloram as required by the Worker Protection Standard PR Notice for in-scope uses be retained.

There is minimal concern for risk to fish and wildlife based on picloram's low toxicity to avian and aquatic test species. However, potential phytotoxic risks to nontarget terrestrial plants from exposure to picloram are very significant. Additionally, picloram is very mobile and persistent which heightens the concern for exposure of nontarget plants since picloram is highly toxic to a wide range of plant species. Picloram is occasionally transported from the site of application and causes unintentional damage to crops and other nontarget plants. The 1992 Pesticides and Ground Water Database survey showed detects in groundwater in 10 states.

Reregistration Decision

Picloram may pose a significant risk to on- and off-site endangered terrestrial, semi-aquatic, and aquatic plant species and may also have adverse effects on other on and off-site nontarget plants. In addition, the Agency is concerned about the potential for further ground water contamination from registered uses of picloram.

However, the Agency has determined that despite phytoxicity and ground water concerns, all the uses of picloram are eligible for reregistration based on A) implementation of risk reduction measures (reduced use rates and frequencies); B) registrant commitment to better define the nature and scope of potential ground water contamination and nontarget plant effects C) a cursory benefits analysis; D) the tightly controlled product distribution system that has been put in place by the sole producer, DowElanco and; E) State regulation of picloram (see section IV).

The residual risks, with the modified use rates and frequencies, are not well understood but could likely remain high. The additional information generated by the registrant's commitment to a mapping program and a monitoring program, may be used to further refine local restrictions and possible prohibitions of use in sensitive areas.

The Agency consulted with several state lead Agencies regarding use practices and their regulatory experience with picloram. These consultations provided valuable guidance in refinement of the reduction in application rates and timing of application.

To further refine the risk assessments in this document, the Agency is requiring additional ecotoxicity, phytoxicity and mixer/loader data for all three derivatives of picloram.

Before reregistering the products containing picloram acid and its derivatives, 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 and acute toxicity testing for each registration . 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 picloram (TGAI) and its derivatives: triisopropanolamine picloram (TIPA-salt), isooctyl/ethylhexyl picloram (IOE) and potassium picloram (K-salt). The document consists of six sections. Section I is the introduction. Section II describes picloram and its derivatives, their 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 picloram and its derivatives. Section V discusses the reregistration requirements. 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(s) are covered by this Reregistration Eligibility Document:

(1) Picloram acid (TGAI)

Chemical Name:	Picloram acid
CAS Registry Number:	1918-02-1
OPP Chemical Code:	005101
Empirical Formula:	$C_6H_3Cl_3N_2O_2$
Trade and Other Names:	Manufacturing Use Only
Basic Manufacturer:	DowElanco

(2) Picloram triisopropanolamine salt (TIPA)

Chemical Name:	Picloram triisopropanolamine salt
CAS Registry Number:	6753-47-5
OPP Chemical Code:	005102
Empirical Formula:	$C_{15}H_{24}Cl_3N_3O_5$
Trade and Other Names:	Tordon 101 Mixture, Grazon P + D, Tordon 101R, Tordon RTU, Pathway.
Basic Manufacturer:	DowElanco

(3) Isooctyl Picloram (IOE)

Chemical Name:	Isooctyl Picloram, also known as ethylhexyl ester.
CAS Registry Number:	26952-20-5
OPP Chemical Code:	005103
Empirical Formula:	$C_{14}H_{19}Cl_3N_2O_2$
Trade and Other Names:	Access
Basic Manufacturer:	DowElanco

(4) Potassium Picloram (K-salt)

Chemical Name:	Potassium Picloram
CAS Registry Number:	2545-60-0
OPP Chemical Code:	005104
Empirical Formula:	$C_6H_2Cl_3KN_2O_2$
Trade and Other Names:	Tordon 22K, Tordon K, Grazon PC, Tordon K salt Liquor.
Basic Manufacturer:	DowElanco

B. Use Profile

The following is a general use profile for the registered uses for picloram. A detailed table of eligible uses as well as the methods, application rates, and use restrictions is included in Appendix A.

1) Chemical: picloram acid

Type of Pesticide: Herbicide
Formulation Types Registered: This is a manufacturing-use product only.

2) Chemical: picloram, triisopropanolamine

Type of Pesticide: Herbicide
Mode of action: pyridinecarboxylic acid herbicide, auxin type

Use groups: Terrestrial feed crop--pastures, rangeland
Terrestrial nonfood crop--industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils
Forestry--forest plantings (reforestation program), forest trees, forest roadsides

Pests: ailanthus, alder, aspen, birch, bitterweed, blackberry, bouncingbet, brackenfern, broom snakeweed, buffalobur, bullnettle, bursage, buttonbush, camphorweed, cedar, cherry, chicory, Chinese tallowtree, clover, cocklebur, common broomweed, croton, dandelion, dock, dogfennel, dogwood, Drummond's goldenweed, elm, field bindweed, fir, fleabane, goldenrod, gorse, green ash, groundsel, gum, hawthorn, hemlock, hickory, honeysuckle, hornbeam, horsenettle, knapweed, kudzu, leafy spurge, loco, locust, maple, marshelder, mesquite, milkweed, oak, persimmon, pine, plantain, poison oak, prickly lettuce, pricklypear, ragweed, rose, rush skeletonweed, sassafras, serviceberry, silverleaf nightshade, smartweed, sourwood, spruce, sumac, sunflower, tansy ragwort, tasajillo, toadflax, tuliptree, upright prairie coneflower, vetch, wild carrot, willow, yankeeweed

Formulation types: Emulsifiable concentrate--10.2% + 39.6% 2,4-D (0.54 lb AE picloram/gal)
Soluble concentrate/liquid (water)--10.2% + 39.6% 2,4-D (0.54 lb AE picloram/gal)

Liquid ready to use--5.4% + 20.9% 2,4-D (0.25 lb AE picloram/gal)

Methods and rates of application:

EMULSIFIABLE CONCENTRATE--to **pastures or rangeland**, in spring or fall when target plants are actively growing, broadcast foliar application at up to **0.54 lb acid equivalent(AE)/acre** by aircraft or ground sprayer.

SOLUBLE CONCENTRATE, LIQUID--to **pastures or rangeland**, in spring or fall when target plants are actively growing, broadcast foliar application at up to **0.54 lb acid equivalent(AE)/acre** by aircraft or ground sprayer.

--to **forest sites**:

• in preparation for reforestation, apply coarse foliar spray at up to **1.62 lb AE/A** by aircraft or ground sprayer, when target plants are actively growing.

• to forest roadsides, wildlife openings in forests, apply in spring or late summer or fall, when target plants are actively growing:

• high volume leaf/stem/root collar treatment at up to **1.08 lb AE/A** by ground spray at up to 200 gal spray/A.

• low volume foliage treatment at up to **1.08 lb AE/A** by ground spray at up to 15 gal spray/A.

• cut surface treatment, at any season except when there is rapid sap flow, apply 5.4 percent or 10.2 percent AE/A of soluble concentrate/liquid, by injector, oil can or brush to cut surfaces of injector wounds, frill/girdle cuts, or stump surfaces. About 10 ml. treats a tree 6 inches in diameter.

• to naturally regenerated spruce and firs in Northeast U.S. for strip thinning, apply up to **1.62 lb AE/A** in bands, using 12-20 gal spray/A, by helicopter using Microfoil or Thru-Valve boom, when trees are actively growing.

--to **non-crop and industrial storage sites and rights-of-way** apply in spring or late summer or fall, when target plants are actively growing:

• high volume leaf/stem/root collar treatment at up to **1.08 lb AE/A** by ground spray at up to 200 gal spray/A.

• low volume foliage treatment at up to **1.08 lb AE/A** by ground spray at up to 15 gal spray/A.

• cut surface treatment, at any season except when there is rapid sap flow, apply 5.4 percent or 10.2 percent AE/A of soluble concentrate/liquid, by injector, oil can or brush to cut surfaces of injector wounds, frill/girdle cuts, or stump surfaces. About 10 ml. treats a tree 6 inches in diameter.

• broadcast stubble treatment, at up to **2.16 lb AE/A** , using ground sprayer, to cut stumps of mowed or hand-cut woody

species, before or during periods of active root growth, soon after cutting,
LIQUID READY TO USE (**0.25 lb AE/gal**)--to **forest and other non-crop sites such as fence row, roadsides and rights-of-way**, at any season (maples should not be treated during spring sap flow), apply frill, girdle, or stump treatment with paintbrush or sprayer, or injection treatment with injection equipment at **0.008 to 0.0013 lb AE/tree.**

Use limitations: Do not apply through any type of irrigation system. Observe 30 days preharvest interval for forage/fodder. Observe 7 days pregrazing interval. Use only once per year.

3) Chemical: picloram, isooctyl/ethylhexyl esters

Type of Pesticide: Herbicide
Mode of action: pyridinecarboxylic acid herbicide, auxin type

Use groups: Terrestrial nonfood crop--industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils
Forestry--forest trees

Pests: ash, aspen, birch, cherry, elm, hackberry, hickory, locust, maple, multiflora rose, oak, oceanspray, pine, poplar, sassafras, tanoak

Formulation types: Soluble concentrate/liquid (oil)--17.1% + 32.5% butoxyethyl triclopyr

Method and rate of application:
Basal bark and soil treatment, **high** volume (to stems less than 6 inches diameter): Use low pressure knapsack, backpack, or power sprayer, at **0.02 lb acid equivalent (AE)/gal** of **oil** spray (100 gal), or **0.02 to 0.03 lb AE/gal** of **oil/water emulsion** spray when needed (best results are obtained when applied during late dormant or active growing season).
Basal bark and soil treatment, **low** volume (to stems less than 6 inches diameter): Use backpack or knapsack sprayer at **0.2 to 0.3 lb AE/gallon** of oil spray when needed. (Best results are obtained when applied during late dormant or active growing season.)
Thinline basal bark treatment, to stems less than 6 inches diameter, apply as a thin stream around the trunk **0.0005 to 0.004 lb AE (2-15**

ml) of undiluted product (1 lb AE/gal) per stem to be treated, using equipment metered or calibrated to deliver these small amounts.

Use limitations: Do not contaminate water intended for irrigation or domestic purposes.
Do not apply to snow or frozen ground.
Do not apply near desirable trees if injury from potential transfer through roots cannot be tolerated.

4) Chemical: **picloram, potassium salt**

Type of Pesticide: Herbicide
Mode of action: pyridinecarboxylic acid herbicide, auxin type

Use groups: Terrestrial food + feed crop--agricultural fallow/idle land, barley, oats, wheat
Terrestrial feed crop--pastures, rangeland
Terrestrial nonfood crop--nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, industrial areas (outdoor)

Pests: absinth wormwood, acacia, aspen, bitterweed, black henbane, blackberry, bouncingbet, brackenfern, buffalobur, bullnettle, burroweed, bursage, buttonbush, cactus, camelthorn, camphorweed, cedar, chaparral, chicory, Chinese tallowtree, clover, cocklebur, common broomweed, common crupina, croton, dock, dogwood, field bindweed, fleabane, fringed sagebrush, goldenrod, gorse, granjeno, groundsel, guava, gum, hemlock, hickory, horsenettle, horseweed, huisache, ironweed, java plum, juniper, knapweed, lambsquarters, lantana, larkspur, leafy spurge, loco, locust, lupine, maple, marshelder, mesquite, milkweed, oak, oxeye daisy, persimmon, pigweed, pine, poison oak, poplar, prickly lettuce, pricklypear, rabbitbrush, ragweed, rush skeletonweed, St. Johnswort, salmonberry, sassafras, Scotch broom, sea hibiscus, silverleaf nightshade, smartweed, snakeweed, sourwood, spruce, sulphur cinquefoil, sumac, sunflower, tansy ragwort, tasajillo, thistle, toadflax, trumpetcreeper, upright prairie coneflower, wild buckwheat, wild carrot, wild licorice, wild parsnip, willow, yankeeweed

Formulation types: Soluble concentrate/liquid (water)--24.4% (can be used as invert emulsion)
Liquid--34.7% (Formulating intermediate)

Methods and rates of application:
EMULSIFIABLE CONCENTRATE (as invert emulsion):
--to **forest sites** preparatory to reforestation, southern US, apply broadcast spray at **1.5 lb AE/A** by air or ground spray after foliage is well developed.

--to **rangeland and permanent grass pasture** (west of Mississippi R.), apply up to **0.5 lb AE/A** as low volume broadcast spray by air or ground equipment, when target vegetation is actively growing.

SOLUBLE CONCENTRATE, LIQUID:

--to **forest sites:**

- preparatory to reforestation (Southern U.S.), apply broadcast spray at **1.5 lb.AE/A** by air or ground spray after foliage is well developed.
- to forest roadsides, wildlife clearings, (southern U.S.), apply:
- low volume broadcast treatment, at **1 lb AE/A** by air or ground sprayer, in spring or late in summer or fall.
- high volume leaf/stem/root collar treatment at **1 lb AE/A** by ground sprayer.
- spot treatment at **0.5 to 2 lb AE/A/season** by ground spray to foliage when target plants are actively growing
- spot concentrate application of up to **24 ml/tree of undiluted product** (0.013 lb AE/tree; max. limit of 0.5 lb AE/A/year) to soil under dripline of Eastern red cedar, in spring or fall.
- injector or frill/girdle treatment (Hawaii) using ca. **0.002 to 0.003 lb AE/tree** of product diluted **1:4** with water, applied when target trees are actively growing.

--to **rangeland and permanent grass pasture** (west of Mississippi R.), apply:

- low volume broadcast spray at up to **0.5 lb AE/A**, by air or ground equipment, when target vegetation is actively growing.
- high volume broadcast spray at up to **0.5 lb AE/A** by ground sprayer, when target vegetation is actively growing.

--to **noncroplands, fencerows (southern U.S.)**, apply:

- low volume broadcast treatment, at **1 lb AE/A** by air or ground sprayer, in spring or late in summer or fall.
- high volume leaf/stem/root collar treatment at **1 lb AE/A** by ground sprayer.
- spot treatment at **0.5 to 2 lb AE/A/season** by ground spray to foliage when target plants are actively growing
- spot concentrate application of up to **24 ml/tree of undiluted product** (0.013 lb AE/tree; max. limit of 0.5 lb AE/A/year) to soil under dripline of Eastern red cedar, in spring or fall.
- injector or frill/girdle treatment (Hawaii) using ca. **0.002 to 0.003 lb AE/tree** of product diluted **1:4** with water, applied when target trees are actively growing.

Use limitations: Do not: apply through any type of irrigation system; graze or feed forage from treated areas for 2 weeks after treatment; or harvest hay from treated grain fields.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of picloram and its derivatives. 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.

The table below summarizes the pesticides use by site:

ESTIMATED ANNUAL U.S. USAGE OF PICLORAM

SITE	SITE ACREAGE (000)	ACRE TREATMENTS (000)	SITE TREATED %	LB A.I. APPLIED (000)
Pasture & rangeland	530,000	2500 - 5000	< 1%	500 - 900
Wheat	64,000	300 - 900	< 2%	25 - 35
Barley	8,000	75 - 150	< 2%	< 7
Oats	6,000	< 25	< 1%	< 2
Cropland not used for crops	107,000	100 - 600	< 1%	50 - 100
Other crops/farmland	267,000	< 700	< 1%	< 100
Forestry (commercial)	482,000	25 - 100	< 1%	25 - 50
Total Agriculture and Forestry	1,464,000	3000 - 7475	< 1%	600 - 1194
Rights-of-way				
Electric utilities	9,400	100 - 180	< 2%	80 - 140
Roadways	11,000	15 - 35	< 1%	10 - 30
Industrial facilities	1,900	< 9	< 1%	< 30
Railroads	1,100	< 6	< 1%	< 6
Pipelines	2,200	15 - 35	< 2%	10 - 30
Total Rights-of-Way	25,600	130 - 265	< 1%	100 - 236
Total	1,489,600	3130 - 7740	< 1%	700 - 1430

Sources:
U.S. EPA proprietary sources
Resources for the Future, Agriculture Usage Database, 1994
DowElanco, Meeting with U.S. EPA, March 1, 1994

D. Data Requirements

Data requested in the revised September 30, 1988 Registration Standard for picloram and its derivatives (triisopropanolamine picloram, isooctyl picloram, and potassium picloram) included studies on product chemistry, ecological effects, toxicology, environmental fate, and residue chemistry. 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

Picloram and its derivatives were registered in the United States in 1964 for use as a systemic herbicide to control woody plants and broadleaf weeds. In 1978 the Agency classified picloram as a Restricted Use pesticide based on hazard to nontarget organisms (specifically nontarget plants both crop and noncrop). Considerable emphasis for restriction was based on recurring reports of phytotoxicity to such economically important crops such as tomatoes, potatoes, and succulent ornamentals caused by contaminated water supplies (1 part per billion [ppb]) range. This action was taken by the Agency through regulations proposed in the September 1, 1977 (42 FR 44170) and finalized in the February 9, 1978 (43 FR 5782) issues of the FEDERAL REGISTER.

On March 29, 1985, the Agency issued a Registration Standard for picloram. The Standard required: 1) precautionary label statements advising against the use of picloram in very permeable soils such as karst limestone and loamy sands; 2) a groundwater monitoring study; 3) retention of Restricted Use classification ; 4) additional wildlife testing on the technical; 5) a field monitoring study to determine concentrations of picloram in runoff water and sediment, leachate, groundwater, and in water and sediment of receiving aquifers to complete a hazard evaluation of wildlife; 6) development of analytical methods for metabolite residues in plant and animal samples; 7) storage stability data; 8) additional oncogenicity data; 9) limiting the level of hexachlorobenzene (HCB) in the technical to a maximum of 200 parts per million (ppm); 9) nontarget area phytoxicity data on the technical; and 10) testing for nitrosamines and certification that the upper limit of nitrosamines occurring in the technical is not greater than 1 ppm.

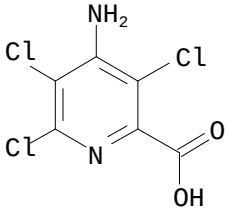
The Agency has since received and reviewed the additional data and has revised its scientific and regulatory conclusions in light of those data, other information on the chemical, and expanded data requirements promulgated in 1984, at 40 CFR Part 158, for registration and reregistration of pesticides under FIFRA. A revised Registration Standard (issued 9-30-88), which supersedes the earlier Standard, is the Agency's updated scientific assessment of the pesticide, and the data needed to support its

continued registration. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the revised Registration Standard.

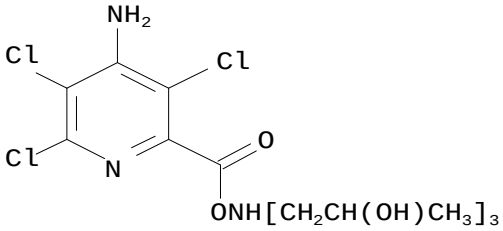
III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

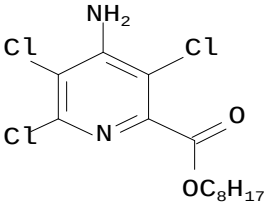
This structure of picloram acid and its derivatives are presented below:



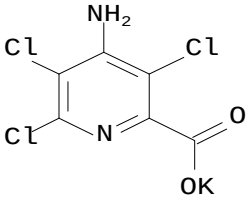
Picloram acid
Empirical Formula: $C_6H_3Cl_3N_2O_2$
Molecular Weight: 241.5
CAS Registry No.: 1918-02-1
Shaughnessy No.: 005101



Picloram triisopropanolamine salt (TIPA)
Empirical Formula: $C_{15}H_{24}Cl_3N_3O_5$
Molecular Weight: 432.6
Shaughnessy No.: 005102



Picloram isooctyl ester (IOE aka EHE)
Empirical Formula: $C_{14}H_{19}Cl_3N_2O_2$
Molecular Weight: 353.5
Shaughnessy No.: 005103



Picloram potassium salt (K-salt)
Empirical Formula: $C_6H_2Cl_3KN_2O_2$
Molecular Weight: 280.6
Shaughnessy No.: 005104

IDENTIFICATION OF ACTIVE INGREDIENT

The picloram acid technical is an off-white to brown powder which decomposes at 215°C, photodegrades, and is non-volatile. The acid is only slightly soluble in water at 430 ppm at 25°C, and is more soluble in ethanol, acetone, and methanol. The picloram salt derivatives are water soluble; the isooctyl ester is not water soluble.

MANUFACTURING-USE PRODUCTS

There are two picloram manufacturing-use products (MPs) registered to DowElanco Company: the 72% picloram acid technical (T; EPA Reg. No. 62719-179) and the 34.7% picloram K-salt formulation intermediate (FI; EPA Reg. No. 62719-30). There are no registered MPs for the TIPA and IOE; TIPA and IOE end-use products (EPs) are manufactured by integrated systems.

At the time of the Registration Standard dated 10/84 and the Final Registration Standard and Tolerance Reassessment (FRSTR) dated 5/18/88, the only registered MP was the 34.7% K-salt FI. The 72% T was registered in 1990, following issuance of the FRSTR. The DowElanco 72% T and the 34.7% K-salt FI are the only MPs subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Picloram FRSTR dated 5/18/88 required that all new data be submitted in support of the reregistration of picloram and its salts and ester. After the 72% T was registered, the product chemistry database submitted since the FRSTR was re-evaluated. Additional MP data were required for the now registered picloram acid technical, and data were required for the "practical equivalent of the technical grade of the active ingredient" for the picloram salts and ester manufactured by integrated systems.

The Picloram Registration Standard dated 3/29/85 required the limiting of the level of hexachlorobenzene (HCB) in the technical to a maximum of 200 ppm and also required testing for nitrosoamines in picloram products. The sole registrant of picloram products has complied with these requirements; no nitrosoamines were detected in picloram products (< 1 ppm) and the level of HCB has been certified to be less than 100 ppm.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base in support of the food uses for picloram (the acid, potassium salt, isooctyl ester, and triisopropanolamine salt) is adequate and will support reregistration eligibility.

a. Acute Toxicity

Table I: Acute Toxicity - Picloram, Acid (94.1% a.i.)

Test	Result	Category
Oral LD_{50} (rat)[1]	> 5000 mg/kg (males) 4012 mg/kg (females)	IV III
Dermal LD_{50} (rabbit)[2]	> 2000 mg/kg (both sexes)	III
Inhalation LC_{50} (rat)[3]	> 0.035 mg/L (both sexes)	I
Eye Irritation[4]	Moderate eye irritant	III
Dermal Irritation[5]	Non irritant	IV
Dermal Sensitization[6]	Non sensitizer	N/A
Delayed Neurotoxicity		N/A

1-6 MRID#s 404794-13 thru -18; HED Document Number 006787

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

Table II: Acute Toxicity - Picloram Potassium Salt (38.8% a.i.)

Test	Result	Category
Oral LD_{50} (rat)[7]	> 5000 mg/kg (males) 3536 mg/kg (females)	IV III
Dermal LD_{50} (rabbit)[8]	> 2000 mg/kg (both sexes)	III
Inhalation LC_{50} (rat)[9]	> 1.63 mg/L (both sexes)	II
Eye Irritation[10]	Moderate eye irritant	III
Dermal Irritation[11]	Non irritant	IV
Dermal Sensitization[12]	Positive skin sensitizer	N/A
Delayed Neurotoxicity		N/A

7-12 MRID#s 404794-01 thru -06; HED Document Number 006787

Table III: Acute Toxicity - Picloram, Isooctyl ester (IOE) (85.9% a.i.)

Test	Result	Category
Oral LD_{50} (rat)[13]	> 3500 mg/kg (both sexes)	III
Dermal LD_{50} (rabbit)[14]	> 2000 mg/kg (both sexes)	III
Inhalation LC_{50} (rat)[15]	> 0.35 mg/L (both sexes)	II
Eye Irritation[16]	Moderate eye irritation	III
Dermal Irritation[17]	Mild dermal irritation	III
Dermal Sensitization[18]	Positive skin sensitizer	N/A
Delayed Neurotoxicity		N/A

13-18 MRID#s 404794-07 thru -12; HED Document Number 006787

Table IV: Acute Toxicity - Picloram, Triisopropanolamine Salt (61% a.i.)

Test	Result	Category
Oral LD_{50} (rat)[19]	> 5000 mg/kg (both sexes)	IV
Dermal LD_{50} (rabbit)[20]	> 2000 mg/kg (both sexes)	III
Inhalation LC_{50} (rat)[21]	> 0.07 mg/L (both sexes)	II
Eye Irritation[22]	Minimal irritant (both sexes)	III
Dermal Irritation[23]	Slight irritant (females) Not an irritant (males)	IV
Dermal Sensitization[24]	Positive	N/A
Delayed Neurotoxicity		N/A

19-24 MRID#s 413812-01 thru -06; HED Document Number 010173

b. Subchronic Toxicity

In a 90-day oral toxicity study, picloram acid was administered via the diet to groups of 15 F344 rats/sex/dose at dosage levels of 0, 15, 50, 150, 300 or 500 mg/kg/day. Based upon liver weight changes and minimal microscopic changes in the liver, the systemic LOEL is 150 mg/kg/day. The NOEL is 50 mg/kg/day. (MRID# 001105-37)

In a 1982 6-month dog dietary study, picloram acid was evaluated at dosage levels of 0, 7, 35 or 175 mg/kg/day. The systemic NOEL is 35 mg/kg/day and the LOEL is 175 mg/kg/day based on decreases in the following: body weight gain, food consumption, liver weights (relative), alkaline phosphatase and alanine transaminase.

Increased liver to body weight ratios and absolute weights were observed in only two males at the 35 mg/kg/day dosage level. (MRID# 001105-34).

In a 21-day dermal toxicity study, the potassium salt of picloram was administered dermally to groups of five New Zealand white rabbits of each sex at doses of 0 (vehicle control), 75.3, 251 or 753 mg/kg/day (0, 65, 217 or 650 mg/kg/day picloram acid equivalents) for a total of 15 applications over the 21-day period. The NOEL is greater than or equal to 753 mg/kg/day for both sexes: hence, a LOEL was not established for either sex. Although the limit dose of 1000 mg/kg/day was not achieved, practical difficulties precluded administering more test material. The study revealed the non-systemic effects of dermal irritation and very slight to well defined edema and/or erythema in both sexes at all dose levels. (MRID# 413849-01)

In a 13-week oral toxicity study in the F344 rat, picloram isooctyl ester was evaluated by dietary administration at dosage levels of 0, 22, 73, 220 or 733 mg/kg/day (0, 15, 50, 150 or 500 mg/kg/day picloram acid equivalents). There were 10 rats/sex/group employed in the study. The LOEL is 220 mg/kg/day, where the findings were increased liver weights in both sexes accompanied by slight/very slight hepatocellular hypertrophy and increased kidney weight in males only. The NOEL is 73 mg/kg/day. (MRID# 422970-01)

In a 21-day dermal toxicity study in the rabbit, picloram isooctyl ester (89.9% purity) was evaluated at dosage levels of 0 (vehicle control) 250, 500 or 1000 mg/kg/day. There were 5 rabbits/sex in each of the study groups. The LOEL is 500 mg/kg/day based upon increased bilirubin (males) and increased BUN (males/females). The NOEL is 250 mg/kg/day. There were dermal responses at the site of application, at all doses, but such do not constitute findings of systemic toxicity. There were no dose related histopathologic findings. (MRID#s 421716-01; 428707-01)

In a 21-day dermal toxicity study the triisopropanolamine salt of picloram was administered dermally to groups of five New Zealand white rabbits of each sex at doses of 0 (vehicle control), 132, 440 or 1320 mg/kg/day (0, 73.8, 246 or 738 mg/kg/day picloram acid equivalents) for a total of 15 applications over the 21-day study period. The NOEL is greater than or equal to 1320 mg/kg/day for both sexes; hence, a LOEL was not established for either sex. The study revealed dermal irritation and very slight to well defined edema and/or erythema among animals of both sexes at all doses. (MRID# 413849-02)

In a 13-week oral toxicity study in the F344 rat, picloram, triisopropanolamine salt was evaluated by dietary administration at dosage levels of 0, 25, 90, 550 or 1800 mg/kg/day. There were 10 rats/sex/group employed in the study. The LOEL is 550 mg/kg/day based on hepatocellular hypertrophy observed in males at 550 and 1800 mg/kg/day with a dose-response relationship. Hepatocellular hypertrophy and increased liver and kidney weights were observed in females at 1800 mg/kg/day. There was decreased body weight gain in both sexes at 1800 mg/kg/day. The NOEL is 90 mg/kg/day. (MRID# 414427-01)

c. Chronic Toxicity

In a 1988 1-year chronic feeding study in the dog, picloram acid was administered orally via the diet at dosage levels of 0, 7, 35 or 175 mg/kg/day. The LOEL is 175 mg/kg/day based on increased liver weight (absolute and relative). The NOEL is 35 mg/kg/day. (MRID# 408343-01)

d. Combined Chronic Toxicity and Carcinogenicity

The following studies were submitted prior to the Picloram Registration Standard (1988) under the same identifier (MRID# 00081275) and were referenced in the Registration Standard.

In a study performed for the NTP by Gulf South Research Institute (GSRI), Osborne-Mendel rats were fed picloram (technical grade 90% pure with 130 ppm HCB) at dosages corresponding to time weighted average (TWA) dosages of 372 mg/kg/day (7437 ppm) and 747 mg/kg/day (14,875 ppm) for 80 weeks. At the highest dose, 747 mg/kg/day, an carcinogenic effect (neoplastic nodules) was seen in females. This study was considered supplementary since the matched control groups were not adequate size, the study was conducted for a shorter than 2-year lifetime exposure limit, and the supporting data to determine if the maximum tolerated dose (MTD) was attained at 747 mg/kg/day was not provided. (MRID# 00081275)

In a second NTP study, $B_6C_3F_1$ mice were fed picloram (technical grade 90% pure with 130 ppm HCB) at dosages of 357 or 714 mg/kg/day for 79 weeks and allowed to recover for 10 weeks prior to sacrifice. Picloram did not show a carcinogenic response up to 714 mg/kg/day for 79 weeks. This study was considered deficient since available information did not assure that an MTD was attained. (MRID# 00081275)

The following studies were submitted in response to the deficiencies cited in the Registration Standard.

In a chronic toxicity/carcinogenicity feeding study conducted in the F344 rat, picloram acid (technical grade 93% containing 197 ppm hexachlorobenzene as an impurity) was evaluated at 0, 20, 60 or 200 mg/kg/day for 2 years. The chronic toxicity LOEL was 60 mg/kg/day as evidenced by altered size and tinctorial properties of centrilobular hepatocytes and increased absolute and/or relative liver weights in both sexes. The NOEL was 20 mg/kg/day. The study was negative for carcinogenicity, but due to concerns that a MTD may not have been achieved and the fact that the test material contained 197 ppm hexachlorobenzene impurity, the study was not considered to fulfill adequately the carcinogenicity testing requirement. (MRID# 001559-40)

In response to the deficiencies cited in the study above, an additional 2-year dietary chronic/carcinogenicity study was conducted (in 1992) using F344 rats administered picloram acid at dosage levels of 0, 250 or 500 mg/kg/day for 104 weeks. Chronic toxicity was observed at 250 mg/kg/day among males only (increased incidence and severity of glomerulonephritis, blood in urine, decreased specific gravity of urine, increased size of hepatocytes that often had altered staining properties). Among females there were chronic effects only at 500 mg/kg/day (increased glomerulonephropathy, increased absolute and relative kidney weight). There was no evidence of carcinogenicity in this study. It should be noted that use of the Osborne-Mendel rat was waived due to lack of availability of the strain of rat. In addition, the level of hexachlorobenzene in the test material employed in this study was 12 ppm. These two studies (MRID# 001559-40, 426193-02) fulfill the guidelines 83-1(a) and 83-2(a) for rats.

In a 1992 2-year dietary carcinogenicity study in B6C3F1 mice, picloram acid was evaluated at doses of 0, 100, 500 or 1000 mg/kg/day. The systemic NOEL in this study is 500 mg/kg/day based on a significant increase in absolute and relative kidney weights in males (at the high dose level). No histopathological lesions were found to corroborate these changes. There was no evidence of carcinogenicity. (MRID# 426193-01)

The dose levels tested in the 1992 carcinogenicity studies in rats and mice were considered adequate for carcinogenicity testing. The treatment did not alter the spontaneous tumor profile in mice or different strains of rats tested under the testing conditions. The chemical was classified as a "Group E - Evidence of non-Carcinogenicity for

humans." This classification applies to the picloram acid and potassium salt forms for which acceptable carcinogenicity studies were available for review by the HED Carcinogenicity Peer Review Committee (5/26/88). Carcinogenicity studies had not been required for the other forms of picloram. However, subsequent to the carcinogenicity peer review meeting, it was reported that 2-ethylhexanol was detected as a metabolite of the picloram ethylhexyl ester in Fisher 344 rats. This metabolite is thought to play a role in the ability of di-(2-ethylhexyl)phthalate (DEHP) to act as a peroxisome proliferator and it has been suggested that peroxisome proliferation might be the/an underlying mechanism in DEHP carcinogenicity. Based on this information the Agency decided it was appropriate to use a Q_1^* for di-(2-ethylhexyl) phthalate and perform an initial assessment of possible risk to workers from potential exposure to picloram ethylhexyl ester.

e. Developmental Toxicity

The HED RfD Peer Review Committee concluded that there was no evidence, based on the available data, that picloram and its salts and ester were associated with significant reproductive or developmental toxicity under the testing conditions.

In the following developmental toxicity studies, the dose levels that appear in parenthesis are picloram acid equivalents where the conversion factors employed were 0.86, 0.68 and 0.56 as applied to doses of potassium salt, isooctyl ester and triisopropanolamine salt, respectively.

Picloram potassium salt was administered to New Zealand rabbits by oral gavage at dosage levels of 0, 40, 200 and 400 mg/kg/day (picloram acid equivalents) during days 6 to 18 of gestation. The maternal NOEL is 40 (34) mg/kg/day, where the LOEL is 200 (172) mg/kg/day based on reduced maternal weight gain during gestation. The developmental NOEL is 400 mg/kg/day and the LOEL was not determined. (MRID# 410695-01, 001387-03, Accession# 252493)

The potassium salt of picloram was administered to CD rats by gastric intubation at dosage levels of 0, 35 (30), 174 (150) and 347 (298) mg/kg/day during day 6-15 of gestation. The test vehicle was distilled water. There was no evidence of developmental toxicity at doses up to and including the high dose of 347 (298) mg/kg/day. The maternal LOEL is 347 (298) mg/kg/day based upon excessive salivation in the dams of the high dose group. Hence, the developmental toxicity NOEL is greater than or equal to 347 (298) mg/kg/day. The maternal toxicity

LOEL is 347 (298) mg/kg/day and NOEL is 174 (150) mg/kg/day. (MRID# 413825-02)

Picloram isooctyl ester was administered to New Zealand white rabbits via oral gavage at dosage levels of 0, 20 (14), 100 (68) or 500 (340) mg/kg/day during days 7-19 of gestation. Developmental toxicity was not observed at any dose level. Hence, the developmental toxicity NOEL is greater than or equal to 500 (340) mg/kg/day. Maternal toxicity was observed at 100 (68) mg/kg/day manifested as an increase in the incidence of clinical signs (decreased feces at 500 (340) mg/kg/day and decreased body weight gain at 100 (68) mg/kg/day and above). Hence, for maternal toxicity, the LOEL is 100 (68) mg/kg/day and the NOEL is 20 (14) mg/kg/day. (MRID# 421211-04)

Picloram isooctyl ester was evaluated in CD rats. The chemical was administered via oral gavage at dosage levels of 0, 100 (68), 500 (340) or 1000 (680) mg/kg/day during days 6-15 of gestation. There was no evidence of developmental toxicity at any dosage level; hence, the developmental toxicity NOEL is greater than or equal to 1000 (680) mg/kg/day. The maternal toxicity LOEL is 500 (340) mg/kg/day based on decreased body weight gain during early gestation, days 6-9. The maternal toxicity NOEL is 100 (68) mg/kg/day. (MRID# 422969-01)

Picloram triisopropanolamine salt was administered to New Zealand white rabbits via oral gavage at dosage levels of 0, 180 (101), 538 (301) or 1,000 (560) mg/kg/day during days 7-19 of gestation (phase 1) and at doses of 0, 54 (30), 180 (101), 538 (301) or 1,000 (560) mg/kg/day (phase II). Developmental toxicity was not observed at any dose level in either of the two phases of the study. Hence, the developmental toxicity NOEL is greater than or equal to 1000 (560) mg/kg/day. Maternal toxicity was observed in both phases of the study at greater than or equal to 180 (101) mg/kg/day manifested as increased rate of abortions at 1000 (560) mg/kg/day; increased incidence of clinical signs at 538 (301) and 1000 (560) mg/kg/day; and decreased food consumption and body weight gain at 180 (101), 538 (301) and 00 (560) mg/kg/day. The maternal toxicity LOEL is 180 (101) mg/kg/day and the NOEL is 54 (30) mg/kg/day. (MRID# 424609-01)

Picloram triisopropanolamine salt was administered to CD rats by gastric intubation at dosage levels of 0, 100 (56), 500 (280) or 1000 (560) mg/kg/day during days 6-15 of gestation. The test vehicle was distilled, deionized water. The picloram salt did not elicit evidence of developmental toxicity at doses up to and including the high dose of 1000 (560) mg/kg/day. The developmental toxicity NOEL is 1000

(560) mg/kg/day. Maternal toxicity was observed at 1000 (560) mg/kg/day manifested as excessive salivation, decreased body weight gain and decreased food consumption. The maternal toxicity LOEL is 1000 (560) mg/kg/day and the NOEL is 500 (280) mg/kg/day. (MRID# 413825-04)

f. Reproductive Toxicity

Picloram acid was evaluated in a 2-generation reproduction study in the CD rat. Dosage levels employed were 0, 20, 200 or 1000 mg/kg/day. The parental LOEL is 1000 mg/kg/day based on histopathological lesions in the kidney of males of both generations and some females. In males of both generations, blood in the urine, decreased urine specific gravity, increased absolute and relative kidney weight, and increased body weight gain was observed at the high dose. The parental LOEL is 1000 mg/kg/day and the NOEL is 200 mg/kg/day. The reproductive LOEL was not identified and the NOEL is 1000 mg/kg/day. (MRID# 420787-01)

g. Mutagenicity

Picloram acid was evaluated in the Ames test using Salmonella typhimurium. Doses ranged up to 5000 ug/plate, with and without metabolic activation. The test substance did not produce a mutagenic response either in the presence or absence of activation. (MRID# 414859-02)

Picloram acid was evaluated for gene mutation in mammalian cells (HGPRT/CHO). As evaluated up to toxic levels (750 ug/ml without metabolic activation; 1250 ug/ml with metabolic activation), the compound was found to be negative for inducing forward mutation in Chinese hamster ovary (CHO) cells. (MRID# 400726-01)

Picloram acid was evaluated for cytogenetic effects on bone marrow cells of rats via intragastric administration at dosage levels of 0 (vehicle), 20, 200 or 2000 mg/kg. The test material did not produce cytogenetic effects in the study. (MRID# 000983-22)

Picloram acid was evaluated for genotoxic potential as administered to primary rat hepatocyte cultures at concentrations of 0 (vehicle), 10, 33.3, 100, 333.3 or 1000 ug/ml. The test material was negative for unscheduled DNA synthesis (UDS, a measure of DNA damage/repair) treated up to cytotoxic levels of (1000 ug/ml). (MRID# 415497-01)

Picloram isooctyl ester was evaluated in the Ames test using Salmonella typhimurium. Dosages ranged from 16.7 to 1667 ug/plate in studies with and without S9 activation. The test compound did not induce a mutagenic response in the presence or absence of metabolic activation. (MRID# 421211-06)

Picloram isooctyl ester was evaluated in two independent Chinese Hamster Ovary Cell HGPRT forward gene mutation assays, one of these with, and the other without, S9 activation. Concentrations of the picloram isooctyl ester employed in the non-activated trial ranged 1.25 to 50 ug/ml as conducted in two assays of overlapping dosage range. The second trial, also conducted in two assays of overlapping dose and including S9 activation, utlilzed dosages ranging from 2.50 to 200 ug/ml. Concentrations $\geq$ 40 ug/ml in the non-activated trial and $\geq$ 125 ug/ml in the activated trial were severely cytotoxic. There was no evidence of a mutagenic response at any dosage level in either the S9 activated trial(s)/or the non-activated trial(s). (MRID# 424140-01)

Picloram isooctyl ester was evaluated in two independent rat lymphocyte cytogenetic assays with and without S9 activation. Concentrations ranging from 2.67 to 800 ug/ml +/-S9 were assayed in Trial 1; severe cytotoxicity was observed at levels $\geq$ 80 ug/ml +/-S9. In Trial 2, no cytotoxicity was seen in cells exposed to 8.04 or 17.4 ug/ml +/-S9 and harvested at 24 hours. However, reductions in the mitotic index (MI) were observed in cells harvested 24 or 48 hours postexposure to 26.8 ug/ml +/-S9. Although a number of minor deficiencies rendered the purported negative results of this study inadequate in initial review, subsequent re-evaluation with additional information and data supplied by the performing laboratory were adequate to upgrade this assay to fully acceptable in demonstrating no potential for inducing chromosomal aberrations. (MRID# 423687-01)

Picloram isooctyl ester was evaluated in the mouse micronucleus assay at single oral gavage doses of 0(2), 500, 1667 or 5000 mg/kg (limit dose) using 24, 48 or 72 hour sacrifice times. The material was found not to be clastogenic. No lethality was reported and there was no evidence of target tissue cytotoxicity. The picloram compound was tested at a sufficiently high level and found not to be clastogenic. (MRID# 421716-02)

Picloram triisopropanolamine salt was evaluated in the Ames test using Salmonella typhimurium. Doses ranged up to 5000 ug/plate, with and without metabolic activation. The test material did not produce a

mutagenic response either in the presence or absence of activation. (MRID# 414859-01)

Picloram triisopropanolamine salt was evaluated by oral administration to mice in the mouse bone marrow micronucleus test, at dosage levels of 0, 300, 1000 or 3000 mg/kg. The test agent was determined to be non-clastogenic in mice, as determined by lack of mutagenic effect at doses up to lethality (3000 mg/kg). (MRID# 415397-01)

Picloram triisopropanolamine salt (MRID# 415397-02) was evaluated for genotoxic (DNA damage/repair) potential when administered to primary rat hepatocyte cultures at concentrations up to 1500 ug/ml. The test material was negative for inducing unscheduled DNA synthesis (UDS) at doses up to toxic levels (1500 ug/ml). (MRID# 415397-02)

h. Metabolism

The absorption, distribution, metabolism and excretion of picloram acid was evaluated in female rats administered a single i.v. or oral gavage dose of 10 mg/kg, an oral gavage dose of 1000 mg/kg ^{14}C-picloram, or 1 mg/kg/day unlabeled picloram by gavage for 14 days followed by a single oral gavage dose of 10 mg/kg ^{14}C-picloram on day 15. The study demonstrates that ^{14}C-picloram is rapidly absorbed, distributed and excreted following oral and i.v. administration. This study alone is not adequate; however, this study is acceptable when considered in conjunction with a male rat metabolism study (MRID# 00098321) which yielded similar results. (MRID# 412096-02)

The absorption, metabolism and excretion of picloram isooctyl ester (also referred to as picloram ethylhexyl ester) was studied in male F344 rats following single oral (gavage) dosing with 15 mg/kg of ^{14}C-picloram isooctyl ester. The ester was absorbed and excreted rapidly. By 48 hours post-exposure, mean recovery of radioactivity was 96.4%. The urine was the major elimination route (68 % of administered dose). The feces and expired $^{14}CO_2$ represented 16.35% and 10.16%, respectively, of the administered dose. Elimination of picloram ethylhexyl ester was rapid, as indicated by 67% recovery at 24 hours post-dosing. The major metabolite was 2-ethyl-1, 6-hexanoic acid. This study supports the fact that picloram ethylhexyl ester is hydrolyzed rapidly to picloram (free acid) and 2-ethyl hexanol, and that picloram ethylhexyl ester does not influence the excretion of picloram in the rat. (MRID# 421716-03)

The absorption, metabolism and excretion of picloram triisopropanolamine salt was studied in male F344 rats following administration of single oral doses (gavage) of 9.5 mg/kg of C^{14}-triisopropanolamine and 9.8 mg/kg of picloram. This level of dosing delivered 20-30 uci per animal in the forms of ^{14}C-triisopropanolamine. The ^{14}C-triisopropanolamine was absorbed readily, with peak plasma radioactivity being observed at 0.25 hours post-dosing. The administered dose of radioactivity as recovered primarily in urine, feces, expired carbon dioxide, tissue/carcass and final cage rinse was 94%. Unchanged triisopropanolamine accounted for 80% of the total radioactivity excreted in the urine. No other metabolites were identified in the 0-6 hour pooled urine sample. The data suggest that the conversion of picloram triisopropanolamine salt to picloram was not affected by the presence of triisopropanolamine. (MRID# 423431-01)

i. Other Toxic Endpoints

Picloram isooctyl ester (also referred to as picloram ethylhexyl ester) bears structural similarity to di(2-ethylhexyl)phthalate (DEHP) in possessing a 2-ethylhexyl moiety. DEHP and certain other substances containing the 2-ethylhexyl moiety have been found to be positive for carcinogenicity in rodent bioassays. 2-Ethylhexanol was detected as a metabolite in the metabolism studies summarized above. This metabolite is also a primary hydrolytic cleavage product of DEHP, a positive rodent liver carcinogen. This metabolite is thought to play a role in the ability of DEHP to act as a peroxisome proliferator and it has been suggested that peroxisome proliferation might be the underlying mechanism in DEHP carcinogenicity. Available data indicate that DEHP is most potent among the 2-ethylhexyl containing compounds tested. For the purposes of carcinogenicity risk assessment for occupational exposure with respect to picloram isooctyl ester, the recommended toxicological endpoint is the Q_1^* value of 3.29×10^{-4} $(mg/kg/day)^{-1}$ obtained for DEHP in a carcinogenicity risk assessment on this compound [D. Turnbull and J.V. Rodricks (1985)]. This Q_1^* is based upon a 2-year carcinogenicity bioassay of DEHP in female mice [National Toxicology Program (1982)] and although this Q_1^* was generated by Turnbull et al., the value was generated using the same model the Agency uses.

Hexachlorobenzene (HCB), a recognized impurity in picloram compounds, is considered to be an animal carcinogen and probable human carcinogen as discussed in the 1988 Registration Standard for picloram.

j. Reference Dose

In the meeting of September 30, 1993, the OPP RfD Peer Review Committee recommended that the RfD for this chemical be based on a NOEL of 20 mg/kg/day for a dose-related increase in size and altered tinctorial properties of centrilobular hepatocytes in males and females at 60 and 200 mg/kg/day in a chronic toxicity study in rats (MRID# 00155940). An uncertainty factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated to be 0.20 mg/kg/day. It should be noted that no regulatory value has been established for this chemical by the World Health Organization (WHO) up to this date. The committee classified picloram as a "Group E" chemical, no evidence of carcinogenicity for humans.

There was no evidence, based on the available data, to suggest that the chemical was associated with significant reproductive or developmental toxicity under the testing conditions.

2. Exposure Assessment

a. Dietary

The qualitative nature of the residue in plants is adequately understood based on a wheat metabolism study. The residue of concern in wheat forage, straw, and grain is conjugated picloram, which is hydrolyzable by acid, base, and ß-glucosidase. The minor metabolites that were identified in grain and straw were 4-amino-6-hydroxy-3,5-dichloropicolinic acid and 4-amino-2,3,5-trichloropyridine. The data support the current uses. Additional plant metabolism studies may be required if picloram uses are expanded to other crops. (MRID#s 00037880, 00041136, 00059411, 00111527, 00157171, and 42579004).

The qualitative nature of the residue in animals is adequately understood. Picloram is the residue of concern in meat, milk, poultry tissues, and eggs. The available ruminant metabolism study indicates that picloram is the major residue in animal tissues of interest and that picloram is not metabolized in ruminants to a significant degree; only minor amounts (< 10% of total radioactive residues) of 4-amino-2,3,5-trichloropyridine were detected in goat fat and liver. In the submitted poultry metabolism study, 99.9% of the recovered radioactivity was found in the excreta and virtually all of the ^{14}C-residues were identified as picloram. (MRID#s 00023105, 00041125, 00161306, 00163216, and 42535301).

Adequate enforcement methods are available for the determination of residues of picloram *per se* in/on plant and animal commodities. All of these methods use GLC with electron capture detection of the methyl ester of picloram. The Pesticide Analytical Manual (PAM), Vol. II lists Methods A and III for plant commodities. DowElanco method ACR 73.3.S2 is a GC/ECD method based on Method III with substantial modifications. Method ACR 73.3.S2 was validated using samples from the wheat metabolism study and is adequate for data collection of picloram residues. Method ACR 79.7.S.1 is adequate for collection of picloram data on grass forage and hay. DowElanco Method ACR 91.4 is adequate for HCB data collection from plant commodities.

PAM Vol. II Methods I and II are used to enforce tolerances for picloram residues in animal commodities. DowElanco GC/ECD methods ACR 67.2 and ACR 67.3 are equivalent to Methods II and I, respectively, except that toluene is used in place of benzene. These animal commodity methods have been validated using samples from the goat metabolism study and are adequate for data collection and tolerance enforcement for milk and animal tissues. (MRID#s 00026748, 00026749, 00026750, 00026751, 00026752, 00026753, 00027288, 00035959, 00045363, 00045366, 00045373, 00045374, 00045375, 00045376, 00045409, 00062818, 00069973, 00073972, 00073974, 00078483, 00085060, 00111404, 00111407, 00131364. 00132986, 00156366, and 42380201).

FDA has tested picloram using the PAM, Vol. I Multiresidue Method for acids and phenols (Sec 221.1). Table 201-D of the volume reports that picloram in nonfat foods is recovered completely through PAM I 221.1 if a 100 mL ethyl ether Florisil elution is included whereas only 6-10% is recovered from fatty foods.

Adequate storage stability data on picloram are available to support the collected samples from metabolism and magnitude of the residue studies in plants and animals. Residues of picloram *per se* are stable under frozen storage conditions in/on: (i) wheat and barley grain, forage, and straw; and grasses for up to 2 years; (ii) egg whites for up to 18 months; (iii) milk for up to 15 months; and (iv) liver and muscle for up to 6 months. Adequate storage stability data for HCB residues are available for grass and small grain commodities; residues of HCB are stable in frozen storage for up to 17 months. (MRID#s 00164725, 40082701, 40435601, 40731901, 41442301, 41976701 and 42494001).

All data requirements for magnitude of picloram residues in plants have been evaluated and deemed adequate. The registered uses of

picloram on barley, oats, and wheat along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. Field trial data representing maximum registered use patterns are available for grasses and support the proposed tolerance of 225 ppm for grass hay; however, residues on grass forage exceed the proposed tolerance of 225 ppm. The data indicate that a value of 300 ppm would be appropriate for grass forage.

The Agency has acceptable field residue data at the 0.5 lb. ae/A and 2 lb. ae/A. However, through negotiations with the registrant the new maximum use rate will be lowered to 1 lb. ae/A. Ordinarily, field residue data would be required for this new maximum use rate, however, since there are minimal dietary concerns involved with picloram, no field residue data will be required for the 1 lb. ae/A maximum use rate. Picloram tolerances are based on the 2 lb. ae/A data and will remain in effect unless the Agency revisits the tolerance setting database and lowers the tolerance based on the 0.5 and 2 lb. ae/A residue field data or the registrant proposes a lower tolerance based upon the 0.5 and 2 lb. ae/A.

Acceptable grain dust data have been submitted for wheat, which show that residues of picloram concentrate 7x in aspirated grain dust. The registrant must propose a suitable tolerance for grain dust.

The available field residue data on HCB residues in/on plants are adequate. HCB residues were nondetectable in/on wheat grain(< 0.001 ppm), grain dust(< 0.001 ppm) and wheat straw (< 0.002 ppm) following applications of registered formulations of picloram according to the maximum registered use patterns. Residues of HCB were < 0.001 ppm in/on grass forage and hay treated using the 2 lb/gal SC/L potassium salt formulation at a rate of 2 lb ae/A, and containing residues of picloram as high as 480 ppm. One hay sample, containing 270 ppm picloram, bore 0.001 ppm HCB. Residues of HCB were shown to dissipate from grass at a greater rate than picloram residues. (MRID#s 00026753, 00036168, 00036170, 00036171, 00045369, 00085060, 00108862, 00108864, 00111404, 00111470, 00111482, 00111557, 00128714, 41905401, 42037601, 42380201, 42535303, and 42784401).

The data requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate. Acceptable wheat grain processing data have been submitted; the wheat processing data will be translated to barley and oats. The wheat data indicate that residues of picloram concentrate up to 5x in bran. HCB residues were

not detected in/on wheat grain or processed fractions. The existing feed additive tolerance of 3 ppm for picloram residues in milled products of wheat (exc. flour) is adequate. (MRID# 42535303).

The ruminant and poultry feeding studies that were reviewed in the Residue Chemistry Chapter of the Picloram Reregistration Standard, dated 10/29/84, are adequate to satisfy animal feeding study data requirements. These feeding studies indicate that the existing tolerances on animal commodities are supported by residue data from dietary intakes exceeding the maximum dietary burden. (MRID#s 00045372, 00045374, 00045376, 00073921, and 00073973).

An acceptable confined rotational crop study has been submitted. Field rotational crop studies are not required; in addition, tolerances for rotational crop commodities need not be established. (MRID# 42641801).

b. Occupational and Residential

Picloram is applied by ground, aerial, wiper applicator, backpack, handheld sprayer/spraywands, tree injection, and paintbrushes. Application types include: aerial and ground broadcast spray treatments; band applications with helicopters; frill, girdle, and stump treatments; spray or paint-on treatment to the base of a target plant; direct injection into a target plant; high-volume spray treatments using ground, handheld, or wiper-applicator equipment; spot treatments (soil or plant) using ground, handheld, low-pressure, or wiper-applicator equipment; basal bark and soil treatments using backpack, power, or knapsack sprayers and low-volume ground equipment.

Minimum application volumes range from using small amounts of undiluted end-use-products in some spot and basal bark treatments to using various formulations diluted in up to approximately 100 gallons per acre in some ground applications. Diluents include water and various petroleum based derivatives. The maximum application rate, regardless of the crop/target for all equipment categories, application targets and formulation types is 2.16 lb active ingredient/acre. All application rates are based on the acid moiety of picloram, the active agent, and not each specific salt or ester of picloram contained in each formulation. For a significant number of other application techniques, picloram essentially is applied at the discretion of the applicator to a particular target of choice (e.g., *ad libitum* or to run-off to a tree trunk in a spot or frill/girdle treatment). For these types of application scenarios, an application rate on a per acre basis was not calculated

because it is not expected to be worse than the backpack/knapsack sprayer scenario which is considered the worst-case.

The maximum duration of any exposure for workers on a yearly basis is likely to range from 10 to 40 days for commercial applicators, i.e., rights-of-way spraying operations are likely to require 40 days.

Occupational-use products and homeowner-use products

At this time no products containing picloram are registered for homeowner use. All products containing picloram are for occupational use (all products are restricted-use pesticides). None of the registered uses are likely to involve applications at residential sites.

Uses within the scope of the Worker Protection Standard

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 within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) 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 picloram are within the scope of the Worker Protection Standard for Agricultural Pesticides (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,
- 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 noncrop areas.

The WPS does not cover workers who are working in an area where a pesticide has been injected directly into plants, i.e., there are no entry restrictions or notification requirements. However, people who handle pesticides that are to be applied by direct injection are covered by the WPS and must receive WPS handler protection. Direct injection does not include chemigation, soil incorporation, soil injection, hack and squirt, or frill and spray application techniques.

Previous Data Requirements

Requirements for mixer/loader/applicator (i.e. handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator (M/L/A) exposure data for picloram have not been required in the past, since no toxicological criteria had been identified at that time. The complete review of the toxicological data submitted to support reregistration indicates that these data are now warranted.

Requirements for post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. Post-application exposure data have not been required in the past, since no toxicological criteria had been triggered for picloram. The complete review of the data submitted to support reregistration now indicates that picloram does trigger the toxicological criteria, but not for the requirement of post-application exposure data.

Occupational and Residential Exposure Assessment

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is an exposure risk for handlers (mixers, loaders, applicators) during use or for persons entering treated sites after application is complete.

The toxicological data base for picloram is adequate and will support reregistration. Studies for acute toxicity indicate that picloram is classified as category III for acute oral toxicity, category III for acute dermal toxicity, category I/II (depending on whether acid, ester or salts) for acute inhalation toxicity, category III/IV (depending on whether acid, ester or salts) for skin irritation potential, and category III for eye irritation potential. The potassium salt, triisopropanolamine salt, and isooctyl ester are classified as skin sensitizers. In addition, picloram has a low vapor pressure.

The toxicology criteria that trigger the requirements for an exposure assessment include: (1) systemic toxicity at 500 mg/kg/day (LOEL) based on the 21-day dermal study conducted, (2) classification of the impurity, hexachlorobenzene as a Group B_2, (probable human carcinogen) having a Q_1^* X 1.7 $(mg/kg/day)^{-1}$, and (3) classification of DEHP as having a Q_1^* 3.29 X 10^{-4} $(mg/kg/day)^{-1}$. (Picloram isooctyl ester bears structural similarity to DEHP since both possess a 2-ethylhexyl moiety.)

There is an exposure risk for *mixers, loaders, applicators, and handlers* for both dermal and inhalation routes during usual use-patterns associated with picloram. Therefore, an occupational and/or residential exposure assessment for handlers is required for picloram. A limited exposure assessment was conducted for picloram using data from the Pesticide Handlers Exposure Database (PHED) and surrogate data from the open literature. No chemical-specific data are available for picloram. It should be noted that all methods of application cited above and in Table V are applicable to the ester but there are no terrestrial food uses for this compound.

Based on the use patterns and potential exposures described above, major exposure scenarios were identified for picloram. Each scenario is defined by the types of equipment that could be used on the four major use-sites on which picloram is applied: terrestrial food crops, terrestrial non-food crops, forestry sites, and terrestrial feed crops. The scenarios include; (1) mixing/loading to support aerial applications, (2) applying with a groundboom sprayer, (3) applying with a fixed-wing aircraft, (4) applying with a rotor-wing, (5) applying with a paintbrush, (6) applying through direct injection into a woody plant, (7) applying with a high-pressure handwand, (8) applying with a hand-cannon along right-of-ways, (9) applying with a wiper applicator, (10) applying with backpack/knapsack equipment, (11) applying with a powered personal sprayer, and (12) applying with a low-pressure handwand. These exposure scenarios are presented in Table V along with the corresponding exposure/risk assessment. The data for five scenarios (5), (7), (9), (10) and (12), were insufficient to complete an exposure/risk assessment. However, for the scenarios for which there are insufficient data, exposures are expected to be no greater than maximum exposure scenario, which is applying with a backpack/knapsack sprayer.

There is a risk associated with *post-application exposure* for persons entering treated sites after application is complete particularly following aerial and ground broadcast spray treatments. However, the crops and sites where picloram is applied are not those where post-application activities (harvesting, scouting, irrigation, etc.) would be expected soon after application is complete. Therefore, an occupational and/or residential exposure assessment for post-application workers is not required for picloram.

Additionally, to clarify the Table V, the Exposure Scenario Description (Table VI) was developed. Table VI summarizes the caveats and parameters specific to each exposure scenario. This table

also includes a description of the sources for each data point as well as general information pertaining to the techniques used to calculate the corresponding exposure values. The "Data Source" is self-explanatory. The "Clothing Scenario" represents the clothing worn by the test subjects during the generation of the referenced exposure values. "Equipment" describes the application techniques used to generate the referenced data. "Formulation" is self-explanatory. "Standard Assumptions" represent the use scenarios employed by EPA to estimate daily exposure levels. The "Comments" section includes any other critical descriptions of the data including information pertaining to the quality of the exposure data.

TABLE V: Summary Exposure Values for Picloram

Exposure Scenario (Scen. #)	Dermal Exposure[a] (mg/lb ai)	Inhalation Exposure[b] (μg/lb ai)	Maximum Label Application Rate (lb ai/cycle)	Daily Maximum[c] Treated	Daily Dermal Exposure[d] (mg/kg/day)	**HCB**[e] Daily Dermal Exposure[d] (mg/kg/day)	Daily Inhalation Exposure[d] (mg/kg/day)	**HCB**[e] Daily Inhalation Exposure[d] (mg/kg/day)
Mixer/Loader Exposure								
Open Mixing Liquids (I)	0.3	0.4	1.08 lb ai/A	500 acres (aerial)	1.2[f]	1.2×10^{-4}	3.1×10^{-3}	3.1×10^{-7}
Applicator Exposure								
Groundboom Application (II)	0.02	1.3	1.08 lb ai/ A [g]	80 acres	1×10^{-2} [f]	1×10^{-6}	1.6×10^{-3}	1.6×10^{-7}
Fixed-Wing Aerial (III)	0.005	0.2	1.08 lb ai/A[g]	500 acres	4×10^{-2}	4×10^{-6}	1.5×10^{-3}	1.5×10^{-7}
Helicopter (IV)	No Data	No Data	1.62 lb ai/A[h]	No Data	No Data	No data	No data	No Data
Paintbrush (V)	290	570 (median)	0.54 lb ai/gal[h]	1 gallon	1.1[f]	1.1×10^{-4}	4.4×10^{-3}	4.4×10^{-7}
Tree Injection/ Hypo-hatchet (VI)	No Data	No Data	0.54 lb ai/gal[h]	No Data	No Data	No data	No data	No Data
High Pressure Handwand (VII)	0.70	0.09	0.036 lb ai/gal spray solution[h]	1000 gallon	1.8×10^{-1} [f]	1.8×10^{-4}	5×10^{-5}	5×10^{-9}
Right-of-Way Hand Cannon[i] (VIII)	No Data	No Data	2.16 lb ai/A[h]	No Data	No Data	No data	No data	No Data
Wiper Applicator (IX)	No Data	No Data	---	No Data	No Data	No data	No data	No Data
Backpack/Knapsack (X)[j]	159.1 mg/hr (average)	36 μg/hr (average)	2.16 lb ai/A[h]	8 hours	4.5 [j,k]	4.5×10^{-4}	4.1×10^{-3}	4.1×10^{-7}
Powered Personal Sprayer (XI)	No Data	No Data	---	No Data	No Data	No data	No data	No Data
Mixer/Loader/Applicator Exposure								
Low Pressure Handwand (XII)	103	39	2.16 lb ai/A[h]	2 acres	3.2[f]	3.2×10^{-4}	2.4×10^{-3}	2.4×10^{-7}

a Exposure units may differ from those defined in headers. Alternate units are noted where appropriate. Dermal unit exposures are reported as the best fit mean, unless noted. The best fit mean is the composite total dermal exposure based on using the geometric mean for log normal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.

b Inhalation exposure values are reported as geometric means (log normal distributions), unless otherwise noted.

c Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

d Daily Exposure (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/cycle)} * \text{Max. Treated}}{70 \text{ kg}}$

e HCB is present as a 0.01% contaminant.

f These estimates for picloram and HCB are reduced by 50% for glove use. The unit exposure reflects PPE in the Exposure Scenario Descriptions Table (VI) for Picloram.

g Luis Report dated 1/4/93, Picloram, triisopropanolamine salt.

h Tordon 101 (EPA Reg. No. 62719-5).

i High Pressure Handwand (Scenario VII) data can be used for Hand Cannon (Scenario VII).

j This scenario represents the worst-case scenario and the exposure is based on only the applicator exposure. The combined mixer, loader and applicator exposure, i.e. if the same individual performed all three tasks, is less than the applicator only exposure.

k The estimate for total deposition is reduced by 75% to reflect use of long pants, long sleeved shirt, and gloves. The unit exposure reflects PPE in the Exposure Scenario Descriptions Table (VI) for Picloram.

TABLE VI: Exposure Scenario Descriptions for Picloram[a]

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Standard Assumptions[b] (8 hr work day)	Comments[c]
Mixer/Loader Exposure					

TABLE VI: Exposure Scenario Descriptions for Picloram[a]

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Standard Assumptions[b] (8 hr work day)	Comments[c]
Open Mixing (I)	PHED	Long Pants, Long-Sleeved Shirt, No gloves	Open Mixing	500 acres (aerial)	Acceptable grades; Dermal = 14 + replicates; Inhalation = 40 replicates
Applicator Exposure					
Groundboom Application (II)	PHED	Long Pants, Long-Sleeved Shirt, No gloves	Open Cab Tractor	80 acres/day	Grades A, B, C; Dermal = 6 + replicates; Inhalation = 56 replicates.
Aerial (III)	PHED	Long pants, long-sleeved shirt, no gloves	All Cab types	500 acres/day	Inhalation grades A, B, C; Dermal all grades; Dermal = 4 - 41 replicates; Inhalation = 25 replicates.
Helicopter (IV)	No Data	No Data	No Data	No Data	No Data
Paintbrush (V)	PHED	Long pants, Long sleeve shirt, no gloves	Paint brush	1 gallon undiluted	Inhalation grade C; Dermal grades B, C; Dermal and Inhalation = 15 replicates.
Tree Injection/Hypo-Hatchet (VI)	No Data	No Data	No Data	No Data	No Data
High Pressure Handwand (VII)	PHED	Long pants, Long-sleeved shirt, no gloves	High pressure portable hand wand on wheels	1000 gallons/day	Inhalation grades B and C; Dermal grade B and C; Dermal and Inhalation = 9 replicates
Right-of Way Cannon (VIII)	No Data	No Data	No Data	No Data	No Data
Wiper Applicator (IX)	No Data	No Data	No Data	No Data	No Data
Backpack/ Knapsack (X)	Abbott et al. 1987	Total Deposition	Knapsack with 1 meter boom	8 hour work day	Laboratory and field recovery available; Dermal = 6 replicates; Inhalation = 12 replicates.
Powered Personal Sprayer (XI)	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator Exposure					
Low Pressure Handwand (XII)	PHED	Long pants, long-sleeved shirt, no gloves	Portable handwand	2 acres/day	Inhalation grades B and C; Dermal all grades; Dermal = 25 to 95 replicates; Inhalation = 95 replicates.

a "No Data" indicates that no data were available to complete an exposure assessment.
b Standard Assumptions based on an 8 hour work day as estimated by OREB. BEAD data were not available.
c If dermal and inhalation grades are not listed separately, then the listed grades pertain to both dermal and inhalation. "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal and inhalation, and grade C for hand rinse method. All grades that do not meet OREB's SOP are listed individually.

Data Requirements

Although data are available to estimate the worker exposure for the maximum exposure scenarios for the purposes of risk assessment, the data sets available are limited in both quantity and quality as shown in Table VI. In order to reduce the uncertainty associated with the exposure assessments and thus the risk assessment and because the following scenarios lack exposure data and have a potential for as high a worker exposure as the backpack/knapsack scenario, these data must be submitted for confirmation purposes:

1) Guideline 231: Estimation of Dermal Exposure at Outdoor Sites for mixer/loaders and applicators using the hand cannon equipment.

2) Guideline 232: Estimation of Inhalation Exposure at Outdoor Sites for mixer/loaders and applicators using the hand cannon equipment.

3) Guideline 231: Estimation of Dermal Exposure at Outdoor Sites for mixer/loaders and applicators using the backpack/knapsack equipment.

4) Guideline 232: Estimation of Inhalation Exposure at Outdoor Sites for mixer/loaders and applicators using the backpack/knapsack equipment.

3. Risk Assessment

a. Dietary

There are two primary dietary exposure/risk analysis considerations for picloram: (1) the chronic dietary exposure/risk to picloram *per se*, and (2) dietary carcinogenicity exposure/risk to HCB, an impurity. An acute oral toxicity endpoint has not been identified for picloram; therefore, an acute dietary exposure/risk analysis was not conducted for picloram per se. Picloram isooctyl ester has no food uses, therefore no dietary exposure is expected. Thus, a dietary carcinogenic exposure/risk analysis was not conducted for picloram IOE.

The chronic analysis for picloram used a Reference Dose (RfD) of 0.2 mg/kg bodyweight per day, based on a NOEL of 20.0 mg/kg body-weight per day from a two-year rat feeding study and an uncertainty factor of 100 to account for interspecies extrapolation and intraspecies variability. The endpoint effects noted were altered size and tinctorial properties of centrilobular hepatocytes in both male and female

rats. HCB is considered a Group B2 carcinogen. The carcinogenicity analysis that was performed for HCB used a Q_1* of 1.7 (mg/kg bodyweight per day)$^{-1}$. The residue values used are summarized in Table VII. Residue values are based on the assumption of tolerance level residues of picloram on crops. Residues of HCB were estimated by assuming presence on all crops in direct proportion to the maximum level of HCB in picloram TGAI as certified by the producer, i.e., at 0.01% of the picloram tolerance. All percent crop treated values were available.

Table VII. Picloram and HCB Residue Values on Foods Used to Determine Dietary Risk. [a]

Commodity	Picloram Residues (ppm)	HCB Residues (ppm)	% crop treated
Barley, grain	0.5	0.00005	2
Barley, milled fractions (exc. flour)	3	0.0003	2
Oats, grain	0.5	0.00005	1
Oat, milled fractions (exc. flour)	3	0.0003	1
Wheat, grain	0.5	0.00005	2
Wheat, milled fractions (exc. flour)	3	0.0003	2
Secondary Residues			
Milk	0.05	0.000011 (whole milk) 0.000265 (milk fat only assuming 4% fat)	
Cattle, fat	0.2	0.00045	
Cattle, kidney	5	0.000023[b]	
Cattle, liver	0.5	0.000023[b]	
Cattle, mbyp (exc kidney and liver)	0.2	0.000023[b]	
Cattle, meat	0.2	0.000023[b]	
Poultry, fat	0.05	0.000007	
Poultry, mbyp	0.05	0.0000001[c]	
Poultry, meat	0.05	0.0000001[c]	
Eggs	0.05	0.000002 (yolk) 0.000000007[c] (white)	
Hogs, fat	0.2	0.000008	
Hogs, kidney	5	0.0000004[c]	
Hogs, liver	0.5	0.0000004[c]	
Hogs, mbyp (exc kidney and liver)	0.2	0.0000004[c]	
Hogs, meat	0.2	0.0000004[c]	
Horses, fat	0.2	0.00045	
Horses, kidney	5	0.000023[b]	
Horses, liver	0.5	0.000023[b]	
Horses, mbyp (exc kidney and liver)	0.2	0.000023[b]	
Horses, meat	0.2	0.000023[b]	
Sheep, fat	0.2	0.00045	
Sheep, kidney	5	0.000023[b]	
Sheep, liver	0.5	0.000023[b]	
Sheep, mbyp (exc kidney and liver)	0.2	0.000023[b]	

Commodity	Picloram Residues (ppm)	HCB Residues (ppm)	% crop treated
Sheep, meat	0.2	0.000023[b]	
Goats, fat	0.2	0.00045	
Goats, kidney	5	0.000023[b]	
Goats, liver	0.5	0.000023[b]	
Goats, mbyp (exc kidney and liver)	0.2	0.000023[b]	
Goats, meat	0.2	0.000023[b]	

a Tolerances are established for residues of picloram per se.
b These residue values were rounded up to the usable six decimal limit for the analysis resulting in a very slight overestimation of the risk.
c These residue values were so small, they rounded to less than 0.000000, the decimal places allowed in the analysis which lowered the risk just slightly.

The *chronic dietary exposure/risk estimates for picloram* are extremely low. For the United States population as a whole, the Theoretical Maximum Residue Contribution (TMRC) is 0.001845 mg/kg bodyweight per day, only 0.9% of the RfD. For this same group, the Anticipated Residue Contribution (ARC) is 0.001053 mg/kg bodyweight per day, only 0.5% of the RfD. The subgroup with the greatest routine chronic exposure/risk is Non-nursing Infants (Less Than One Year Old), which has a TMRC of 0.004753 mg/kg bodyweight per day (2.4% of the RfD) and an ARC of 0.003805 mg/kg bodyweight per day (1.9% of the RfD). All of the exposure/risk for the U.S. population as a whole and each of the 22 subgroups are contributed by published tolerances.

The *HCB upper-bound carcinogenicity exposure/risk estimate*, which is performed only for the U.S. population as a whole, was an ARC of 3.94×10^{-7} mg/kg bodyweight per day and produced a calculated ARC upper-bound carcinogenicity risk estimate of 6.7×10^{-7}. As a note, the estimated chronic toxicity ARC exposures and risks for HCB, using an RfD of 8×10^{-4} mg/kg bodyweight per day and the same residue figures that were used in the carcinogenicity analysis, were very low. For all groups and subgroups, the exposure was 1×10^{-6} mg/kg bodyweight per day or less and the calculated risk was less than 0.14% of the RfD. The following commodities contributed the large majority of the HCB carcinogenicity and chronic toxicity exposure/risk estimate:

Commodity	Carcinogenic ARC Exposure*	Carcinogenic ARC Risk**
Cattle (beef)	0.000000195	0.33 (49.5%)
Milk	0.000000193	0.33 (49.0%)
Totals for both	0.000000388	0.66 (98.50%)

* In units of mg/kg bodyweight per day
* *In units of E-6 (percent of the total risk--and exposure)

The Picloram chronic dietary TMRC and ARC exposure/risk estimates are exceedingly low, about 1/200th of the RfD for each of the

groups and subgroups. There appears to be no reason for concern with regards to chronic dietary exposure to Picloram at this time.

The refined, ARC upper-bound dietary carcinogenicity risk estimate for the U.S. population as a whole for Picloram's impurity Hexachlorobenzene is 0.7 E-6; a risk below 1.0 E-6 is generally considered to be negligible. It is also likely that this upper-bound risk estimate is a substantial overestimate because the worst-case scenarios and assumptions were used for determining HCB residues. The rounding of the residue level numbers also may have contributed to overestimation of the HCB exposure/risk because more happened to require upward rounding. The estimated dietary carcinogenicity risk from HCB, when dietary exposure to HCB is considered only for its occurrence as an impurity of picloram, is within Agency acceptability guidelines. It should be noted that HCB also occurs as an impurity in several other pesticide technical products, so overall dietary exposure to HCB is likely to be appreciably higher than HCB considered simply as a picloram impurity as considered in this analysis.

b. Occupational and Residential

Picloram acid, potassium salt, triisopropanolamine and isooctyl ester

In order to adequately determine the risk associated with a chemical the toxicological end-points of concern must be identified in relation to the duration of the exposures. The toxicological endpoints of significance for occupational exposure are as follows:

1) There are no short term (one to seven day exposures) toxicological concerns indicated for occupational exposure.

2) The intermediate term exposure (1 week to several months) toxicological endpoints are indicated by the 21-day dermal rabbit studies based upon increased bilirubin (males) and BUN (blood urea nitrogen males/females). The NOELs range from 250 to 1320 mg/kg/day for the picloram compounds. For the purposes of risk assessment, the lowest LOEL of 500 mg/kg/day should be used as the toxicological end-point (rather than 250 mg/kg/day). The effects observed at the LOEL of 500 mg/kg/day from the 21-day dermal rabbit study using picloram isooctyl ester were minimal and of questionable biological significance. In addition, studies conducted over a longer period of time by the oral route do not show effects until a dose level of 500 mg/kg/day.

3) Long-term non-cancer toxicological endpoints for worker exposure are not required based on the use patterns of this chemical (< 90 days/year worker exposure).

The Margins of Exposure (MOE) for workers involved with mixing/loading and applying these chemicals for 7 to 40 days/year may be estimated by the following equation:

$$MOE = \frac{\text{NOEL (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

For regulatory purposes the toxicological endpoint of concern is 500 mg/kg/day (LOEL) based on the 21-day dermal rabbit study conducted with the picloram isooctyl ester (MRID#s 421716-01, 428707-01). The highest potential worker exposure by the dermal and inhalation routes is represented by applicators in the backpack/knapsack sprayer scenario at 4.5 mg/kg/day exposure; and the lowest by applicators in the groundboom scenario at 0.012 mg/kg/day exposure. Therefore, the range of MOEs for workers involved in mixer/loader and/or application activities is between 111 and 42,000. The risk to mixers/loaders/applicators is considered to be minimal. The MOEs for picloram are summarized in the Table VIII below:

TABLE VIII: The Margins of Exposure (MOE) for Picloram *per se*

Scenario / Mixer(M), Loader (L), Applicator (A)	Daily Dermal and Inhalation Exposure (mg/kg/day)	Margin of Exposure (MOE)
	Picloram	Picloram
Open Mixing Liquids (aerial) (I) / M,L	1.2	417
Groundboom Application (II) / A	0.012	42,000
Fixed-Wing Aerial (III) / A	0.042	12,000
Helicopter (IV) / A	-[b]	-
Paintbrush (V) / A	1.10	455
Tree Injection/Hypo-hatchet (VI) / A	-	-
High Pressure Handwand (VII) / A	0.18	2778
Right-of-Way Hand Cannon (VIII) / A	-	-
Wiper Applicator (IX) / A	-	-
Backpack/Knapsack (X) / A	4.50	111
Powered Personal Sprayer (XI) / A	-	-
Low Pressure Handwand (XII) / M,L,A	3.20	156

[a] It should be noted that the MOE was calculated using a dermal LOEL and the combined dermal and inhalation exposure which would not be considered appropriate except that the inhalation exposure is so low it represents less that 0.1% of the dermal exposure for the scenarios.

[b] No Data. Exposures for the scenarios for which there are no data are expected to be no greater than the maximum exposure scenario, backpack/knapsack.

[c] M/L, and A wear gloves

Hexachlorobenzene (HCB) and Picloram Isooctyl Ester

The Agency has classified HCB as a probable human carcinogen (Group B_2) based on an increased incidence of malignant tumors in two species, hemangioendothelioma in hamsters and hepatocellular carcinoma in rats, as well as confirmed reports of hepatoma in both of these species. A Q_1^* of 1.7 $(mg/kg/day)^{-1}$ was derived using data regarding the incidence of hepatocellular carcinoma in female rats. For these reasons, an occupational carcinogenic risk assessment associated with picloram is required since HCB could be present up to 100 ppm.

Picloram isooctyl ester (also referred to as picloram ethylhexyl ester) bears structural similarity to di(2-ethylhexyl)phthalate (DEHP) in possessing a 2-ethylhexyl moiety. DEHP and certain other substances containing the 2-ethylhexyl moiety have been found positive for carcinogenicity in rodent bioassays. 2-Ethylhexanol was detected as a metabolite in the metabolism studies summarized above. This metabolite

is also a primary hydrolytic cleavage product of DEHP, a known rodent liver carcinogen. This metabolite is thought to play a role in the ability of DEHP to act as a peroxisome proliferator and it has been suggested that peroxisome proliferation might be the underlying mechanism in DEHP carcinogenicity. Available data indicate that DEHP is most potent among the 2-ethylhexyl containing compounds tested. For the purposes of carcinogenicity risk assessment for occupational exposure with respect to picloram isooctyl ester the recommended toxicological endpoint is the Q_1^* value of 3.29×10^{-4} $(mg/kg/day)^{-1}$ obtained for DEHP in a carcinogenicity risk assessment on this compound. [D. Turnbull and J.V. Roderick (1985)] This Q_1^* is based upon a 2-year carcinogenicity bioassay of DEHP in female mice [National Toxicology Program (1982)] and although this Q_1^* was generated by Turnbull and Rodricks, the value was generated using the same model the Agency uses.

The estimated excess carcinogenic risk to agricultural workers from HCB and picloram isooctyl ester based on the use patterns (Tables V and VI) for picloram are calculated as follows:

Excess Carcinogenic Risk = Q_1^* x LADD

where LADD represents the lifetime (35 work years/ 70 average Lifetime years) *times* the Average number of work days over a year (40 work days/365 days) *times* the Daily Dose for each exposure scenario (mg/kg/day) from Table V for HCB and Table VIII for picloram isooctyl ester. The daily dose includes the dermal and inhalation exposures combined. A dermal absorption factor of 100% was assumed for both chemicals since an adequate dermal absorption study is not available.

All exposure scenarios are appropriate for risk assessment for HCB. The highest potential worker exposure by the dermal and inhalation routes is represented by applicators in the backpack/knapsack sprayer scenario at 4.50×10^{-4} mg/kg/day exposure; and the lowest by applicators in the groundboom scenario at 1.16×10^{-6} mg/kg/day exposure. The excess carcinogenic risk estimates for workers from exposure to HCB are between 4.19×10^{-5} and 1.07×10^{-7}.

Picloram isooctyl ester is generally applied by spot treatment and the exposure and risk are expected to be no greater than that determined for the backpack sprayer. Since backpack sprayers represent the highest exposure scenario, it is also representative of the worst-case scenario. The potential worker exposure for this scenario by the dermal and

inhalation routes is 4.50 mg/kg/day exposure. The excess carcinogenic risk estimate for workers from exposure to picloram isooctyl ester is 8.6 x 10^{-5}. The groundboom scenario is not represented since picloram isooctyl is currently not applied by this method.

These risk assessments are considered worst-case since (1) a 100% dermal absorption factor was used (although the dermal absorption is expected to be < 23% for HCB in picloram and < 10% for picloram isooctyl ester), (2) a Q_1^* from DEHP was used for the picloram isooctyl ester which assumes the peroxisome proliferator mechanism of carcinogenicity to be valid, and (3) the picloram isooctyl toxicity endpoint was used as most representative, but it also happens to be more toxic by comparison to the other forms of picloram. There is a degree of uncertainty associated with this risk assessment which is highly dependent on the quality and quantity of the exposure values summarized in Table VI and the choice of the toxicity endpoint. Additional exposure data for the most highly exposed scenario would reduce the uncertainty.

This is a restricted use chemical that has no residential uses at this time; therefore, there are no human risks associated with residential uses.

Entry into a treated area soon after the application of picloram is expected to be rare given the cultural practices typically associated with the use-sites (rights-of-way, forestry, pastures, rangelands, and small grains) defined by the picloram labels at this time. Furthermore, if entry should occur, the potential exposures are expected to be minimal due to the characteristics of those use-sites. However, due to the toxicity concerns associated with picloram, EPA has determined that entry should not be permitted immediately following application. Therefore, the Agency is establishing restrictions on entry to treated areas.

WPS Entry Restriction: For occupational end-use products containing picloram as an active ingredient, the Agency is requiring a 12-hour restricted-entry interval for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) (except when it is applied by direct injection into the treated plants).

NonWPS Entry Restriction: For occupational end-use products containing picloram as an active ingredient, the Agency is requiring a prohibition on entry until sprays have dried for each use of the product

that is outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

C. Environmental Assessment

1. Environmental Fate

The principal environmental risks of picloram relate to contamination of surface and groundwater, and damage to nontarget terrestrial plants including crops, in areas adjacent to areas of application, via runoff or drift, and possibly from more distant areas where groundwater is used for irrigation or discharged into surface water. Nontarget plants, in areas adjacent to areas of application, may be exposed to chemical concentrations many times the levels that have been associated with toxic effects. Some incidents of purported damage to crops have in fact been reported. Additional concerns are identified relating to endangered terrestrial mammals and endangered aquatic animals.

Picloram (in all of the forms considered) is among the most mobile of currently registered pesticides, and in some soils it is nearly recalcitrant to all degradation processes. As of 1992, detections of picloram in ground water have been reported to the Agency for 10 states.

Limitations of the quantitative ecological risk assessment include: a. Risk assessments are based on a single assumed application, because labels for the most part do not specify maximum annual rates. b. Risks are not assessed quantitatively for nontarget organisms exposed via irrigation with contaminated surface or ground water at sites distant from areas of application. Effects at distant locations are plausible in view of the high persistence, mobility, and phytotoxicity of these chemicals.

These chemicals are expected to be similar in their biological and chemical characteristics in the environment. As a consequence of this similarity, the different active ingredients are not usually distinguished in the ecological chemistry and fate review (Section 1), which refers to "picloram" or "the chemical" generically. The ecological effects review (Section 2) distinguishes among active ingredients on the basis of use profiles of registered products containing a given active ingredient. In particular, picloram acid is not used as an end product, and so the ecological risk assessment is limited to the salts (TIPA and potassium) and IOE.

a. Environmental Chemistry, Fate and Transport

The four active ingredients are expected to have very similar fate and transport characteristics in the environment. For the three excluding

IOE, the part of the molecule that is principally responsible for biological activity is the anion, which is chemically identical for all three active ingredients. For all three, the molecule will dissociate in the environment to yield the free anion, and the dissociation process is governed by a rate constant (pKa) that is practically the same in value for all three: literature submitted by the registrant indicates measured pKa approximately 2 for the acid and salts (Osteryoung and Wittaker, 1980; Reim, 1989; Woodburn et al. 1989; Skurlatov et al., 1983). IOE is expected to degrade rapidly (measured aerobic half-life 2 days), to forms with the same anion as the acid and the salts. Consequently, IOE is expected to have environmental fate characteristics very similar to those of the other active ingredients.

The acid and salts are highly soluble in water (> 100 ppm). The Picloram acid water solubility is 560 ppm, while that of the Potassium salt is 740,000 ppm at 20^0 C. From these values, it follows that at typical soil pH (5-9) the anionic form comprises greater than 99% of the dissolved chemical, regardless of the original molecular species. Therefore, regardless of the original molecular form, the physical/chemical properties of the anion may be used to predict the environmental fate of the applied molecule or formulation. IOE water solubility is considerably lower at 0.23 ppm at 20^0 C. However, again, IOE degrades quickly to the highly soluble anion.

Based on the high solubility of picloram in water, and on resistance to biotic and abiotic degradation processes, as well as the proven mobility of the chemical under both laboratory and field conditions, it appears that the major route of dissipation for the chemical is leaching. Based on low vapor pressure of picloram, volatilization from soils will not be an important dissipation mechanism.

Picloram acid has a significant number of physical/chemical characteristics in common with various pesticides known to leach to ground water. Picloram acid has a water solubility of 560 ppm, and is anionic at the environmentally significant pH ranges. Picloram is stable to hydrolysis in acidic, neutral and basic media. Data on aerobic soil metabolism show that picloram acid degrades with half-lives ranging from 167 to 513 days in seven soils, with carbon dioxide the major degradate. (Two minor degradates are 4-amino-3,5-dichloro-2-pyridinol and 4-amino-2,3,5-trichloro pyridine.) Data on anaerobic soil and anaerobic aquatic metabolism indicate that picloram acid is stable to anaerobic degradation, with over 90% of the chemical not degraded after 300 days of incubation. Soil photolysis data indicate that picloram acid is stable when irradiated on soil. Batch equilibrium studies of soils

with varying cation exchange capacity indicate that the chemical will be very mobile (Freundlich $Kd_{(ads)}$ values < 1), for soils with organic matter (OM) content as high as 4.2%.

No acceptable ground water monitoring studies have been submitted to the Agency; however, available soil residue studies clearly indicate that picloram has very high potential to leach into ground water in most soils and the chemical has been detected in 10 states to date (USEPA 1992; 734/12-92-001) . For picloram that reaches surface waters through runoff there would be some degradation, as indicated by the aqueous photolysis study which showed a first-order half-life of 2.6 days for the acid, at 25°C.

Forestry and terrestrial field data available to the Agency indicate that picloram is extremely mobile under field conditions. In a forestry dissipation study conducted in South Carolina, picloram applied at the maximum application rate of 2.0 lb ai/A (see Use Profile Section) was detectable 840 days after application, in the deepest samples (1.8 m). In a study conducted in North Carolina, picloram applied at 2 lbs ai/A to a bare soil plot and short grass plot (both with 4.01% OM) was detected in all sampling intervals beyond 8 weeks, in the deepest soil samples (75 to 90 cm). In a field dissipation study conducted in Montana (MRID #42535302, 42558302), picloram applied at half the maximum label rate (i.e. at 1 lb ai/A) was detectable 790 days after application in the 48 to 60 inch soil layer (maximum sampling depth 72 inches; soil with 2.2% OM). In a forestry dissipation study conducted near Ostrander Washington, picloram applied at half the maximum label rate to exposed soil was detectable nine months after treatment in the deepest samples (36 inches). (Soil with 3.7% OM.)

Data recently submitted to the Agency by T.L. Lavy and colleagues (University of Arkansas) indicate that picloram leached but did not degrade over a three-year period in a Crevasse loamy fine sand treated at depths of 0 to 1.5 meters (data resulted from cooperative special project CR-815154-03-0). In fact, nearly 100% of the applied chemical leached from the treated soil over the first three years of the study, but none of the picloram degraded. In a Captina silt loam, picloram was mostly degraded within six months to one year, depending on soil depth. Given the high persistence of picloram in coarse-textured soils, it appears unlikely that picloram will degrade once it reaches ground water, even over a period of several years.

Supplemental laboratory studies by Watson et al. (1989) found that picloram was more persistent and mobile in a coarse-textured soil

(sandy loam with 61% sand and about 1.4% organic matter) than in a finer textured soil (loam with 33% sand and about 3% organic matter).

Given the low octanol-water partition coefficient, significant bioaccumulation in aquatic organisms is not anticipated.

b. Environmental Fate Assessment

The MCL for picloram has been established at 500 ppb. Picloram has been classified as a Group E chemical. Picloram generally does not pose a threat to human health at the levels that have been detected in ground water to this date.

As described in greater detail in Section 2, concerns are related principally to effects on nontarget plants. Exposure to nontarget plants may occur via the following transport mechanisms.

- Exposure of terrestrial plants in areas adjacent to areas of application, by drift and/or runoff from areas of application.

- Exposure of crops by irrigation with contaminated surface or ground water.

- Exposure of aquatic plants, via runoff or drift from application areas, and via discharge of contaminated ground water into surface water.

Ground Water. Data currently available to EPA indicate that picloram has been detected in ground water in 10 states at concentrations ranging up to 30 ppb. The following concerns have been identified:

- **high mobility and persistence**. Environmental fate data indicate that picloram is mobile and persistent in laboratory and field studies. Picloram (in all of the forms considered) is among the most mobile of the currently registered pesticides. In some soils it is nearly recalcitrant to all degradation processes.

- **ground water quality**. The *Pesticides in Ground Water Database* (USEPA 1992; 734/12-92-001) indicates that as of 1992, detections of picloram in ground water have been reported in Iowa, Kansas, Maine, Minnesota, Montana, North Dakota, South Dakota, Texas, Virginia, and Wyoming. Concentrations in ground water range up to 30 ppb. Picloram has been detected

in a variety of environments in these states, although below the toxicity threshold for human health.

Considering the widespread use of picloram and the detections in many states, the Agency is concerned about degradation of water quality in picloram use areas. Despite a specialized use pattern, eventual contamination of ground water is virtually certain in areas where residues persist in the overlying soil. Once in ground water, the chemical is unlikely to degrade even over a period of several years.

Surface Water. Picloram has high potential to contaminate surface water by runoff from use areas. Regardless of the original chemical form, substantial quantities of the anion will be available for runoff for several months following application, considering its persistence in the environment. As indicated leaching will be the major route of dissipation from soil. Picloram that leaches into ground water may contaminate surface water in places where ground water discharges into surface water.

Except in clear shallow water with substantial mixing, or waters with short hydraulic residence times, picloram is expected to be persistent in surface water. Picloram is susceptible to direct photolysis in water, but not to abiotic hydrolysis or volatilization. Biological degradation will be slow under aerobic or anaerobic conditions.

Based on the K_d values observed, picloram in runoff and in surface water will be mostly dissolved in the water rather than absorbed to the surface of suspended particles.

The STORET database maintained by the USEPA Office of Drinking Water indicates that picloram in an unspecified form has been reported for 420 of 744 surface water samples, collected at 135 sampling locations, before 1988. Of these detections 85% were at concentrations 0.13 ug/L or lower and the maximum was 4.6 ug/L. The maximum concentration reported was 4.6 µg/l.

At present, the Agency does not have data from monitoring of picloram in surface water. However, picloram is regulated under the Safe Drinking Water Act (SDWA), so water supply systems are now required to sample for it. An MCL of 500 µg/l and a 1-10 day health advisory of 20,000 µg/l have been established.

These values are not likely to be exceeded by annual or short term average concentrations; however considering the application rates, mobility, and persistence of picloram, occasional exceedances cannot be ruled out. Therefore the Agency will carefully review picloram data collected under SDWA and in the U.S. Geological Survey NAWQA Program when it becomes available.

2. Ecological Effects

a. Ecological Effects Data

The following acute and chronic studies have been reviewed and can be used in risk assessment for birds for the four active derivatives of Picloram.

(1) Non-target Terrestrial Animals

(a) Birds

Picloram Acid P.C. Code: 005101

GLN#	TEST TYPE	MRID#	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-1(a)	Mallard, Acute Oral LD_{50}	Accession #'s 261883 265983 40054501 MRID # 157173	7/1/87	core	93.8	1983	LD_{50} > 2150 mg/kg

This avian study conducted with technical grade acid indicates that it is practically nontoxic to birds on an acute oral basis (LD_{50} > 2150 mg/kg). This was the only avian study conducted with the acid.

Picloram TIPA Salt P.C. Code: 005102

GLN#	TEST TYPE	MRID#	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-2(a)	Quail, Dietary LC_{50}	not listed	10/14/82	supplemental (not completed with TGAI)	10.2	1975	LC_{50} > 10,000 ppm
71-2(b)	Mallard, Dietary LC_{50}	not listed	10/14/82	supplemental (not completed with TGAI)	10.2	1975	LC_{50} > 10,000 ppm
71-4(a) (Not required)	Ring-neck pheasant,Avian Reproduction	not listed	10/14/82	supplemental (not completed with TGAI or correct test species)	10.2	1974	NOEC = 2.8 kg/ha
71-4(a) (Not required)	Chicken, Avian Reproduction	not listed	10/14/82	supplemental (not completed with TGAI or correct test species)	10.2	1974	NOEC = 2.8 kg/ha

The avian dietary studies conducted with a product with 10.2 % of technical grade active ingredient indicate that the test material is practically nontoxic to birds on an acute dietary basis (LC_{50} > 5620). Additionally, two reproduction studies put NOECs at 2.8 kg/ha.

Picloram IOE P.C. Code: 005103

GLN#	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-2(a)	Quail, Dietary LC_{50}	Accession #'s 265982	6/29/87	core	100	1986	LC_{50} > 5620 ppm
71-2(a)	Quail, Dietary LC_{50}	164726	5/5/88	core	Tech. (% not given)	1986	LC_{50} > 5620 ppm

The avian dietary studies conducted with technical grade active ingredient indicate that IOE is practically nontoxic to birds on an acute dietary basis (LC_{50} > 5620).

Picloram Potassium Salt P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-1(a)	Mallard, Acute Oral LD_{50}	164726	5/20/88	core	tech. (% not given)	1985	LD_{50} > 2250 mg/kg
71-1(a)	Quail, Acute Oral LD_{50}	164727	5/20/88	core	tech. (% not given)	1985	LD_{50} > 2250 mg/kg
71-2(a)	Quail, Dietary LC_{50}	REOPIC 08	10/14/82	supplemental because study was not conducted with TGAI	11.6	1975	LC_{50} > 10,000 ppm
71-2(a)	Mallard, Dietary LC_{50}	REOPIC 07	10/14/82	supplemental because study was not conducted with TGAI	11.6	1975	LC_{50} > 10,000 ppm
71-2(a)	Mallard, Dietary LC_{50}	129070	10/14/82	supplemental because study was not conducted with TGAI	24.4	1975	LC_{50} > 10,000 ppm

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-2(a)	Quail, Dietary LC_{50}	129068	10/14/82	supplemental because study was not conducted with TGAI	24.4	1975	LC_{50} > 10,000 ppm
71-2(a)	Quail, Dietary LC_{50}	Accession #'s 261883 265983 40054501	7/1/87	core	38.6	1982	LC_{50} > 5620 ppm
71-4(a) (not required)	Chicken, Avian Reproduction	not given	10/14/82	supplemental was not conducted with TGAI and required species was not used	24.4	1978	NOEL = 11.2 kg/ha

The two avian acute oral studies conducted with technical grade active ingredient imply that Picloram Potassium Salt is practically nontoxic on an acute oral basis (LD_{50} > 2250 mg/kg). Testing on products containing 11.6, 24.4, and 38.6% of technical grade active ingredient indicate that this salt is practically nontoxic on an acute dietary basis (LC_{50} > 5620). A poultry study revealed a NOEC of 11.2 kg/ha for reproductive effects.

(b) Mammals

Essential results, by active ingredient are:

- Picloram acid, the parent compound, is practically nontoxic to mammals based on an acute oral rat LD_{50} > 5000 mg/kg for males and a LD_{50} = 4012 mg/kg for females. Acute inhalation LC_{50} > 0.035 mg/l for both sexes.

- The TIPA salt tested with 33.9% a.i. is practically nontoxic to mammals based on an acute oral rate LD_{50} > 5000 mg/kg for males and females. The LC_{50} for an acute inhalation is > 0.07 mg/l.

- IOE is practically nontoxic to mammals based on an acute oral rate LD_{50} = 2830 mg/kg for males and LD_{50} = 3250 mg/kg for females.

- The Picloram Potassium Salt TIPA salt tested with 38.8% a.i. is practically nontoxic to mammals based on an acute oral rate LD_{50} > 5000 mg/kg for males and a LD_{50} = 3536 mg/kg for females. The LC_{50} for an acute inhalation is > 1.63 mg/l.

(2) Non-target Aquatic Animals

(a) Freshwater Animals

The following table summarizes the acute and chronic data which can be used in risk assessment for freshwater organisms for the four active ingredients of Picloram.

Picloram Acid P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(a)	Bluegill, Acute LC_{50}	00129078	10/15/82	core	92.74	1978	LC_{50} = 19.4 mg/l
72-1(a)	Bluegill, Acute LC_{50}	112016	10/14/82	core	92.9	1974	LC_{50} = 14.5 mg/l
72-1(c)	Rainbow, Acute LC_{50}	112016	10/14/82	core	92.9	1974	LC_{50} = 5.50 mg/l
72-2(a)	Daphnia, Acute LC_{50}	0096-008	12/21/88	core	90	1977	LC_{50} = 34.4 mg/l
72-6	Aquatic Org. Accum. (Bluegill)	1218947 (acces. no.)	7/29/82	core, but was classified as supplemental because it was never required for registration	99.6	1980	< 1 (Won't accum.in aquatic organisms)
72-6	Aquatic Org. Accum. (Channel Catfish)	none listed	10/14/82	core, but was classified as supplemental because it was never required for registration	99.6	1980	< 1 (Won't accum.in aquatic organisms)
N.A.	Field runoff conditions for cutthroat trout	129085	12/6/82	Supplemental because it was never required for registration	90	1979	Study concludes that conc. as low as 610 µg/l will affect survival & growth.
N.A.	Field runoff conditions for cutthroat trout	REOPICO2	10/14/82	supplemental because it was never required for registration	90	1979	Study concludes that conc. as low as 290 µg/l will affect survival & growth.

The above table characterizes the Picloram acid as moderately toxic to freshwater fish with a LC_{50} of 5.5 mg/l (ppm) and slightly toxic to freshwater invertebrates (LC_{50} of 34.4 mg/l). Field runoff studies conducted with cutthroat trout conclude that concentrations as low as 290

µg/l and 610 µg/l will affect survival & growth of cutthroat trout. However, since these studies were only conducted on the acid and not one of the salts or ester which are the actual end-use products, these data were not used in the risk assessment.

There are no records indicating that tests for freshwater invertebrates (Daphnia magna) have been conducted. The acid is not used as an end product, so this test is not required.

Picloram TIPA Salt P.C. Code: 005102

GLN#	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(c)	Rainbow, Acute LC_{50}	not listed	10/14/82	supplemental	98-99	1968	LC_{50} = 375 mg/l
72-1(d)	Rainbow, Acute LC_{50} - TEP	not listed	10/29/82	supplemental	8.1	1968	LC_{50} = 25 mg/l
72-1(d)	Rainbow, Acute LC_{50} - TEP	not listed	10/29/82	supplemental	2.5	1968	LC_{50} = 1250 mg/l
No guideline requirement	Coho salmon, Acute LC_{50}	not listed	10/29/82	supplemental	10.2	1979	LC_{50} = 20 mg/l

The above table characterizes this Picloram salt as slightly toxic to freshwater fish with a LC_{50} of 25 mg/l (ppm). However, a test with coho salmon yielded a LC_{50} of 20 ppm.

Picloram IOE P.C. Code: 005103

There are no data for freshwater organisms for IOE. An acute LC_{50}s for a coldwater fish (rainbow trout), a warmwater fish (Bluegill), and a freshwater invertebrate (Daphnia magna) are required.

Picloram Potassium Salt P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(a)	Bluegill, Acute LC_{50}	GS0096-007	10/29/82	supplemental due to lack of raw data	91	1966	LC_{50} = 24 mg/l
72-1(c)	Rainbow, Acute LC_{50}	GS0096-007	10/29/82	supplemental due to lack of raw data	91	1966	LC_{50} = 13 mg/l
72-1(d)	Rainbow, Acute LC_{50}	Not given	10/14/82	core for formulated product only	24.4	1977	LC_{50} = 26 mg/l
72-2(a)	Daphnia, Acute LC_{50}	151783	5/20/85	core	93.8	1984	LC_{50} = 68.3 mg/l
72-2(b)	Daphnia, Acute LC_{50} (TEP)	Not given	10/14/82	supplemental (not conducted with TGAI)	88.6	1977	LC_{50} = 226 mg/l
72-4(a)	Rainbow Trout, Early life Stage	151784	2/12/85	core	93.8	1984	LOEC = 0.88 mg/l NOEC = 0.55 mg/l MATC = 0.70 mg/l
72-4(b)	Life-Cycle Aquatic Invertebrate	151783	5/20/85	core	93.8	1984	MATC = 14.6 mg/l NOEC = 11.8 mg/l LOEC = 18.1 mg/l

The above table characterizes this Picloram Potassium salt as moderately toxic to freshwater fish with a LC_{50} of 13 mg/l (ppm) and slightly toxic to freshwater invertebrates (LC_{50} of 68.3 mg/l). The fish early life stage and the Life-Cycle Aquatic Invertebrate Studies gave LOECs of 0.88 mg/l and 18.1 mg/l respectively as indicated.

(b) Marine and Estuarine Organisms

As the use of products containing picloram may be expected to enter a marine/estuarine environment a limited amount of data which can be used in risk assessment for marine/estuarine organisms is required. The data presently reviewed for the marine/estuarine studies are presented below.

Picloram Acid P.C. Code: 005101

There are no marine/estuarine data for the parent compound Picloram acid. As no products containing the acid are used for anything other than manufacturing use products, no data requirements are required at this time.

Picloram TIPA Salt P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-3(e)	Oyster, Shell deposition EC_{50}	not listed	10/14/82	supplemental (not tested with TGAI)	10.3	1975	$10 < EC_{50} < 18$ ppm
72-3(f)	Shrimp, Acute EC_{50}	not listed	10/14/82	supplemental (not tested with TGAI)	10.3	1975	$EC_{50} = 306$ ppm

The above table characterizes this Picloram salt as slightly toxic to marine/estuarine mollusc with an EC_{50} between 10 and 18 mg/l (ppm) and practically nontoxic to marine crustaceans (EC_{50} = 306 ppm). As this salt is lacking data on marine/estuarine fish, an acute marine/estuarine fish study is required.

Picloram IOE P.C. Code: 005103

There is no data for marine/estuarine or freshwater organisms for IOE. As the use of products containing picloram may be expected to enter a marine/estuarine environment a limited amount of data which can be used in risk assessment for marine/estuarine organisms is required. An acute LC/EC_{50} study for marine/ fish, mollusc, shrimp is required.

Picloram Potassium Salt P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-3(e)	Oyster, 48-h Embryo Larvae EC_{50}	111560	10/14/82	core for formulated product only	11.6	1975	EC_{50} > 1000 ppm
72-3(e)	Oyster, 48-h Embryo Larvae EC_{50}	129073	10/14/82	core for formulated product only	24.9	1975	18 ppm < EC_{50} < 32 ppm

The above table also characterizes this Picloram salt as slightly toxic to marine/estuarine mollusks and invertebrates with an EC_{50} between 18 and 32 mg/l (ppm). As with the TIPA salt this salt is lacking data on marine/estuarine fish; an acute marine fish study will be required.

(3) Non-Target Insects Data

Available data for honeybees suggest that picloram is practically nontoxic on an acute basis. In each study available there was no significant mortality at the highest dose level evaluated. In the table that follows, the toxicity (LD_{50} or LC_{50}) is reported as larger than the highest dose evaluated, for example "LD_{50} > 25 µg/bee" indicates that doses up to 25 µg/bee were evaluated, with no significant mortality observed at that level. The table indicates the highest dose evaluated in each study.

Picloram Acid P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
141-1	Honey Bee LC_{50} Study	None	10/29/82	supplemental; test conducted with a mixture	8.7 as mixture	1965	LC_{50} > 1000 ppm
No required guideline	Honeybee LC_{50}	Not given	12/14/82	supplemental (not required guideline requirement)	Aqueous emulsion (% not given	1965	LC_{50} > 4,000 ppm
No required guideline	Honeybee LC_{50}	129066	10/29/82	supplemental (not required guideline requirement)	Aqueous emulsion (% not given)	1965	LC_{50} > 500 ppm

Picloram TIPA Salt P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
141-1	Honey Bee Acute Contact Study	413669-01	4/90/92	core	5.68	1989	LD_{50} > 100 µg/bee
No required quideline	Honeybee LC_{50}	No given	10/29/82	supplemental	8.7	1965	LC_{50} > 1000 ppm

Picloram IOE P.C. Code: 005103

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	YEAR	RESULT
141-1	Honey Bee Acute Contact Study	421211-07	1/4/93	core	89.7	1991	LD_{50} > 25 µg/bee
141-1	Honey Bee Acute Contact Study	426259-01	6/3/93	core	4.7 as mixture	1992	LD_{50} > 25 µg/bee

Picloram Potassium Salt P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	YEAR	RESULT
141-1	Honey Bee Acute Contact Study	413669-02	4/92	core	35.2	1989	LD_{50} > 100 µg/bee
No required guideline	Honeybee LC_{50}	Not given	12/14/82	supplemental because test not conducted with TGAI	23.6	1965	LC_{50} > 5,000 ppm
No required guideline	Honeybee LC_{50}	Not given	10/29/82	supplemental because test not conducted with TGAI	8.7	1965	LC_{50} > 500 ppm

(4) Non-Target Plants Data (Terrestrial, Aquatic)

Generally, nontarget plant data are required only for herbicides and fungicides, but may be required for any pesticide if phytotoxicity concerns cannot be resolved from the open literature or existing Agency data bases. Testing can be accomplished at the Tier 1 and/or Tier 2 level. Before the implementation of the current policy paper ("the White Paper"or "New Paradigm") resulting from the Ecological Fate and Effects Task Force, the Agency requested Tier 3 field studies when the Estimated Environmental Concentration (EEC) exceeded the EC_{25} for terrestrial plants or the EC_{50} for aquatic plants. After reevaluating the appropriateness of Tier 3 field studies, the Agency no longer routinely requires these studies. The Tier 1 level tests are carried out at the maximum label rate, and if more than 50% adverse effects are noted for aquatic plants and 25% adverse effects for terrestrial plants, Tier 2 testing will be required. Tier 2 tests use multiple dosages to determine an EC_{50} or EC_{25} and a NOEC for the plant species tested in Tier 1. Nontarget phytotoxicity data are required automatically at the Tier 2 level for all herbicides applied aerially, via mist blowers, and with most irrigation equipment. In many cases Tier 1 tests are bi-passed and the registrant begins with Tier 2 tests. The current data base is presented in the tables below.

Picloram Acid P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-1(b)	Vegetative Vigor Tier 1	261128 (accession no.)	4/29/86	supplemental (needs to be repeated or go to Tier 2)	not given	1985	No valid results
122-2	Aquatic plant Tier 1	261128 (accession no)	4/29/86	core for Selenastrum. capricornutum	93.4	1986	EC_{50} = 36.9mg/l
122-2	Aquatic plant - freshwater & saltwater species (Euglena gracilis & Pedisastrum sp.)	none listed	10/29/82	supplemental	91	1970	NOEC < 24 mg/l

Picloram TIPA Salt P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-2	Aquatic plant - freshwater & saltwater species (Euglena gracilis & Pedisastrum sp.)	none listed	10/29/82	supplemental	91	1970	NOEC < 24 mg/l
123-1(a)	Seed Germination /Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean and EC_{25} missing for barley)	6.094	1989	Seed Germ. Soybean EC_{25} = 2.3 & NOEC < 0.25 g ae/ha Barley EC_{25} > 70 & NOEC = 35 g ae/ha Seed Emerg. Soybean EC_{25} = 0.027 & NOEC < 0.031 g ae/ha Wheat EC_{25} = 38.8 & NOEC = 17.5 g ae/ha
123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean & tomato)	6.094	1989	Tomato EC_{25} = 0.22 & NOEC < 0.125 g ae/ha Wheat EC_{25} = 227.7 & NOEC = 70 g ae/ha
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	414077-01	5/26/93	core for S. capricornutum only	5.7	1990	EC_{50} = 234 mg/l NOEC = 18.5 mg/l

Picloram IOE P.C. Code: 005103

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
123-1(a)	Seed Germination/ Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (NOEC lacking for drybean)	11.7	1989	Seed Germ. Drybean EC_{25} = 1.5 & NOEC < 0.25 g ae/ha Barley EC_{25} = 3.6 & NOEC = 1.1 Seed Emerg. Drybean EC_{25} = 0.004 & NOEC < 0.031 g ae/ha Wheat EC_{25} = 28.4 & NOEC = 8.8 g ae/ha
123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean)	11.7	1989	Soybean EC_{25} = 0.24 & NOEC < 0.125 g ae/ha Wheat EC_{25} = 235.3 & NOEC = 70 g ae/ha
123-2	Growth and Reproduction of Aquatic Plants - Tier 2	426459-01	6/15/93	core for S. capricornutum only	4.7 as mixture	1993	EC_{50} = 4.9 mg/l NOEC = 3.2 mg/l LOEC = 5.5 mg/l

Picloram Potassium Salt P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-1(b)	Vegetative Vigor Tier 1	261128 (accession no.) (Hemphill, D.D.)	4/29/86	supplemental (needs raw data or go to Tier 2)	not given for Tordon 22K	1986	Info. in summary form. Need raw data.
123-2	Growth and Reproduction of Aquatic Plants - Tier 2	414077-02	5/26/93	core for S. capricornutum only	35.2	1990	EC_{25} = 52.6 mg/l NOEC = 13.1 mg/l
123-1(a)	Seed Germination/ Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (lacks NOECs for soybean & drybean and lacks EC_{25} for barley)	0.2885	1989	Seed Germ. Soybean EC_{25} = 3.5 & NOEC = 0.25 g ae/ha Barley EC_{25} > 70 & NOEC = 4.4 g ae/ha Seed Emerg. Soybean EC_{25} = 0.014 & NOEC < 0.031 g ae/ha Wheat EC_{25} = 23.5 & NOEC = 8.8 g ae/ha
123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	core for veg. vigor test of potassium alt only	0.2885	1989	Soybean EC_{25} = 0.4 & NOEC = 0.125 g ae/ha Wheat EC_{25} = 310 & NOEC = 70 g ae/ha

Note: Only studies on which the Agency can make a judgement are included in the table above.

(5) Adequacy of Toxicity Data

Based on Picloram's extreme phytotoxicity, its persistence under typical environmental conditions, and its extreme propensity to leach into ground water in all soil types the following additional data are needed as confirmatory data to support this risk assessment.

Picloram TIPA Salt P.C. Code: 005102

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing EC_{25}s and NOECs for most sensitive plants
123-1(b)	Vegetative Vigor - Tier 2	Need missing EC_{25}s and NOECs for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-1(b)	Vegetative Vigor - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, Rights of Way's (ROWs), aerial treatments, etc. all aquatic plant species must to tested. These include Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, & a freshwater diatom.
72-3(d)	Toxicity to Marine/Estuarine Fish LC_{50} (TEP)	This study is a minimum core requirement for all active ingredients.
72-4(a)	Early Life Stage - Fish	This pesticide is highly persistent and likely to be present in water on a recurrent basis.

Picloram IOE P.C. Code: 005103

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing NOEC for most sensitive plants
123-1(b)	Vegetative Vigor - Tier 2	Need missing NOEC for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-1(b)	Vegetative Vigor - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, Right of Ways (ROWs), aerial treatments, etc. all aquatic plant species must to tested. These include Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, & a freshwater diatom.
72-1(b)	Bluegill, Acute LC_{50} (TEP)	This study is a minimum core requirement for all active ingredients
72-1(d)	Rainbow, Acute LC_{50} (TEP)	This study is a minimum core requirement for all active ingredients
72-2(b)	Toxicity to Freshwater Invertebrates (Daphnia magna) (TEP)	This study is a minimum core requirement for all active ingredients

Guideline #	Study	Reason Requesting
72-3(d)	Toxicity to Marine/Estuarine Fish LC_{50} (TEP)	This study is a minimum core requirement for all active ingredients
72-3(e)	Toxicity to Marine/Estuarine Mollusc EC_{50} (TEP)	This study is a minimum core requirement for all active ingredients
72-3(f)	Toxicity to Marine/Estuarine Shrimp EC_{50} (TEP)	This study is a minimum core requirement for all active ingredients
72-4(a)	Early Life Stage - Fish	This pesticide is highly persistent and likely to be present in water on a recurrent basis.

Picloram Potassium Salt P.C. Code: 005104

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing EC_{25}s and NOEC for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-1(b)	Vegetative Vigor - Tier 2	Need EC_{25}s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, Right of Ways (ROWs), aerial treatments, etc. all aquatic plant species must to tested. These include Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, & a freshwater diatom.
72-3(d)	Toxicity to Marine/Estuarine Fish LC_{50} (TEP)	This study is a minimum core requirement for all active ingredients

b. Ecological Effects Risk Assessment

The Agency's principal index of ecological risk is a risk quotient or RQ, calculated by dividing a value of exposure by a value of toxicity. The assessment in this document was developed just before a recent standardization of terminology and does not use the new standard definitions. *These differences relate to presentation and do not concern actual findings*. The differences between usage in this document and the new standard definitions are clarified below.

Usage in this document

- LOC = Estimated environmental concentration (EEC) value that results in a concern
  = k × [toxicity index, e.g., LC50 or MATC].
- k depends on endpoint.
- RQ = EEC / LOC
  = EEC / (k × toxicity index).
- RQ is how many times the EEC exceeds the LOC, so there is a concern when RQ exceeds 1.

Example. For endangered small mammal exposed to TIPA salt,

- EEC = 528 ppm, LC50 = 4545 ppm. There is a concern if the EEC exceeds a tenth of the LC50 (k = 1/10). It does:
  LOC = 0.1 × 4545 = 454.5.
- RQ = 528/454.5 = 1.16.
- RQ > 1 so there is a concern.

New standard definition

- RQ = EEC/[toxicity index] by definition.
- LOC is the RQ value that results in a concern, and depends on endpoint.
- LOC in new standard terminology equals k for this document.

Example (same endpoint).

- LOC = 0.1 for endangered small mammal.
- RQ = 528/4545 = 0.116.
- RQ > LOC so there is a concern.

Details of the computation of levels of concern are presented in the sequel in sections devoted to specific categories of nontarget organisms. The toxicity measure is most often an ECp or some variant (effective concentration for p% response, e.g. EC50 for 50% response). Depending on the type of biological response measured, an ECp may be the concentration corresponding to a p% change in mean response (e.g. p% reduction in mean weight), or the concentration corresponding to p% of organisms responding (usually p% mortality). In some cases, the toxicity measurement is a low-effect level (LEL), i.e. the lowest dose that resulted in a recognizable effect in a laboratory experiment. Standard exposure scenarios for ecological risk involve transport by runoff or drift of chemical applied to a target plot, to adjacent land or water. Specific details of exposure scenarios are presented in (2) below.

The following important limitations of the standard exposure scenarios are noted here. a. For picloram active ingredients, risk calculations are based on a single assumed application, because, as indicated in the Use Profile Section, labels for the most part do not specify maximum annual rates. b. The standard exposure scenarios do not address the potential of picloram to contact nontarget plants as a result of irrigation with contaminated surface or ground water. Further consideration of these issues would be necessary in order to do a more complete risk assessment for the chemical.

The principal findings and data gaps of the Agency's quantitative risk assessment are summarized as follows, by category of nontarget organism.

Terrestrial Plants. Risks to nontarget terrestrial plants are very significant (endangered species and otherwise) for all active ingredients and all application methods considered. The following table of risk quotients represents the most significant results of the Agency's quantitative risk assessment. For these quotient values, the toxicity measure is the LC25 for soybean seedling emergence, which is the concentration that causes a quarter of seedlings to fail to emerge. The EEC values used in these computations represents exposure to nontarget plants in areas adjacent to the areas of application, with standard assumptions regarding drift or runoff (Section below on Calculation of EECs).

Number of Times the Level of Concern (LOC) is Exceeded by the Estimated Environmental Concentration (EEC)[a] (Based on Terrestrial Plants)

Active Ingredient	Application Method		
	Unincorporated Ground	Aerial/ Soil	Aerial/ Foliar
TIPA Salt	4600 ×	7500 ×	550 ×
IOE[b]	5700 ×	-	-
Potassium Salt	8100 ×	13000 ×	280 ×

[a] For example (row 1 column 2) the EEC for TIPA salt administered to the ground without incorporation is 4600 times a concentration level of concern.

[b] With current registered products, IOE is applied only using backpack sprayers.

For example, a quotient of 4600 is obtained for TIPA administered by ground application without incorporation. This means that estimated

concentrations in the environment are 4600 times a magnitude that, in the laboratory context, causes 25% of soybean seedlings to fail to emerge. (The "×" symbol is used in the table to emphasize this interpretation.) Soybean seedling emergence was chosen for this calculation because, in keeping with standard practice, it has the smallest of available EC25 measurements (greatest apparent sensitivity) among the measurement endpoints available, representing four different terrestrial plant response variables. The other response variables considered also had quotients mostly greater than one, indicating substantial risk.

Based on reports of incidents involving damage to crops, a complete risk assessment would require additional phytotoxicity data for various crops including potatoes, tobacco, soybeans, corn, watermelons, tomatoes, bell peppers, hay, and pasture.

Aquatic Organisms (Plants and Animals). Data requirements are not fulfilled for aquatic plants or for aquatic animals. There are currently no registered aquatic uses of picloram; however, again, picloram is exceptionally mobile and persistent, and therefore has exceptional potential for exposure of aquatic organisms, relative to other pesticides with terrestrial uses only. Also, picloram has been shown to be very toxic to terrestrial plants, for which the database is more complete than for aquatic plants.

For aquatic animals, estimated exposures exceed levels of concern in two cases: Levels of concern are exceeded for endangered fish species for the potassium salt administered by ground application without incorporation, and for endangered mollusks based on the TIPA salt applied aerially. A complete risk assessment for aquatic animals would require the following acute toxicity studies. For IOE, no aquatic toxicity studies are available. The minimal set of additional studies would comprise coldwater fish (rainbow trout), warmwater fish (bluegill), freshwater invertebrate, and marine invertebrate. For potassium and TIPA salts, a marine fish study would be required. In addition a fish early life cycle study would be required for TIPA salt and IOE. Availability of complete toxicity data could likely result in identification of additional concerns for aquatic animals, because exposures approach levels of concern for various combinations of species, chemical and application method.

For aquatic plants, only one species has been tested (*Selenastrum carpricornutum*), of the five that are normally required. The *Selensastrum* data did not indicate a concern. The additional studies would have substantial informational value in view of the high mobility, persistence, and phytotoxicity of the chemicals. The aquatic vascular

plant study (*Lemna sp*.) could be particularly important, because of the demonstrated high toxicity to several terrestrial vascular species.

Given the low octanol-water partition coefficient, significant bioaccumulation in aquatic organisms is not anticipated.

Terrestrial birds and mammals. For mammals, exposure to endangered terrestrial species will likely exceed levels of concern for TIPA and potassium salts, administered by all application methods considered. For non-endangered species, exposures were not found to exceed levels of concern.

For birds (endangered and non-endangered), exposures were not found to exceed levels of concern based on acute or chronic toxicity.

Terrestrial plant. For terrestrial plants, use rates that would result in estimated environmental concentrations below levels of concern vary by application procedure and product, but are uniformly lower than 1% of current label rates.

(1) Calculation of Estimated Environmental Concentrations

EEC calculations are based on maximum use rates identified in the previous section (2.2 lb ai/A for TIPA salt; 2 lb ai/A for IOE and Potassium salt), along with additional assumptions regarding transport, dilution, and concentration. As indicated, *results are based on a single application*. This section describes the procedures used by EFED for calculating EECs: the numerical results are presented in sections devoted to specific categories of nontarget organisms.

Nontarget Terrestrial vertebrates, dietary exposure. EEC values for assessment of risk to terrestrial vertebrates are based on the procedure of Kenaga and Hoerger, as described in the ecological risk Standard Evaluation Procedure (USEPA, 1986; 540/9-85-001). Results are *illustrated for TIPA salt*: Corresponding to a single application of TIPA salt at 2.2 lb ai/A, the dietary EECs based on the method of Kenaga and Hoerger are given by wildlife use site as follows.

Use Sites	Residues (ppm) (TIPA salt)
Range grasses (short)	528
Long grasses	242
Leaves and leafy crops	275
Forage crops (small insects)	128
Pods containing seeds (large insects)	26
Fruits	15
Soil (Top 1 inch)	49

Corresponding to an application of TIPA salt at 2.2 lb ai/A, the EEC is the maximum value (528 ppm), based on short range grasses. For an application of IOE or potassium salt applied at 2 lb ai/A the EEC is 480 ppm (= 528 × 2/2.2).

Nontarget Terrestrial Plants. EEC values are based on the assumption that chemical applied to a target plot is transported by drift and/or runoff (depending on the application method), to an adjacent "nontarget" plot, of area equal to that of the target plot, where it is distributed evenly. Application methods, considered separately for picloram active ingredients, are unincorporated ground application, and aerial application (foliar and soil).

- For unincorporated ground applications exposure to nontarget organisms is assumed to result from runoff. The fraction of chemical applied that is transported to the nontarget plot is based on water solubility as follows:

Water Solubility (ppm)	% Runoff
< 0.001	0.1
0.001 to 10	1
10 to 100	2
> 100	5

Therefore, it is assumed that 5% of chemical applied is transported by runoff for TIPA salt and potassium salt, 1% for IOE. Total mass transported by runoff (per application) is therefore as follows:

Active Ingredient	EEC	(%Runoff × Appl.Rate)
TIPA salt	0.11 lb ai/A	(=2.2 × 0.05),
IOE	0.02 lb ai/A	(=2.0 × 0.01),
Potassium salt	0.10 lb ai/A	(=2.0 × 0.05).

However, IOE is expected to degrade rapidly to forms with high water solubility (over 100 ppm). For IOE, substitution of a 5% runoff assumption would multiply by 5 various risk quotients presented in the sequel.

- For aerial application to soil it is assumed that the chemical is transported by *both runoff and drift,* and the EEC is calculated as the sum of terms representing these two transport mechanisms.

EEC (lb/A) = Runoff (lb/A) + Drift (lb/A)

It is assumed that the nontarget plot receives 5% of the chemical administered to the nontarget plot, *by drift*. The quantity transported *by runoff* is given by

Maximum Appl. Rate (lb/A)	×	60% Application Efficiency	×	%Runoff.

Percentage runoff is calculated based on water solubility in the same way as just described for unincorporated ground application.

- For aerial application to foliage, it is assumed that the nontarget plot receives 5% of the quantity applied on the target plot, by drift.

Nontarget Aquatic Organisms (Plants and Animals). It is assumed that a fraction of chemical applied to a 10-acre plot is transported by drift and/or runoff to a body with surface area one acre and depth 6 feet ("deep" water body) or 6 inches ("shallow" water body). Identification of risk levels of concern is based on the shallow water body scenario (6 inch depth) for endangered species, and on the deep water body scenario (6 feet depth) for non-endangered species.

• For unincorporated ground applications, it is assumed that *transport is by runoff*. The fraction of material transported from a 10-acre catchment is estimated based on solubility, as for terrestrial plant exposures (5% for TIPA salt and potassium salt, 1% for IOE). It is assumed that all of the runoff from the 10-acre catchment is intercepted by the 1-acre water body. The mass loading for the receiving water body (w.b.) is therefore given by

Mass Loading (lb./A w.b.)	=	Maximum Appl.Rate (lb./A catchment)	×	% Runoff	×	10 A catchment / A surface

Conversion of the mass loading to an EEC (in ppb), is based on the assumed depth of the water body. For the deeper water body the EEC is obtained by multiplying the mass loading by 61.2 (≈61) ppb/(lb./A). For the more shallow water body the same mass will be concentrated in a volume one twelfth of the volume of the deeper water body, so the conversion factor is 734 ppb/(lb.A) (= 61.2 × 12).

For example, the EEC for TIPA salt in the deeper water body is

67 ppb = 2.2 x 0.05 x 10 x 61

• For aerial applications (not assessed separately for soil and foliage), transport is by *both runoff and drift*, and the resulting EEC is the sum of terms representing these two transport mechanisms. For *runoff*, it is assumed that 60% of the material applied is susceptible to runoff (60% is the "application efficiency"). Of that fraction, the assumed percentage runoff is based on water solubility as described for nontarget terrestrial plants (5% for TIPA salt and potassium salt, 1% for IOE). All of the runoff from a 10-acre catchment is received by a 1-acre water body. Accordingly the mass loading resulting from runoff is given by

Mass Loading (lb./A w.b.)	=	Maximum Appl.Rate (lb./A catchment)	×	60% Appl. Efficiency	×	%Runoff	×	10 A catchment / A surface

For input by *drift*, it is assumed that the water body receives 5% of the quantity applied to an adjacent equal-area plot. Finally, the total mass loading (representing drift plus runoff) is converted to an EEC (in ppb) by the procedure just described for unincorporated ground applications. (Multiply by 61 for the deeper water body or by 734 for the more shallow water body.)

(2) Non-target Terrestrial Animals

(a) Avian Acute Risk

For avian acute risk, exposure levels of concern are LC50/2 for non-endangered species and LC50/10 for endangered species. Calculation of the EEC representing dietary exposure is based on maximum application rates identified in the Use Profile Section (repeated in tables following), using procedures described in Section (1), for nontarget terrestrial vertebrates.

Additional calculations that are standard for granular pesticide formulations, involving numbers of LD_{50}s per square feet, are not applicable to products containing picloram salts and IOE.

Endangered Bird Species. As indicated in the following table, the estimated exposure levels do not exceed levels of concern.

Acute Avian Dietary Risk for *Endangered* Species[1]

Active Ingredient	Dietary LC_{50} (ppm)	Highest Calculated EEC (ppm)	Risk Quotient (RQ) EEC/(LC50/10)
TIPA Salt	> 10000	528	< 0.528
IOE	> 5620	480	< 0.854
Potassium Salt	> 5620	480	< 0.854

[1] Non-endangered species: RQ values are values given for endangered species, divided by 5. (All RQ < 1.)

Non-Endangered Bird Species. Estimated exposures do not exceed levels of concern for non-endangered bird species. Risk assessment for non-endangered species is

similar to that for endangered species (just described), except that levels of concern are calculated as LC50/2 rather than LC50/10. It follows that for nonendangered species, the RQ values are < 0.11 for TIPA salt, < 0.17 for IOE and Potassium salt.

(b) Avian Chronic Risk

For avian chronic risk, estimated exposures do not exceed levels of concern. Levels of concern are lowest effect levels (LEL). Supplemental studies conducted more than 10 years ago give NOELs 2.8 kg ai/ha (15.2 lb ai/A) for TIPA salt and 11.2 kg ai/ha (60.9 lb ai/A) for Potassium salt. (NOEL = "No Observed Effect Level" < LEL). By the method of Kenaga and Hoerger, the EEC corresponding to 15.2 lb ai/A NOEL is 3648 ppm (= 15.2 lb ai × 240 ppm/lb ai). This is substantially larger than the previously-computed EEC of 528 (corresponding to the maximum label use rate of 2.2 lb ai/A). In short, the actual environmental concentration is estimated to be much lower than a value that produced no discernable effect.

(c) Mammalian Acute Risk

Quantitative risk assessment for mammals is similar to that for birds, but requires, in addition, conversion of LD50 values (mg ai per kg body weight) to LC50 values in the same units as the EECs (ppm). Exposure levels of concern are calculated as LC50/2 for non-endangered species and LC50/10 for endangered species. Calculation of the EEC representing dietary exposure is based on maximum application rates identified in Section (1) (repeated in tables following), using procedures described in Section (2) for nontarget terrestrial vertebrates.

Conversion of LD50s to LC50s is represented by the following formula:

$$LC50 = \frac{\text{LD50 (mg/kg) x Body Weight (gms)}}{\text{Weight Consumed (gms)}}$$

Assumptions regarding body weight and food consumption are here based on Davis and Golly (1963).

The RQ calculations for an endangered mammal are illustrated in the following table, for picloram TIPA salt. LC50s are for three species that are representative of small wild mammals. The lowest relevant LD50 measurement was more than 5000 mg/kg:

Risk Quotient Calculation Illustrated for a Hypothetical Endangered Mammal with LC50 5000 mg/kg, Based on picloram TIPA salt

Species	Body Weight (gms)	Daily Food Intake		LC50 (ppm)[1]	Risk Quotient (RQ)[2]
		% Body Weight	grams		
Meadow vole (herbivore)	46	61	28.1	8185	0.645
Old-field mouse (granivore)	13	16	2.1	30952	0.17
Least shrew (Insectivore)	5	110	5.5	4545	1.16

[1] Based on LD50 = 5000 mg/kg.
[2] RQ = EEC / (0.1 × LC50);
EEC = 528 ppm
Non-Endangered: use RQ = EEC / (0.5 × LC50)

Acute Risk to Endangered Mammalian Species. Risk quotients computed as just described are presented in the following table. These results indicate exceedance of exposure levels of concern for acute risk, for endangered insectivores from exposure to picloram TIPA and Potassium salts, and for mammalian herbivores exposed to IOE.

Acute Risk Quotients for Endangered Mammals

Active Ingredient (P.C Code)	Mammal LC50 (ppm)	Highest Calculated EEC Value (ppm)	Risk Quotient (EEC/ (0.1 × LC50)
TIPA Salt (5102) LD_{50} > 5000 mg/kg	8185 Meadow vole (herbivore)	528	0.645
	3095 2 Old field mouse (granivore)		0.17
	4545 Least shrew (insectivore)		1.16
IOE (5103) LD_{50} = 2830 mg/kg	4632 Meadow vole (herbivore)	480	1.036
	17519 Old field mouse (granivore)		0.274
	2572.7 Least shrew (insectivore)		1.866

Acute Risk Quotients for Endangered Mammals

Active Ingredient (P.C Code)	Mammal LC50 (ppm)	Highest Calculated EEC Value (ppm)	Risk Quotient (EEC/ (0.1 × LC50)
Potassium Salt (5104) LD_{50} = 3536 mg/kg	5788.5 Meadow vole (herbivore) 21889.5 Old field mouse (granivore) 3214.6 Least shrew (insectivore)	480	0.829 0.219 1.5

Acute Risk to Nonendangered Mammal Species. Estimated exposures do not exceed levels of concern for nonendangered mammals. Levels of concern are calculated as LC50/2, rather than LC50/10 as for endangered mammals. Therefore RQ values for nonendangered mammals are equal to the values displayed above for endangered mammals, divided by 5. The maximum RQ value for nonendangered mammals is therefore 0.37 (= 1.866/5), corresponding to IOE and least shrew.

(d) Mammalian Chronic Risk

Because risks are low for acute effects, as just described, chronic toxicity studies are not required. For both endangered and non-endangered mammal species, levels of concern for chronic effects are lowest effect levels (LEL).

(3) Non-target Terrestrial Plants

For non-target terrestrial plants (endangered or nonendangered), exposure levels of concern are equated to the lowest relevant EC25 measurements. Risk is assessed by application method: unincorporated ground, aerial to soil, or aerial to foliar. Calculation of EECs is based on maximum application rates identified Section (1), repeated in subsequent tables.

Unincorporated Ground Application. The following table gives risk quotients for each active ingredient, along with the application rates that would yield RQ = 1. As described previously, EECs are based on the assumption that chemical applied to a target plot is transported by runoff to an adjacent

nontarget plot, with the assumed percentage runoff based on water solubility. The results displayed below indicate that picloram salts and IOE are very likely to affect nontarget plants (especially dicots) in areas adjacent to areas of application. The requirement for Tier 3 plant field testing has been met; however the Agency does not routinely require these studies.

Terrestrial Plants Exposed via Runoff, Unincorporated Ground Application (Endangered or Non-endangered)					
Active Ingredient (P.C Code)	Seed Germination EC_{25} Seedling Emergence LC_{25} (lb ai/A)	Maximum Application Rate (lb ai/A)	% Runoff Based on Solubility	EEC (lb ai/A)	Risk Quotient (EEC/EC_{25})
TIPA Salt (5102)	0.002 (Dicots-Soybeans) > 0.035 (Monocots-barley) 0.0000239 (Dicots-Soybeans) 0.0346 (Monocots-wheat)	2.2	5	0.11	55 < 3.14 4603 3.18
IOE (5103)	0.0013376 (Dicots-Drybeans) 0.0032103 (Monocots-barley) 3.5×10^{-6} (Dicots-Soybeans) 0.0253259 (Monocots-wheat)	2.0	1	0.02	14.99 6.23 5714 0.790
Potassium Salt (5104)	0.0031 (Dicots-Soybeans) 0.062 (Monocots-Barley) 0.0000124 (Dicots-Soybeans) 0.02 (Monocots-Wheat)	2.0	5	0.1	32.3 1.61 8065 5

Aerial Application to Soil. As described previously, EECs are based on the assumption that chemical applied to a target plot is transported by both drift and runoff to an adjacent nontarget plot of equal area. Results of these calculations (displayed in the following table) indicate that picloram salts pose significant risks to nontarget plants (especially dicots) in areas adjacent to application plots, when the chemical is applied aerially to soil. The same result is obtained for IOE; however IOE is currently applied only using backpack sprayers.

Risks to Nontarget Terrestrial Plants (Endangered, Non-Endangered), Aerial/Soil Application					
Active Ingredient (P.C Code)	Seed Germination EC_{25} Seedling Emergence LC_{25} (lb ai/A)	Maximum Application Rate (lb ai/A)	%Runoff Based on Solubility	EEC (lb ai/A)	Risk Quotient (EEC/EC_{25})
TIPA Salt (5102)	0.002 (Dicots-Soybeans) 0.035 Monocots-barley) 0.0000239 (Dicots-Soybeans) 0.062 (Monocots-wheat)	2.2	5	0.18	90 5.1 7531 2.9
IOE (5103)	0.0013376 (Dicots-Drybeans) 0.0032103 (Monocots-barley) 3.5×10^{-6} (Dicots-Soybeans) 0.0253259 (Monocots-wheat)	2.0	1	0.032	23.9 9.9679 9143 1.2635
Potassium Salt (5104)	0.0031 (Dicots-Soybeans) 0.062 (Monocots-Barley) 0.0000124 (Dicots-Soybeans) 0.02 (Monocots-Wheat)	2.0	5	0.16	51.6 2.5 12,903 8

Aerial Application - Foliar. As described previously, EECs are calculated under the assumption that 5% of the chemical applied to a nontarget plot is transported by runoff to an adjacent nontarget plot of equal area. The resulting risk quotient values (displayed in the following table) indicate that picloram salts pose significant risks to nontarget dicot plants and root crops in areas adjacent to application areas when the chemical is applied by foliar aerial applications. The same result is obtained for IOE; however IOE is currently applied only using backpack sprayers.

Risk to Nontarget Terrestrial Plants (Endangered, Non-endangered) from Aerial Foliar Application.					
Active Ingredient (P.C Code)	Vegetative Vigor EC_{25} (lb ai/A)	Maximum Application Rate (lb ai/A)	% Runoff Based on Drift	EEC (lb ai/A)	Risk Quotient (EEC/EC_{25})
TIPA Salt (5102)	0.0002 (Dicots-Tomatoes) 0.20 (Monocots-Wheat) 0.012 (Root crops-Radish)	2.2	5	0.11	550 0.55 9.2
IOE (5103)	0.000214 (Dicots-Soybeans) 0.2098307 (Monocots-Wheat) 0.0346893 (Root crops-Radish)	2.0	1	0.02	93. 0.095 0.58
Potassium Salt (5104)	0.00036 (Dicots-Soybeans) 0.276 (Monocots-Wheat) 0.062 (Root crops-Radish	2.0	5	0.1	277.7 0.36 1.6

Additional Phytotoxicity Information. The use of products containing picloram has on occasion resulted in unintentional damage to crops outside of areas where applied. Based on the data available, picloram appears to have caused adverse effects to trees, grasses, shrubbery, strawberries, watermelons, potatoes, grapes, peanuts, and soybeans. Three incidents are reported of damage to potatoes. Therefore confirmatory toxicity data are needed for various crops, and for potatoes in particular.

(4) Non-target Aquatic Plants

For nontarget aquatic plants, a complete risk assessment involves toxicity tests for five plant species. At present data are available only for *Selenastrum capricornutum* (a freshwater green alga).

Standard quantitative risk calculations have been performed based on the *S. capricornutum* toxicity measurements. This incomplete risk assessment, which is not presented here in detail, indicates that exposure levels of concern are not exceeded for picloram salts and IOE. This result does not indicate that current picloram uses are benign for nontarget aquatic plants in general: testing of the additional species are being required as confirmatory data.

(5) Non-target Aquatic Animals

(a) Acute Risks

Acute risk to non-target aquatic animals is presumed low for risk quotient (RQ) values less than 1, calculating RQ as EEC/(0.1 × LC50) (nonendangered species) or EEC/(0.05 × LC50) (endangered species), based on the lowest relevant LC50 measurement. The calculation of EECs depends upon the maximum use rates identified in the Use Profile Section and formula given in Section (1). EEC calculations assume that a proportion of chemical applied in a 10 acre drainage basin is transported by drift and/or runoff (depending on the application method) to a 1 acre water body, depth 6 feet or 6 inches. Again, concentration levels of concern are based on the 6 inch depth for endangered species and on 6 foot depth for non-endangered species.

A reasonably complete acute risk assessment would require, at minimum, the following acute toxicity studies not presently available: for TIPA salt and IOE, LC50s for a coldwater fish (rainbow trout), a warmwater fish (bluegill), and a freshwater invertebrate (*Daphnia magna*); for potassium salt the LC50 for bluegill. For IOE, there are no available acute toxicity data for freshwater marine/estuarine organisms.

Standard calculations have been performed using the available toxicity data. The results are presented in detail only for endangered species, for which in some cases the risk quotients approach or exceed one. For non-endangered species, risk quotients can be obtained as 0.5 times the values presented for endangered species. This incomplete risk assessment has identified the following ecological risk concern: The potassium salt is likely to affect endangered fish with unincorporated ground application (risk quotient = 1.13). With plausible levels of variation in sensitivity among species, it is not improbable that additional concerns would be identified if the minimal toxicity data requirements identified were fulfilled. An additional risk quotient greater than one is obtained with the endangered species risk assessment for TIPA salt, based on the eastern oyster shell deposition test (unincorporated ground application); however, currently there are no federally listed marine or estuarine organisms.

Unincorporated Ground Applications, Endangered Species. As described previously for aquatic organisms (plants and animals) EEC calculations assume that chemical applied to a target plot is

transported by runoff to an adjacent plot of equal area, at a rate that depends on water solubility of the chemical. Results are presented separately for TIPA salt and potassium salt in the following tables. (For IOE there are no available aquatic toxicity data.) For TIPA and potassium salt, it is assumed that 5% of chemical applied is transported to the nontarget plot, based on the high water solubility of these chemicals.

For *nonendangered species*, risk quotients will equal 0.5 times the values presented.

Risk Quotients (RQ) for Endangered Aquatic Animals, based on Unincorporated Ground Applications

1. Picloram TIPA salt Applied at 2.2 lb. ai/A

Species	LC_{50} (ppb)	RQ 6 Feet Deep ($67.1/(0.05 \times LC_{50})$)	RQ 6 Inch Deep ($807.4/(0.05 \times LC_{50})$)
Coho Salmon (FW fish - coldwater)	20,000	0.067	0.807
Marine Shrimp	306,000	0.0044	0.0528
Eastern Oyster (Shell deposition)	10,000	0.134	1.615

2. Picloram IOE: no toxicity data.

3. Picloram Potassium Salt Applied at 2.0 lb. ai/A

Species	LC_{50} (ppb)	RQ 6 Feet Deep ($61/(0.05 \times LC_{50})$)	RQ 6 Inch Shallows ($734/(0.05 \times LC_{50})$)
Rainbow Trout (FW fish - coldwater)	13,000	0.0938	1.13
Daphnia (FW Invertebrate)	68,300	0.0179	0.215
Eastern Oyster (Embryo Larvae)	18,000	0.0677	0.816

Aerial or Mist Blower Applications (endangered species). EECs are calculated as described in Section (1) for aquatic organisms (both animals and plants), under the assumption that a water body with 1 acre surface receives input of chemical by both drift and runoff from the 10-acre plot.

Results are presented separately for TIPA salt and potassium salt in the following tables. (For IOE there are no available aquatic toxicity data and no aerial or mist blower applications, only backpack.) For *nonendangered species*, risk quotients will equal 0.5 times the values presented. The results for the TIPA salt and the oyster shell deposition study indicate a concern for endangered species of mollusks.

Risk Quotients (RQ) for Endangered Aquatic Animals based on Aerial Application

1. Picloram TIPA Salt Applied at 2.2 lb. ai/A

Species	LC_{50} ppb	RQ 6 Feet Deep ($47/(0.05 \times LC_{50})$)	RQ 6 Inch Shallows ($566/(0.05 \times LC_{50})$)
Coho Salmon (FW fish - coldwater)	20,000	0.047	0.57
Marine Shrimp	306,000	0.0030	0.037
Eastern Oyster (Shell deposition)	10,000	0.094	1.13

2. Picloram IOE: No toxicity data.

3. Picloram Potassium Salt Applied of 2.0 lb. ai/A

SPECIES	LC_{50} ppb	RQ 6 FEET DEEP ($42.7/(0.05 \times LC_{50})$)	RQ 6 INCH SHALLOWS ($514.5/(0.05 \times LC_{50})$)
Rainbow Trout (FW fish - coldwater)	13,000	0.066	0.79
Daphnia (FW Invertebrate)	68,300	0.12	0.15
Eastern Oyster (Embryo Larvae)	18,000	0.047	0.57

(b) Chronic Risk

Subdivision E, Section 72-4 of FIFRA requires submission of a fish early life-cycle test for pesticides that are likely to be highly persistent in the aquatic environment. The only picloram active ingredient for which this requirement is satisfied is potassium salt. *Chronic fish studies are needed for the remaining active ingredients*.

For risks of chronic effects, levels of concern are equated to Maximum Acceptable Concentrations (MATC). For the picloram potassium salt, MATCs for the fish early life stage and aquatic invertebrate life-cycle tests are 700 ppb and 14600 ppb respectively. Neither of these values exceeds relevant EECs based on the

application methods considered here (unincorporated ground application and aerial application).

(6) Non-target Insects

As indicated in discussion of toxicity data, honey bee acute toxicity studies indicate that all active ingredients of picloram are practically nontoxic to that species, with contact LD50 > 25 mg per bee.

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 ingredient 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 picloram acid and its derivatives as 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 picloram acid and its derivatives. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of picloram acid and its derivatives, 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 picloram acid and its derivatives and to determine that picloram and its derivatives can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing picloram acid and its derivatives as the active ingredients are eligible for reregistration conditional upon implementation of the mitigation measures specified in this document. 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 picloram acid and its derivatives 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 picloram acid and its derivatives, 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 ingredients picloram acid and its derivatives, the Agency has sufficient information on the health effects of picloram and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency concludes that products containing picloram for all uses are eligible for reregistration provided the risk mitigation measures specified in this document are implemented.

The Agency has determined that picloram, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of picloram and its derivatives are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.292:

The tolerances listed in 40 CFR §180.292 are for residues of picloram *per se*. Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.292 for the following commodities: barley grain; barley forage; barley straw; oat grain; oat forage; oat straw; wheat grain; wheat forage; wheat straw; fat, meat, kidney, liver, and meat by-products of cattle; goats, hogs, horses, and sheep; and fat, meat, and meat by-products of poultry, milk, and eggs. See Table IX for modifications in commodity definitions.

Sufficient field residue data are available for grasses, although the data indicate that the established tolerance of 80 ppm for picloram residues in/on grass forage is not adequate. Tolerances of 225 ppm have been proposed for picloram residues in/on grass forage and hay. The available data support the proposed tolerance for grass hay but show that a higher tolerance must be proposed for grass forage. The data indicate that a level of 300 ppm would be appropriate.

The Agency has acceptable field residue data at the 0.5 lb. ae/A and 2 lb. ae/A. However, through negotiations with the registrant the new maximum

use rate will be lowered to 1 lb. ae/A. Ordinarily, field residue data would be required for this new maximum use rate, however, since there are minimal dietary concerns involved with picloram, no field residue data will be required for the 1 lb. ae/A maximum use rate. Picloram tolerances are based on the 2 lb. ae/A data and will remain in effect unless the Agency revisits the tolerance setting database and lowers the tolerance based on the 0.5 and 2 lb. ae/A residue field data or the registrant proposes a lower tolerance based upon the 0.5 and 2 lb. ae/A.

A wheat grain dust study has shown that a tolerance must be proposed. The available data indicate that a tolerance of 4 ppm would be appropriate for grain dust.

The established tolerances for picloram residues in/on flax seed and flax straw will be proposed for revocation, as there is no registered use of picloram on flax.

Tolerances Listed Under 40 CFR §185.4850 and 40 CFR §186.4850:

The tolerances listed in 40 CFR §185.4850 and 40 CFR §186.4850 are for residues of picloram *per se*. Sufficient data are available to ascertain the adequacy of the established food/feed additive tolerances listed in 40 CFR §185.4850 and 40 CFR §186.4850 for barley, oat, and wheat milled fractions (excluding flour).

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of picloram. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

Table IX. Tolerance Reassessment Summary for Picloram

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.292:			
Barley, grain	0.5	0.5	
Barley, green forage	1	1	*Barley, forage*
Barley, straw	1	1	
Cattle, fat	0.2	0.2	
Cattle, kidney	5	5	
Cattle, liver	0.5	0.5	

(continued)

Table C *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cattle, mbyp (exc kidney and liver)	0.2	0.2	*Cattle, mbyp (exc. liver and kidney)*
Cattle, meat	0.2	0.2	
Eggs	0.05	0.05	
Flax, seed	0.5	Revoke	No registered use
Flax, straw	0.5	Revoke	No registered use
Goats, fat	0.2	0.2	
Goats, kidney	5	5	
Goats, liver	0.5	0.5	
Goats, mbyp (exc kidney and liver)	0.2	0.2	*Goats, mbyp (exc. liver and kidney)*
Goats, meat	0.2	0.2	
[Grain dust]	none	4	Registrant must propose tolerance
Grasses, forage	80	300	Revised tolerance proposal of 225 ppm pending (PP#6F3367); registrant must propose higher tolerance/*Grass, forage*
[Grass, hay]	none	225	Tolerance pending (PP#6F3367)/*Grass, hay*
Hogs, fat	0.2	0.2	
Hogs, kidney	5	5	
Hogs, liver	0.5	0.5	
Hogs, mbyp (exc kidney and liver)	0.2	0.2	*Hogs, mbyp (exc. liver and kidney)*
Hogs, meat	0.2	0.2	
Horses, fat	0.2	0.2	
Horses, kidney	5	5	
Horses, liver	0.5	0.5	
Horses, mbyp (exc kidney and liver)	0.2	0.2	*Horses, mbyp (exc. liver and kidney)*
Horses, meat	0.2	0.2	
Milk	0.05	0.05	

(continued)

Table C *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Oats, grain	0.5	0.5	
Oats, green forage	1	1	*Oats, forage*
Oats, straw	1	1	
Poultry, fat	0.05	0.05	
Poultry, mbyp	0.05	0.05	
Poultry, meat	0.05	0.05	
Sheep, fat	0.2	0.2	
Sheep, kidney	5	5	
Sheep, liver	0.5	0.5	
Sheep, mbyp (exc kidney and liver)	0.2	0.2	*Sheep, mbyp (exc. liver and kidney)*
Sheep, meat	0.2	0.2	
Wheat, grain	0.5	0.5	
Wheat, green forage	1	1	*Wheat, forage*
Wheat, straw	1	1	
Tolerances listed under 40 CFR §185.4850			
Barley, milled fractions (exc. flour)	3	3	
Oat, milled fractions (exc. flour)	3	3	
Wheat, milled fractions (exc. flour)	3	3	
Tolerances listed under 40 CFR §186.4850			
Barley, milled fractions (exc. flour)	3	3	
Oat, milled fractions (exc. flour)	3	3	
Wheat, milled fractions (exc. flour)	3	3	

2. Restricted Use Classification

All the picloram derivatives (potassium picloram, triisopropanolamine picloram and isooctyl picloram) are currently classified as restricted use pesticides by regulation (40 CFR section 152.175) on the basis of being a

hazard to non-target organisms both crop and non-crop. Picloram will remain a restricted use pesticide. Picloram may also be considered for restricted use for ground water concerns once the Ground Water Restricted Use Rule is finalized. The eligibility determination made at this time is based upon a presumption that registrations will conform to all applicable regulatory conditions included in the final restricted use rule for groundwater.

3. State Management Plan

EPA is proposing regulations that will: 1) designate certain pesticides to be subject to EPA-approved State Management Plans (SMPs) as a condition of their legal sale and use; and 2) establish these SMPs as an "other regulatory restriction" by specifying procedures and criteria for SMP development, review and approval, as provided under the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA) Section 3(d). In proposing these individual pesticides to be subject to SMPs, EPA has determined that these pesticides may pose an unreasonable adverse effect to the environment by their ground-water contamination potential, in the absence of effective local management measures provided in a State plan. Any uses of picloram allowed pursuant to the final rule will be predicated on a finding that such uses will not pose unreasonable adverse effects on the environment when used pursuant to the conditions contained in the rule. Upon promulgation of this rule, the labels for these pesticides will be changed to require use in accordance with an EPA-approved SMP, and to prohibit sale and use in those States without such an EPA-approved SMP, after a period (to be established in the rule) allowed for development and approval of these State plans. The eligibility determination made at this time is based upon a presumption that registrations will conform to all applicable requirements of the final regulation addressing this issue.

Picloram is not now one of the pesticides that EPA will be proposing to be subject of a SMP. However, the Agency may consider picloram as a candidate for a SMP at some later date.

4. Reference Dose

A reference dose (RfD) for the picloram acid and its derivatives was calculated to be 0.20 mg/kg/day based on a NOEL of 20 mg/kg/day body-weight per day from a two-year chronic rat feeding study. An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability. The picloram chronic dietary exposure/risk estimates are extremely low. For the United States population as a whole, the Theoretical Maximum Residue Contribution (TMRC) is 0.9% of the RfD. For this same group, the Anticipated Residue Contribution (ARC) is 0.5% of the RfD. Because the dietary exposure/risk is so low, about 1/200th of the RfD, there are no concerns regarding chronic dietary exposure to picloram at this time.

5. Cancer Risk Assessment

The Agency has classified picloram as a Group E (evidence of non-carcinogenicity for humans). Even though picloram was shown to be non-carcinogenic, a cancer risk assessment was performed on the maximum concentration of the impurity HCB, since HCB has been classified by the Agency as a Group B_2 (probable human carcinogen). The refined, ARC dietary carcinogenicity risk estimates for the United States population as a whole for the impurity, HCB, is 7×10^{-7}. A risk less than 1.0×10^{-6} is generally considered to be negligible.

Picloram IOE bears structural similarity to di(2-ethylhexyl)phthalate (DEPH) in that both possess a 2-ethylhexyl moiety. DEPH and certain other substances containing the 2-ethylhexyl moiety have been found to be carcinogenic. The Agency performed a cancer risk assessment for workers and found that the risk associated with post-application exposure is not a major concern since exposure to workers is minimal due to the use patterns defined by the picloram IOE labels and the cultural practices typically associated with a broad spectrum herbicide of this type. This ester formulation is not used on food.

6. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish in the Federal Register a description of the program and have available enforceable county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Worker Protection

a. Compliance with Worker Protection Standard

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 Worker Protection Standard for Agricultural Pesticides (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 Reentry

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established on the basis of 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: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

At this time some registered uses of picloram are within the scope of the Worker Protection Standard for agricultural pesticides (WPS) and some are outside the scope of the WPS. EPA has determined that entry should not be permitted immediately following

application. Therefore, the Agency is establishing restrictions on entry to treated areas. For each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) (except when it is applied by direct injection into the treated plants), the Agency is requiring a 12-hour restricted-entry interval on all occupational end-use products containing picloram as an active ingredient. For each use of the product that is outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS), the Agency is requiring a prohibition on entry until sprays have dried on occupational end-use products containing picloram as an active ingredient.

The WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. The Agency believes that these existing WPS protection are sufficient to mitigate post-application exposures of workers who contact surfaces treated with picloram. The WPS REI in effect until now was a 12-hour REI placed on picloram products by PR Notice 93-7.

When picloram is applied by direct injection into treated plants, there are no entry restrictions. The WPS does not cover workers who are working in an area where a pesticide has been injected directly into plants, therefore, there are no entry restrictions or notification requirements.

Personal Protective Equipment (PPE) Requirements

Mixer/loader/applicator 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):

- In the RED document for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements 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.

- 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 special toxicological concerns about picloram that warrant the establishment of active-ingredient based PPE requirements. The MOE's for some of the use-scenarios for handlers (mixers, loaders, applicators, etc.) are acceptable only with the addition of chemical-resistant gloves.

To the Agency's knowledge, at this time some of the registered uses of picloram are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. However, the minimum (baseline) PPE requirements for both the WPS and nonWPS uses are the same, since the potential exposure to handlers is similar for WPS and nonWPS uses.

The minimum (baseline)PPE for all WPS and nonWPS uses of picloram end-use products is: chemical-resistant gloves.

Personal Protective Equipment (PPE) Requirements

Early Entry PPE The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry by workers 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 restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency 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 the Agency 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 there are special toxicological concerns about picloram and picloram is classified as toxicity category III or IV for acute dermal toxicity and skin irritation potential, the PPE required for early entry is coveralls, chemical-resistant gloves, shoes, and socks. Since picloram is classified as toxicity category III for eye irritation potential, no protective eyewear is required. The Agency will not require a respirator for early-entry workers, since the WPS places very specific restrictions on early entry and the Agency believes that these existing WPS protections are sufficient to mitigate post-application inhalation exposures of workers.

There are no special toxicological concerns about picloram that warrant the establishment of active-ingredient-based early entry PPE requirements.

Entry Restrictions for Occupational-Use Products (nonWPS uses)

At this time some registered uses of picloram are outside the scope of the WPS. The Agency is requiring the following entry restrictions for all nonWPS occupational uses of picloram end-use products:

"Do not enter or allow others to enter the treated area until sprays have dried."

Entry Restrictions for Residential-Use Products

At this time no products containing picloram are registered for residential use.

8. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is completed, there may be further refinements in spray drift management practices.

9. Ground Water and Surface Water Advisories

Because picloram has been shown to be exceptionally mobile and persistent the Agency is requiring ground and surface water advisories.

To better refine the extent and nature of the ground water contamination, the Agency has required a surveillance/monitoring program. Based on the data, the Agency may require further registrant action, including prohibition in vunerable areas or possible cancellation.

See section V for labeling statements.

10. Phytotoxic Concerns

The Agency is very concerned about the phytotoxicity effects of picloram. As an indication of potential for mitigation of phytotoxic effects *by use reduction*, one can estimate the maximum use rate that would correspond to an environmental concentration not exceeding the level of concern. The reciprocal of the risk quotients (i.e. 1/RQ) gives the *fraction* of the current use rate that would result in an EEC equal to the LOC. For example, if the risk quotient is 2, then a halving of the application rate would result in an EEC equal to the LOC. Results of such calculations, based on RQ values in tables found in section 3, vary according to product and application procedure, but uniformly indicate that application rates less than 1% of current rates would be required, for the EECs to not exceed the LOCs.

Currently, most of the picloram products can be applied at any season and there are no limitations or restrictions on the maximum number of treatments per season. The maximum rates per application are also unclear for some products.

Products containing picloram are on occasion transported from where they are applied so that crops and other nontarget plants are damaged unintentionally. Not withstanding these serious phytotoxic concerns, the Agency believes that sufficient measures are in place such that all the uses for picloram are eligible for reregistration. These measures include a) implementation of risk reduction measures; b) monitoring programs and current state regulation of picloram c) a cursory benefits analysis and; d) the tightly controlled product distribution system that has been put in place by the sole producer, DowElanco.

a. Risk Reduction Measures

- The Agency is requiring lower application rates and limits on the number and frequency of applications for all use patterns:

○ the broadcast rate for range and pasture use will be lowered from the current maximum of 2.0 lb. ae/A to 0.5 ae/A for control of broadleaf weeds and woody plants. For the control of noxious weeds, a broadcast application of up to 1.0 lb. ae/A may be used annually. Spot treatment will be lowered to a maximum of 1.0 lb. ae/A with no more than 50% of an acre being treated. Spot treatments and broadcast treatments can be applied during the same growing season only if the total amount applied does not exceed 1.0 lb. ae/A per annual growing season. The range and pasture use accounts for over 85% of picloram's use.
○ the forestry use rate will be lowered from a maximum of 2.2 lbs. ae/A to 1.0 lb. ae/A for spot and broadcast treatment. Use will be allowed only once every 2 years. There is no interval currently listed on the label.
○ the rights-of-Ways use rate will be lowered from a maximum of 2.2 lb ae/A to 1 lb ae/A annually. There is no interval currently listed on the label.

- Finally picloram will remain classified for restricted use and may be identified as a candidate for the State Management Plan.

b. Monitoring and Other Programs

- Through negotiations with the Agency the registrant has committed to a state ground water monitoring/surveillance plan. The plan will be based on modeling which will be completed by 6-30-95. Parameters of the monitoring/surveillance program (e.g. location, duration, etc.) will be defined based on the results of the modeling effort. The results of the monitoring/surveillance program, will determine if additional data (e.g. prospective study) may be required or if other appropriate regulatory action is necessary.

- Additionally, through negotiations with the Agency, the registrant has committed to provide financial support to the Heritage programs for the six states with the highest usage of picloram. These six states cover 75% of all picloram usage in pounds and most geographic/climatic conditions. State Heritage programs are responsible for mapping and monitoring sensitive habitat in 48 states. A geographical information system (GIS) will be developed that will relate sensitive habitat to land use and land characteristics. The registrants financial support of the State Heritage programs will greatly facilitate and speed the mapping and implementation of the Endangered Species Task force efforts. This program will enhance the capability of the states to identify sensitive habitat, based on the presence of endangered species and other considerations. Ultimately, this approach will help secure protection for sensitve habitats/endangered species while providing state and federal

agencies with the critical information needed to identify any further mitigation measures should picloram use be found to effect any sensitive habitat/endangered species.

- Although these measures will reduce risks, the remaining potential risk to nontarget plants and the potential for ground water contamination are still expected to be high.

- The Agency has also consulted with State Lead Agencies in States with high picloram use (TX, OK, KS, MT, ND, NE, WY, SD and WA). Most of the states responded and identified picloram as an important weed control chemical. States believe they have programs in place to adequately deal with phytotoxicity. The States responses were also useful in establishing acceptable modifications of reduced application rates and treatment frequencies.

c. Benefits

The Agency has done a cursory benefits analysis for picloram and found that it is an extremely effective herbicide at relatively low rates. It also controls a wide spectrum of unwanted broadleaf and brush species without causing injury to grass.

Some alternatives for picloram are 2,4-D, triclopyr, dicamba, clopyralid and tebuthiuron. However, it should be noted that in order to achieve the same spectrum of control as picloram, especially for weed control in rangeland and pasture, a combination of 2,4-D and some other herbicide (e.g. triclopyr or dicamba) would probably have to be used.

The Agency has not completed its evaluation of the carcinogenic potential of 2,4-D. New chronic studies for 2,4-D are due to the Agency in the spring of 1995. Therefore, the Agency would be concerned about restricting picloram use in favor of 2,4-D at this time. Picloram alternatives will generally have to be used at higher rates to achieve control. Additionally, picloram is the only effective herbicide that can control pricklypear cactus, a significant economic pest in range and pastureland.

d. DowElanco's Stewardship

DowElanco has instituted a strict product distribution system. There are only 53 companies that DowElanco allows to distribute picloram. Of the 53 companies, 19 companies account for 90% of the total sales in the U.S.. All 53 companies and their employees must attend DowElanco training program(s) annually in order to continue to

sell picloram. Additionally, every company has a contractual obligation to represent strict DowElanco product stewardship or otherwise lose their privilege to sell picloram. This limited distribution approach allows consistent product stewardship and enables Dow to effect use recommendations/changes immediately throughout the U.S.

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 picloram acid and its derivatives 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:

- **For Triisopropanolamine Picloram**
  - Guideline 72-3(d), Toxicity to marine/estuarine fish (TEP)
  - Guideline 72-4(a), Early life stage - fish
  - Guideline 123-1(a), Seed germination/emergence
  - Guideline 123-1(b), Vegetative vigor
  - Guideline 123-2, Aquatic plant growth (marine diatom)

- **For Isooctyl Picloram**
  - Guideline 72-1(b), Bluegill, Acute LC_{50} (TEP)
  - Guideline 72-1(d), Rainbow, Acute LC_{50} (TEP)
  - Guideline 72-2(b), Invertebrate toxicity (Daphina magna)
  - Guideline 72-3(d), Toxicity to marine/estuarine fish (TEP)
  - Guideline 72-3(e), Toxicity to marine/estuarine mollusk (TEP)
  - Guideline 72-3(f), Toxicity to marine/estuarine shrimp (TEP)
  - Guideline 72-4(a), Early life stage - fish
  - Guideline 123-1(a), Seed germination/emergence
  - Guideline 123-1(b), Vegetative vigor
  - Guideline 123-2, Aquatic plant growth (diatoms, algae)

- **For Potassium Picloram**
  - Guideline 72-3(d), Toxicity to marine/estuarine fish (TEP)
  - Guideline 123-1(a), Seed germination/emergence
  - Guideline 123-1(b), Vegetative Vigor
  - Guideline 123-2, Aquatic plant growth (marine diatom)

- **Mixer/Loader/Applicator Exposure Monitoring**

  Guideline 231, Estimation of Dermal Exposure at Outdoor Sites for mixer/loaders and applicators using the hand cannon equipment.
  Guideline 232, Estimation of Inhalation Exposure at Outdoor Sites for mixer/loaders and applicators using the hand cannon equipment.
  Guideline 231, Estimation of Dermal Exposure at Outdoor Sites for mixer/loaders and applicators using the backpack/knapsack equipment.
  Guideline 232, Estimation of Inhalation Exposure at Outdoor Sites for mixer/loaders and applicators using the backpack/knapsack equipment.

- **Ground Water/Surveillance Monitoring**

Through negotiations with the Agency the registrant has committed to a state ground water monitoring/surveillance plan. The plan will be based on modeling which will be completed by 6-30-95. Parameters of the monitoring/surveillance program (e.g. location, duration, etc.) will be defined based on the results of the modeling effort and in cooperation with the States. The results of the monitoring/surveillance program, will determine if additional data (e.g. prospective study) may be required or if other appropriate regulatory action is necessary.

- **State Heritage Programs for Endangered Species**

Through negotiations with the Agency, the registrant has committed to provide financial support to the Heritage programs for the six states with the highest usage of picloram. These six states cover 75% of all picloram usage in pounds and most geography/climatic conditions. State Heritage programs are responsible for mapping and monitoring sensitive habitat/endangered species in 48 states. A geographical information system (GIS) will be developed that will relate sensitive habitat to land use and land characteristics. The registrants financial support of the State Heritage programs will greatly facilitate and help speed up the mapping and implementation of the Endangered Species Task Force efforts. Ultimately, this approach will help secure protection for sensitve habitats/endangered species while providing state and federal agencies with the critical information needed to identify any further mitigation measures should picloram use be found to affect any sensitive habitat/endangered species.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA

regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions For Use:

"Only for formulation into an _____ [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide uses(s)] for the following uses(s): _____ (fill blank only with those uses that are being supported by MP registrant)."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s)."

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

a. Reduced Use Rates and Increased Intervals

- Labels must be amended to reflect the following changes in maximum application rates and treatment intervals:

    - the broadcast rate for range and pasture use is lowered from the current maximum of 2.0 lb. to 0.5 ae/A for control of broadleaf weeds and woody plants. For the control of noxious weeds, a broadcast application of up to 1.0 lb. ae/A may be used annually. Spot treatment will be lowered to a maximum of 1.0 lb. ae/A with no more than 50% of an acre being treated. Spot treatments and broadcast treatments can be applied during the same growing season only if the total amount applied does not exceed 1.0 ae/A per annual growing season.
    - the forestry use rate is lowered from a maximum of 2.2 lb.'s ae/A to 1.0 lb. ae/A for spot and broadcast treatment. Use is allowed only once every 2 years.
    - the rights-of-ways use rate is lowered from a maximum of 2.2 lb. ae/A to 1 lb. ae/A annually.

b. Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing picloram:

- **Personal Protective Equipment for Handlers (mixers, loaders, applicators, etc.)** :

The minimum (baseline) handler personal protective equipment (PPE) for all WPS and nonWPS uses of picloram end-use products is chemical-resistant gloves. The remaining PPE for handlers is to be based on the toxicity of the end-use product. See PR Notice 93-7 or more recent Agency guidance for instructions on establishing PPE for occupational handlers.

- **Entry Restrictions for Occupational-Use Products (WPS uses):**

The Agency is establishing a 12-hour restricted-entry interval (REI). Personal protective equipment required for WPS-permitted early entry into treated areas that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls, chemical-resistant gloves, socks, and shoes.

- **Entry Restrictions for Occupational-Use Products (NonWPS Uses):**

For nonWPS uses of picloram the Agency is requiring the following: "Do not enter or allow others to enter the treated area until sprays have dried."

The following statements are required on all picloram end-use product labeling:

Application Restrictions:
"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:
"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the WPS (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:
"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:
"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

In addition, because picloram potassium salt, picloram isooctyl ester, and picloram triisopropanolamine salt are classified as skin sensitizers, the following statement is required in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products containing picloram in those forms:

"Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals."

Type of Respirator: If the acute inhalation toxicity of the end-use product is in category I or II, a respirator is required for pesticide handlers. The following type of respirator is appropriate to mitigate picloram inhalation concerns:

"A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

c. Spray Drift Labelling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produced larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for

aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of the smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions)

indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away form the sensitive areas).

d. Ground Water Statements

The following ground water advisory language must be placed on all picloram labels:

> "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."

e. Surface Water Statements

The following surface water advisory language must be placed on all picloram labels:

> "This chemical can contaminate surface water through spray drift. Under some conditions, picloram may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."

f. Phytotoxicity Statements

The following phytotoxicity advisory language must be placed on all picloram labels:

"This pesticide is toxic to some plants at very low concentrations. Non-target plants may be adversely affected if pesticide is allowed to drift from areas of application."

Precautionary hazard labelling should include the following based on PR Notice 93-3.

"Do not apply this product to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark."

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"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell picloram 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 Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	@ Max. Rate Max. /crop cycle	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES:													
FOOD/FEED USES													
PASTURES				Use Group: TERRESTRIAL FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
Broadcast., Foliar., Ground.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
RANGELAND				Use Group: TERRESTRIAL FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
Broadcast., Foliar., Ground.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.54 lb (AE) A	*	NS	NS	NS	NS	NS	NS	AL, AR, GA, LA, MS, NM, OK, TX		C46, CAE, G01(7), H12(30), S09(3)
NON-FOOD/NON-FEED													
FOREST PLANTINGS (REFORESTATION PROGRAMS)				Use Group: FORESTRY									
Broadcast., Foliar., Aircraft.	SC/L	NA	1.62 lb (AE) A	*	NS	NS	NS	NS	NS	NS			C46, CAE
Broadcast., Foliar., Ground.	SC/L	NA	1.62 lb (AE) A	*	NS	NS	NS	NS	NS	NS			C46, CAE
FOREST TREES (ALL OR UNSPECIFIED)				Use Group: FORESTRY									
Frill treatment., When needed., Oil can (or other stream type applicator).	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			C46, CAE
Frill treatment., When needed., Paintbrush.	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Frill treatment., When needed., Squirt bottle.	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES												
NON-FOOD/NON-FEED (con't)												
FOREST TREES (ALL OR UNSPECIFIED) (con't)				Use Group: FORESTRY (con't)								
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, CAE
Girdle treatment., When needed., Oil can (or other stream type applicator).	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, CAE
Girdle treatment., When needed., Paintbrush.	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Girdle treatment., When needed., Squirt bottle.	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, CAE
Stump treatment., When needed., Paintbrush.	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, C58, CAE
Stump treatment., When needed., Sprayer.	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, C58, CAE
Tree injection treatment., When needed., Tree injection equipment.	RTU	NA		UC	* NS NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
	SC/L	NA		UC	* NS NS	NS	NS	NS	NS			C46, C58, CAE
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast., Foliar., Ground.	SC/L	NA	1.08 lb (AE) A	*	NS NS	NS	NS	NS	NS			C46, CAE

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	@	Max. # Apps Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES														
NON-FOOD/NON-FEED (con't)														
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)														
Frill treatment., When needed., Oil can (or other stream type applicator).	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Frill treatment., When needed., Paintbrush.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Frill treatment., When needed., Squirt bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Girdle treatment., When needed., Oil can (or other stream type applicator).	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Girdle treatment., When needed., Paintbrush.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Girdle treatment., When needed., Squirt bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	1.08 lb (AE) A		*	NS	NS	NS	NS	NS	NS			C46, CAE
Stump treatment., When needed., Paintbrush.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Stump treatment., When needed., Sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE
Tree injection treatment., When needed., Tree injection equipment.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS	AL, AR, DE, FL, GA, LA, MD, MS, NC, OK, SC, TN, TX, VA		CAE

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LEGEND
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HEADER ABBREVIATIONS
Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
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 noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
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
M : Medium
F : Fine
O : Others

FORMULATION CODES
RTU : LIQUID-READY TO USE
SC/L : SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : 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, 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, tablet, 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
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C58 : May be applied undiluted.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
G01 : __ day(s) pregrazing interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AL : Alabama
AR : Arkansas
DE : Delaware
FL : Florida
GA : Georgia
LA : Louisiana
MD : Maryland
MS : Mississippi
NC : North Carolina
NM : New Mexico
OK : Oklahoma
SC : South Carolina
TN : Tennessee
TX : Texas
VA : Virginia

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. Dose /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
NON-FOOD/NON-FEED													
FOREST TREES (ALL OR UNSPECIFIED)				Use Group: FORESTRY									
Basal bark and soil treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Low volume sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
INDUSTRIAL AREAS (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP									
Basal bark and soil treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
NON-FOOD/NON-FEED (con't)													
INDUSTRIAL AREAS (OUTDOOR) (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Basal bark treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Low volume sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP									
Basal bark and soil treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Low volume sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Basal bark and soil treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark and soil treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Basal bark and soil treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., Not on label., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Backpack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Knapsack sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Low volume sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13
Basal bark treatment., When needed., Power sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS		C13

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
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 noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
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
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: 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, 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, tablet, 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
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C13 : Groundwater restriction.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
FOOD/FEED USES													
AGRICULTURAL FALLOW/IDLELAND				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast., Fallow., Aircraft.	SC/L	NA	.25 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., Fallow., Low pressure ground.	SC/L	NA	.25 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., Foliar., Aircraft.	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., Postharvest., Aircraft.	SC/L	NA	.25 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., Postharvest., Low pressure ground.	SC/L	NA	.25 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Spot treatment., Fallow., Sprayer.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Spot treatment., Foliar., Sprayer.	SC/L	NA	2 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Spot treatment., Postharvest., Sprayer.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Wipe-on/wiper treatment., Foliar., Wick applicator.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
BARLEY				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.023 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14), G83(14), H01(50)
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.023 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14), G83(14), H01(50)
OATS				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14), G83(14), H01(50)
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14), G83(14), H01(50)
PASTURES				Use Group: TERRESTRIAL FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14)
	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX		C13, C46
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE, G01(14)
	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	OK, NM, TX		C13, C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
FOOD/FEED USES (con't)													
PASTURES (con't)				Use Group: TERRESTRIAL FEED CROP (con't)									
Frill treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
Girdle treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Spot soil treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	OK, TX NM	C13, C46
Spot treatment., Foliar., Low pressure ground.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), G83(14), S09(14)
Spot treatment., Foliar., Sprayer.	SC/L	NA	2 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
Tree injection treatment., Foliar., Tree injection equipment.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
Wipe-on/wiper treatment., Foliar., Roller.	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Wipe-on/wiper treatment., Foliar., Wick applicator.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
RANGELAND				Use Group: TERRESTRIAL FEED CROP									
Broadcast., Foliar., Aircraft.	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Frill treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
Girdle treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Spot soil treatment., Foliar., Not on label.	SC/L	NA		UC	*	NS	NS	NS	NS	NS	NS	OK, TX NM	C13, C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES												
FOOD/FEED USES (con't)												
RANGELAND (con't)				Use Group: TERRESTRIAL FEED CROP (con't)								
Spot treatment., Foliar., Low pressure ground.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
Spot treatment., Foliar., Sprayer.	SC/L	NA	2 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
Tree injection treatment., Foliar., Tree injection equipment.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI	C46, CAE, G01(14), S09(14)
Wipe-on/wiper treatment., Foliar., Roller.	SC/L	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS	NM, OK, TX	C13, C46
Wipe-on/wiper treatment., Foliar., Wick applicator.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), S09(3)
WHEAT				Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast., Foliar., Aircraft.	SC/L	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), H01(50)
Broadcast., Foliar., Low pressure ground.	SC/L	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE, G01(14), G83(14), H01(50)
NON-FOOD/NON-FEED												
FOREST PLANTINGS (REFORESTATION PROGRAMS)				Use Group: FORESTRY								
Broadcast., Foliar., Aircraft.	SC/L	NA	1.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE
Broadcast., Foliar., Ground.	SC/L	NA	1.5 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast., When needed., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE
	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE
Broadcast., When needed., Ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE
Broadcast., When needed., Low pressure ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011	C46, CAE
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE
Spot treatment., When needed., Sprayer.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS		CAE

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
	SC/L	NA	2 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Wipe-on/wiper treatment., When needed., Wick applicator.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast., When needed., Aircraft.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Broadcast., When needed., Low pressure ground.	SC/L	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Directed spray., When needed., Low pressure ground.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI		C46, CAE, G01(14), S09(14)
Frill treatment., When needed., Not on label.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI		C46, CAE, G01(14), S09(14)
Girdle treatment., When needed., Not on label.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI		C46, CAE, G01(14), S09(14)
Spot treatment., When needed., Sprayer.	SC/L	NA	2 lb (AE) A	*	NS	NS	NS	NS	NS	NS	011		C46, CAE
Tree injection treatment., When needed., Tree injection equipment.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	HI		C46, CAE, G01(14), S09(14)
Wipe-on/wiper treatment., When needed., Wick applicator.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	011		C46, CAE

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
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 noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
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
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: 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, 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, tablet, 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
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C13 : Groundwater restriction.
C46 : Do not apply through any type of irrigation system.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
G01 : __ day(s) pregrazing interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

011 : West of the Mississippi River
HI : Hawaii
NM : New Mexico
OK : Oklahoma
TX : Texas

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 0096 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0096 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. Data Requirement (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. Use Pattern (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. Bibliographic citation (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

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	CSF, dated 11/02/93
61-2A	**Start. Mat. & Mnfg. Process**	All	41094901
61-2B	**Formation of Impurities**	All	41094901
62-1	**Preliminary Analysis**	All	41094902
62-2	**Certification of limits**	All	CSF, dated 11/02/93
62-3	**Analytical Method**	All	41094902
63-2	**Color**	All	41094903
63-3	**Physical State**	All	41094903
63-4	**Odor**	All	41094903
63-5	**Melting Point**	All	41094903
63-6	**Boiling Point**	All	N/A
63-7	**Density**	All	41094903
63-8	**Solubility**	All	41094903
63-9	**Vapor Pressure**	All	41094903
63-10	**Dissociation Constant**	All	41094903
63-11	**Octanol/Water Partition**	All	41094903
63-12	**pH**	All	41094903
63-13	**Stability**	All	41094903

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A/B	**Acute Avian Oral - Quail/Duck**	A,B,C,J	00261883, 00265983, 40054501, 00157173
71-2A	**Avian Dietary - Quail**	A,B,C,J	22923
71-2B	**Avian Dietary - Duck**	A,B,C,J	22923
72-1A	**Fish Toxicity Bluegill**	A,B,C,J	00129076, 00129078, 00112016
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,J	112016
72-2A	**Invertebrate Toxicity**	A,B,C,J	00129076, 00141979, 00151783, 40094602
72-3A	**Estuarine/Marine Toxicity - Fish**	A,B,C,J	00111560, 00129073
72-4A	**Early Life Stage Fish**	A,B,C,J	129085
72-4B	**Life Cycle Invertebrate**	A,B,C,J	151784
72-6	**Aquatic Organism Accumulation**	A,B,C,J	128947
123-1A	**Seed Germination/Seedling Emergence**	A,B,C,J	See Potassium Salt
123-1B	**Vegetative Vigor**	A,B,C,J	See Potassium Salt
123-2	**Aquatic Plant Growth**	A,B,C,J	See Potassium Salt
141-1	**Honey Bee Acute Contact**	A,B,C,J	36935
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,J	40479413
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,J	40479414
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,J	40479415
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,J	40479416

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,J	40479417
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,J	40479418
82-1A	**90-Day Feeding - Rodent**	A,B,C,J	110537
82-1B	**90-Day Feeding - Non-rodent**	A,B,C,J	110534
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C,J	41384901
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C,J	00155940, 42619302
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,J	40834301
83-2A	**Oncogenicity - Rat**	A,B,C,J	00155940, 42619302
83-2B	**Oncogenicity - Mouse**	A,B,C,J	42619301
83-3A	**Developmental Toxicity - Rat**	A,B,C,J	41382502
83-3B	**Developmental Toxicity - Rabbit**	A,B,C,J	41069501
83-4	**2-Generation Reproduction - Rat**	A,B,C,J	42078701
84-2A	**Gene Mutation (Ames Test)**	A,B,C,J	41485902
84-2B	**Structural Chromosomal Aberration**	A,B,C,J	40072601, 00098322
84-4	**Other Genotoxic Effects**	A,B,C,J	41549701
85-1	**General Metabolism**	A,B,C,J	41209602, 00098321

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,C,J	164749
161-2	**Photodegradation - Water**	A,B,C,J	00164943, 41092501
161-3	**Photodegradation - Soil**	A,B,C,J	41260101
162-1	**Aerobic Soil Metabolism**	A,B,C,J	128976
162-2	**Anaerobic Soil Metabolism**	A,B,C	128976
162-3	**Anaerobic Aquatic Metabolism**	A,B,C,J	128976
163-1	**Leaching/Adsorption/Desorption**	A,B,C,J	00111473, 41209601
163-2	**Volatility - Lab**	A,B	Waived
163-3	**Volatility - Field**	A,B	Waived
164-1	**Terrestrial Field Dissipation**	A,B,C	42579002, 42579001, 42535302, 42448302
164-3	**Forest Field Dissipation**	J	42579003, 41395301
164-5	**Long Term Soil Dissipation**	A,B,C,J	Reserved
165-1	**Confined Rotational Crop**	A,B,C	42641801
165-2	**Field Rotational Crop**	A,B,C	Reserved
165-4	**Bioaccumulation in Fish**	A,B,C,J	128947
165-5	**Bioaccumulation - Aquatic NonTarget**	A,B,C,J	Reserved
166-1	**Ground Water - Small Prospective**	A,B,C,J	Reserved
166-2	**Ground Water - Small Retrospective**	A,B,C,J	Reserved
201-1	**Droplet Size Spectrum**	A,B,C,J	DATA GAP
202-1	**Drift Field Evaluation**	A,B,C,J	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	00037880, 00041136, 00059411, 00111527, 00157171, 42579004
171-4B	**Nature of Residue - Livestock**	A,B	00023105, 00041125, 00161306, 00163216, 42535301
171-4C/D	**Residue Analytical Method - Plants and Animals**	A,B	00026748, 00026749, 00026750, 00026751, 00026752, 00026753, 00027288, 00035959, 00045363, 00045366, 00045373, 00045374, 00045375, 00045376, 00045409, 00062818, 00069973, 00073972, 00073974, 00078483, 00085060, 00111404, 00111407, 00131364, 00132986, 00156366, 42380201
171-4E	**Storage Stability**	A,B	00164725, 40082701, 40435601, 40731901, 41442301, 41976701, 42494001
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	00045374, 00045376, 00073973, 00045372, 00073921, 00035959

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K	**Crop Field Trials:**		
	Barley grain	A,B	00036168, 00036170, 00036171, 00045369, 00128714, 42380201
	Oat grain	A,B	00036168, 00036170, 00036171, 00045369, 00128714, 42380201
	Wheat grain	A,B	00036168, 00036170, 00036171, 00045369, 00128714, 42380201
	Barley forage and straw	B	00036168, 00036170, 00036171, 00128714, 42380201
	Oat forage and straw	B	00036168, 00036170, 00036171, 00128714, 42380201
	Wheat forage and straw	B	00036168, 00036170, 00036171, 00128714, 42380201
	Grass forage	B	00108862, 00108864, 00111404, 00111470, 00111482, 00111557, 00128714, 00156366, 41905401, 42037601, 42784401
	Flax seed	B	00026753, 00085060
	Flax straw	B	00026753, 00085060

Data Supporting Guideline Requirements for the Reregistration of Picloram Acid (005101)

REQUIREMENT		USE PATTERN	CITATION(S)
171-4L	**Processed Food:**		
	Wheat	A	42535303

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Triisopropanolamine Picloram (005102)

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	N/A
61-2A	**Start. Mat. & Mnfg. Process**	All	41594601
61-2B	**Formation of Impurities**	All	43065001, 41594601
62-1	**Preliminary Analysis**	All	43065001, 41594602
62-2	**Certification of limits**	All	N/A
62-3	**Analytical Method**	All	N/A
63-2	**Color**	All	42840803
63-3	**Physical State**	All	42840803
63-4	**Odor**	All	42840803
63-5	**Melting Point**	All	42840803
63-6	**Boiling Point**	All	N/A
63-7	**Density**	All	42840803
63-8	**Solubility**	All	43307401, 43027801
63-9	**Vapor Pressure**	All	Letter (1993) from G. Murphy, DowElano
63-10	**Dissociation Constant**	All	42840809
63-11	**Octanol/Water Partition**	All	43065001
63-12	**pH**	All	42840803
63-13	**Stability**	All	42840803

Data Supporting Guideline Requirements for the Reregistration of Triisopropanolamine Picloram (005102)

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
72-3D	**Estuarine/Marine Toxicity Fish-TEP**	A,B,C,J	**DATA GAP**
72-4A	**Early Life Stage Fish**	A,B,C,J	**DATA GAP**
123-1A	**Seed Germination/Seedling Emergence**	A,B,C,J	41296501, 43276601, **DATA GAP**
123-1B	**Vegetative Vigor**	A,B,C,J	41296501, 43276601, **DATA GAP**
123-2	**Aquatic Plant Growth**	A,B,C,J	41407701, **DATA GAP**
141-1	**Honey Bee Acute Contact**	A,B,C,J	41366901
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,J	41381201
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,J	41381203
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,J	41381204
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,J	41381205
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,J	41381206
82-1A	**90-Day Feeding - Rodent**	A,B,C,J	41442701
82-1B	**90-Day Feeding - Non-rodent**	A,B,C,J	Waived
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C,J	41384902
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C,J	41442701

Data Supporting Guideline Requirements for the Reregistration of Triisopropanolamine Picloram (005102)

REQUIREMENT		USE PATTERN	CITATION(S)
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,J	Reserved
83-2A	**Oncogenicity - Rat**	A,B,C,J	Reserved
83-2B	**Oncogenicity - Mouse**	A,B,C,J	Reserved
83-3A	**Developmental Toxicity - Rat**	A,B,C,J	41382504
83-3B	**Developmental Toxicity - Rabbit**	A,B,C,J	42460901
83-4	**2-Generation Reproduction - Rat**	A,B,C,J	Reserved
84-2A	**Gene Mutation (Ames Test)**	A,B,C,J	41485901
84-2B	**Structural Chromosomal Aberration**	A,B,C,J	41539701
84-4	**Other Genotoxic Effects**	A,B,C,J	41539702
85-1	**General Metabolism**	A,B,C,J	42343101
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,C,J	See Picloram Acid
161-2	**Photodegradation - Water**	A,B,C,J	See Picloram Acid
161-3	**Photodegradation - Soil**	A,B,C,J	See Picloram Acid
162-1	**Aerobic Soil Metabolism**	A,B,C,J	See Picloram Acid
162-2	**Anaerobic Soil Metabolism**	A,B,C	See Picloram Acid
162-3	**Anaerobic Aquatic Metabolism**	A,B,C,J	See Picloram Acid
163-1	**Leaching/Adsorption/Desorption**	A,B,C,J	See Picloram Acid
163-2	**Volatility - Lab**	A,B	Waived

Data Supporting Guideline Requirements for the Reregistration of Triisopropanolamine Picloram (005102)

REQUIREMENT		USE PATTERN	CITATION(S)
163-3	**Volatility - Field**	A,B	Waived
164-1	**Terrestrial Field Dissipation**	A,B,C,J	See Picloram Acid
164-3	**Forest Field Dissipation**	J	See Picloram Acid
164-5	**Long Term Soil Dissipation**	A,B,C,J	Reserved
165-1	**Confined Rotational Crop**	A,B,C	See Picloram Acid
165-2	**Field Rotational Crop**	A,B,C	Reserved
165-4	**Bioaccumulation in Fish**	A,B,C,J	See Picloram Acid
165-5	**Bioaccumulation - Aquatic NonTarget**	A,B,C,J	Reserved
166-1	**Ground Water - Small Prospective**	A,B,C,J	Reserved
166-2	**Ground Water - Small Retrospective**	A,B,C,J	Reserved
166-3	**Ground Water - Irrigated Retrospective**		Not Applicable
201-1	**Droplet Size Spectrum**	A,B,C,J	DATA GAP
202-1	**Drift Field Evaluation**	A,B,C,J	DATA GAP
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	See Picloram Acid
171-4B	**Nature of Residue - Livestock**	A,B	See Picloram Acid
171-4C	**Residue Analytical Method - Plants**	A,B	See Picloram Acid
171-4D	**Residue Analytical Method - Animal**	A,B	See Picloram Acid

Data Supporting Guideline Requirements for the Reregistration of Triisopropanolamine Picloram (005102)

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	**Storage Stability**	A,B	See Picloram Acid
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	See Picloram Acid
171-4K	**Crop Field Trials**	A,B	See Picloram Acid
171-4L	**Processed Food**	A,B	See Picloram Acid

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Isooctyl Picloram (005103)

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	N/A
61-2A	**Start. Mat. & Mnfg. Process**	All	41094904
61-2B	**Formation of Impurities**	All	41094904
62-1	**Preliminary Analysis**	All	42840811
62-2	**Certification of limits**	All	N/A
62-3	**Analytical Method**	All	N/A
63-2	**Color**	All	42840804
63-3	**Physical State**	All	42840804
63-4	**Odor**	All	42840804
63-5	**Melting Point**	All	42840804
63-6	**Boiling Point**	All	N/A
63-7	**Density**	All	42840804
63-8	**Solubility**	All	42840808, 42840810
63-9	**Vapor Pressure**	All	42840806
63-10	**Dissociation Constant**	All	N/A
63-11	**Octanol/Water Partition**	All	42840807
63-12	**pH**	All	N/A
63-13	**Stability**	All	42840804
ECOLOGICAL EFFECTS			

Data Supporting Guideline Requirements for the Reregistration of Isooctyl Picloram (005103)

REQUIREMENT		USE PATTERN	CITATION(S)
71-2A	**Avian Dietary - Quail**	C,J	00265982, 00164726
72-1A	**Fish Toxicity Bluegill**	C,J	40094602
72-1B	**Fish Toxicity Bluegill - TEP**	C,J	**DATA GAP**
72-1D	**Fish Toxicity Rainbow Trout- TEP**	C,J	**DATA GAP**
72-2B	**Invertebrate Toxicity - TEP**	C,J	**DATA GAP**
72-3D	**Estuarine/Marine Toxicity Fish-TEP**	C,J	**DATA GAP**
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	C,J	**DATA GAP**
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	C,J	**DATA GAP**
72-4A	**Early Life Stage Fish**	C,J	**DATA GAP**
123-1A	**Seed Germination/Seedling Emergence**	C,J	41296501, 43276601, **DATA GAP**
123-1B	**Vegetative Vigor**	C,J	41296501, 43276601, **DATA GAP**
123-2	**Aquatic Plant Growth**	C,J	42645901, **DATA GAP**
141-1	**Honey Bee Acute Contact**	C,J	42121107, 42625901
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	C,J	40479407
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	C,J	40479408
81-3	**Acute Inhalation Toxicity - Rat**	C,J	40479409
81-4	**Primary Eye Irritation - Rabbit**	C,J	40479410

Data Supporting Guideline Requirements for the Reregistration of Isooctyl Picloram (005103)

REQUIREMENT		USE PATTERN	CITATION(S)
81-5	**Primary Dermal Irritation - Rabbit**	C,J	40479411
81-6	**Dermal Sensitization - Guinea Pig**	C,J	40479412
82-1A	**90-Day Feeding - Rodent**	C,J	42297001
82-1B	**90-Day Feeding - Non-rodent**	C,J	Waived
82-2	**21-Day Dermal - Rabbit/Rat**	C,J	42171601, 42870701
83-1A	**Chronic Feeding Toxicity - Rodent**	C,J	Reserved
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	C,J	Reserved
83-2A	**Oncogenicity - Rat**	C,J	Reserved
83-2B	**Oncogenicity - Mouse**	C,J	Reserved
83-3A	**Developmental Toxicity - Rat**	C,J	42121102, 42296901
83-3B	**Developmental Toxicity - Rabbit**	C,J	42121103, 42121104
83-4	**2-Generation Reproduction - Rat**	C,J	Reserved
84-2A	**Gene Mutation (Ames Test)**	C,J	42121106
84-2B	**Structural Chromosomal Aberration**	C,J	42171602
84-4	**Other Genotoxic Effects**	C,J	42414001
85-1	**General Metabolism**	C,J	42171603
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
231	**Estimation of Dermal Exposure at Outdoor Sites**	C,J	**DATA GAP**

REQUIREMENT		USE PATTERN	CITATION(S)
232	**Estimation of Inhalation Exposure at Outdoor Sites**	C,J	**DATA GAP**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	C,J	131365
161-2	**Photodegradation - Water**	C,J	42811901
161-3	**Photodegradation - Soil**	C,J	See Picloram Acid
162-1	**Aerobic Soil Metabolism**	C,J	40178601
162-2	**Anaerobic Soil Metabolism**	C	See Picloram Acid
162-3	**Anaerobic Aquatic Metabolism**	C,J	Waived
163-1	**Leaching/Adsorption/Desorption**	C,J	See Picloram Acid
163-2	**Volatility - Lab**	C,J	Waived
163-3	**Volatility - Field**	C,J	Waived
164-1	**Terrestrial Field Dissipation**	C	See Picloram Acid
164-2	**Aquatic Field Dissipation**	C,J	Not Applicable
164-3	**Forest Field Dissipation**	J	See Picloram Acid
164-5	**Long Term Soil Dissipation**	C,J	Reserved
165-3	**Accumulation - Irrigated Crop**	C,J	Not Applicable
165-4	**Bioaccumulation in Fish**	C,J	42121108
165-5	**Bioaccumulation - Aquatic NonTarget**	C,J	Reserved
166-1	**Ground Water - Small Prospective**	C,J	Reserved

Data Supporting Guideline Requirements for the Reregistration of Isooctyl Picloram (005103)

REQUIREMENT		USE PATTERN	CITATION(S)
166-2	**Ground Water - Small Retrospective**	C,J	Reserved
201-1	**Droplet Size Spectrum**	C,J	**DATA GAP**
202-1	**Drift Field Evaluation**	C,J	**DATA GAP**

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Potassium Picloram (005104)

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	41094907, CSF dated 12-2-94
61-2A	**Start. Mat. & Mnfg. Process**	All	41094907
61-2B	**Formation of Impurities**	All	41094907, CSF dated 12-2-94
62-1	**Preliminary Analysis**	All	41094908, 43065001
62-2	**Certification of limits**	All	41094908
62-3	**Analytical Method**	All	41094908
63-2	**Color**	All	42840801
63-3	**Physical State**	All	42840801
63-4	**Odor**	All	42840801
63-5	**Melting Point**	All	42840801
63-6	**Boiling Point**	All	N/A
63-7	**Density**	All	42840801
63-8	**Solubility**	All	42978101
63-9	**Vapor Pressure**	All	Letter (1993) from G. Murphy, DowElanco
63-10	**Dissociation Constant**	All	42840809
63-11	**Octanol/Water Partition**	All	43065001
63-12	**pH**	All	42840801
63-13	**Stability**	All	42840801

Data Supporting Guideline Requirements for the Reregistration of Potassium Picloram (005104)

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A/B	**Acute Avian Oral - Quail/Duck**	A,B,C,J	00157174, 00164726, 00164727
71-2A	**Avian Dietary - Quail**	A,B,C,J	164727
71-2B	**Avian Dietary - Duck**	A,B,C,J	See Picloram Acid
72-1A	**Fish Toxicity Bluegill**	A,B,C,J	00129063, 00041475
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,J	00129063, 00041475
72-2A	**Invertebrate Toxicity**	A,B,C,J	151783
72-3D	**Estuarine/Marine Toxicity Fish-TEP**	A,B,C,J	**DATA GAP**
72-4A	**Early Life Stage Fish**	A,B,C,J	151784
72-4B	**Life Cycle Invertebrate**	A,B,C,J	151783
123-1A	**Seed Germination/Seedling Emergence**	A,B,C,J	43276601, **DATA GAP**
123-1B	**Vegetative Vigor**	A,B,C,J	43276601, **DATA GAP**
123-2	**Aquatic Plant Growth**	A,B,C,J	41407702, **DATA GAP**
141-1	**Honey Bee Acute Contact**	A,B,C,J	41366902
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,J	40479401
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,J	40479402
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,J	40479403

Data Supporting Guideline Requirements for the Reregistration of Potassium Picloram (005104)

REQUIREMENT		USE PATTERN	CITATION(S)
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,J	40479404
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,J	40479405
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,J	40479406
81-7	**Acute Delayed Neurotoxicity - Hen**	A,B,C,J	Not Required
82-1A	**90-Day Feeding - Rodent**	A,B,C,J	110537
82-1B	**90-Day Feeding - Non-rodent**	A,B,C,J	110534
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C,J	41384901
82-3	**90-Day Dermal - Rodent**	A,B,C,J	Not Required
82-4	**90-Day Inhalation - Rat**	A,B,C,J	Not Required
82-5A	**90-Day Neurotoxicity - Hen**	A,B,C,J	Not Required
82-5B	**90-Day Neurotoxicity - Mammal**	A,B,C,J	Not Required
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C,J	155940
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,J	40834301
83-2A	**Oncogenicity - Rat**	A,B,C,J	42619302
83-2B	**Oncogenicity - Mouse**	A,B,C,J	42619301
83-3A	**Developmental Toxicity - Rat**	A,B,C,J	41382501, 41382502
83-3B	**Developmental Toxicity - Rabbit**	A,B,C,J	41069501
83-4	**2-Generation Reproduction - Rat**	A,B,C,J	42078701
84-2A	**Gene Mutation (Ames Test)**	A,B,C,J	41485902
84-2B	**Structural Chromosomal Aberration**	A,B,C,J	98322

REQUIREMENT		USE PATTERN	CITATION(S)
84-4	**Other Genotoxic Effects**	A,B,C,J	41549701
85-1	**General Metabolism**	A,B,C,J	00098321, 41209602
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
231	**Estimation of Dermal Exposure at Outdoor Sites**	A,B,C,J	**DATA GAP**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	A,B,C,J	**DATA GAP**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,C,J	See Picloram Acid
161-2	**Photodegradation - Water**	A,B,C,J	Waived, see Picloram Acid
161-3	**Photodegradation - Soil**	A,B,C,J	Waived, see Picloram Acid
162-1	**Aerobic Soil Metabolism**	A,B,C,J	See Picloram Acid
162-2	**Anaerobic Soil Metabolism**	A,B,C	See Picloram Acid
162-3	**Anaerobic Aquatic Metabolism**	A,B,C,J	See Picloram Acid
163-1	**Leaching/Adsorption/Desorption**	A,B,C,J	See Picloram Acid
163-2	**Volatility - Lab**	A,B	Waived
163-3	**Volatility - Field**	A,B	Waived
164-1	**Terrestrial Field Dissipation**	A,B,C,J	See Picloram Acid
164-3	**Forest Field Dissipation**	J	See Picloram Acid
164-5	**Long Term Soil Dissipation**	A,B,C,J	Reserved
165-1	**Confined Rotational Crop**	A,B,C	See Picloram Acid
165-4	**Bioaccumulation in Fish**	A,B,C,J	See Picloram Acid

REQUIREMENT		USE PATTERN	CITATION(S)
165-5	**Bioaccumulation - Aquatic NonTarget**	A,B,C,J	Reserved
166-1	**Ground Water - Small Prospective**	A,B,C,J	Reserved
166-2	**Ground Water - Small Retrospective**	A,B,C,J	Reserved
201-1	**Droplet Size Spectrum**	A,B,C,J	**Data Gap**
202-1	**Drift Field Evaluation**	A,B,C,J	**Data Gap**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	See Picloram Acid
171-4B	**Nature of Residue - Livestock**	A,B	See Picloram Acid
171-4C	**Residue Analytical Method - Plants**	A,B	See Picloram Acid
171-4D	**Residue Analytical Method - Animal**	A,B	See Picloram Acid
171-4E	**Storage Stability**	A,B	See Picloram Acid
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	See Picloram Acid
171-4K	**Crop Field Trials**	A,B	See Picloram Acid
171-4L	**Processed Food**	A,B	See Picloram Acid

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

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.

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42078701 Breslin, W.; Zielke, G.; Kociba, R. (1991) Picloram: Two-Generation on Diet Reproduction Study in Sprague-Dawley Rats: Lab Project Number: K-038323-057F0: K-038323-057F1W: K-038323-057F1. Unpublished study prepared by The Toxicology Research Lab. & The Dow Chemical Co. 1225 p.

42619301 Stott, W.; Yano, B.; Haut, K.; et al. (1992) Picloram: Two-year Dietary Oncogenicity Study in B6C3F1 Mice: Lab Project Number: K-038323-058. Unpublished study prepared by The Dow Chemical Co. 919 p.

42619302 Cosse, P.; Stebbins, K.; Sames, K.; et al. (1992) Picloram: Two-year Dietary Chronic Toxicity/Oncogenicity Study in Fischer 344 Rats: Lab Project Number: K-038323-056. Unpublished study prepared by The Dow Chemical Co. 983 p.

MRID **CITATION**

42840801 Murphy, G. (1993) Determination of Color, Physical State, Odor, Melting Point, Density, pH and Stability of Picloram Potassium Salt (K) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR93047. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 10 p.

42840809 Reim, R. (1993) Determination of the Conditional Acid Dissociation Constant of Picloram by Normal Pulse Polarography: Lab Project Number: ML-AL 89-040540R. Unpublished study prepared by The Dow Chemical Co. 10 p.

42978101 Murphy, G. (1993) Determination of Solubility of Picloram Potassium Salt (K) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR93049. Unpublished study prepared by DowElanco, Formulations Science Technology Lab. 17 p.

43065001 Murphy, G. (1993) Response to Letter Written by Walter I. Waldrop (Received 12/3/93): Subject: Picloram Registration Standard: Lab Project Number: GM122293A. Unpublished study prepared by DowElanco, Analytical and Product Chemistry. 8 p.

43276601 Schwab, D. (1994) Evaluating the Effects of Picloram on the Germination, Emergence, and Vegetative Vigor of Non-Target Terrestrial Plants: Final Report: Lab Project Number: 41404. Unpublished study prepared by ABC Laboratories, Inc. 137 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Picloram acid and its derivatives (Case # 0096). 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 Picloram acid and its derivatives 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. Picloram 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. Purpose

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. Applicability

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. Background

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. Relationship of this Notice to Other OPP Policy and Guidance

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 data 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 submitted 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 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 one study, they should be included as an appendix to that study.

- If such materials relate to more than one 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. Transmittal Document

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), §3(c)(2)(B) data call-in, §6(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 and 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. Individual Studies

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 com-plete 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 mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

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

a. Safety Studies. 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. Product Chemistry Studies. 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 series (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 §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. 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 study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

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.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or ©	Page 15
Supplemental Statement	Only if confidentiality is	Page 14

of Data Confidentiality Claims	claimed on a basis other than 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. Study title. 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. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). 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. Study Date. 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. Performing Laboratory Identification. 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. Supplemental Submissions. 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. Facts of Publication. 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 §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(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 pet-itions 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. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than 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. Reference to Previously Submitted Data

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 not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

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.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three 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. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four 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
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

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

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. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous corres-pondence 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 tran-smittal 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: _____
Signature Name

Company Name _____

Company Contact: _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

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

ATTACHMENT 3

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.

ATTACHMENT 4

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.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (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 REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
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)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(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	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§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 Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

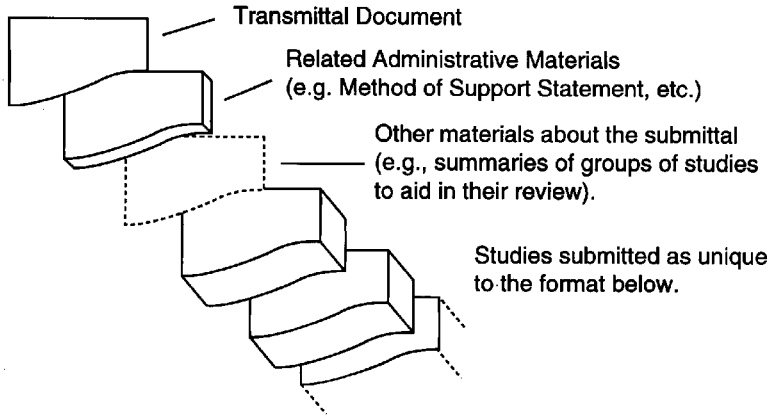
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

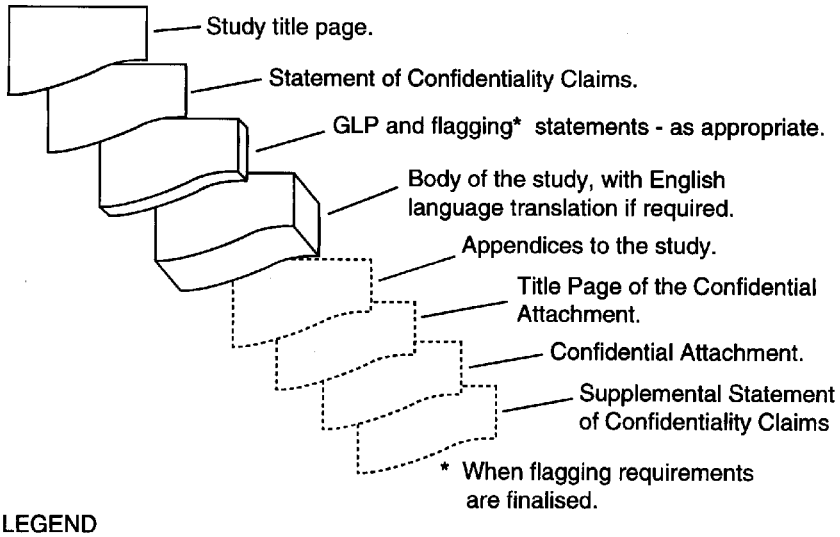
Submitter_____

ATTACHMENT 7.

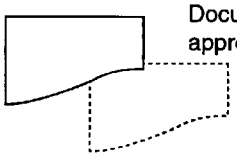
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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 l0(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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 Requirements Status and Reqistrant'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. Also included is a list of all 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 Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section 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 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data 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 Requirements Status and Registrant's Response Forms (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 Reqistrant'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 Reqistrant'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 Reqistrant'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 Reqistrant'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. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

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

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 Requirements Status and Registrant's Response Form 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 and proof of the other registrant's receipt of that offer (such as a certified mail receipt). 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)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In 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, all of the 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, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form 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 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 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)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing 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 registration number of the product for which data will be submitted must 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.1., 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.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response 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 Requirements Status and Registrant's Response Form 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 only 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 Requirements Status and Reqistrant's 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 after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless 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 registered a 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.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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 Requirements Status and Registrant's Response Forms (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,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

PICLORAM GENERIC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Picloram and its derivatives.

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 Picloram. 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 Picloram 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 Picloram are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Picloram are needed. These data are needed to fully complete the reregistration of all eligible Picloram 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 Venus Eagle at (703) 308-8045.

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

Venus Eagle, 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: Picloram

PICLORAM PRODUCT SPECIFIC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Picloram. 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 Picloram 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 Picloram are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Picloram 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 Picloram products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Picloram, please contact Venus Eagle at (703) 308-8045.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Emily Mitchell at (703) 308-8583.

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

Emily Mitchell
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: **Picloram**

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. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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 preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted 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.

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 response forms. You do not need to complete any item on the Requirements Status and 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 Requirements Status and Registrant's Response 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. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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 preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted 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 Requirements Status and Reqistrant's 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

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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	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 and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	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
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

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 apply 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 lowvolume 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

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S DECISION ON BATCHING PRODUCTS CONTAINING PICLORAM 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 picloram 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 5), 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, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table I lists the single batch for picloram.

Batch No.	EPA Reg. No.	% of Picloram	Formulation Type
1	62719-6	24.2	liquid
	62719-17	24.4	liquid
	62719-181	24.4	liquid

Table II lists the 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.

EPA Reg. No.	% of Picloram & other Active Ingredients	Formulation Type
62719-5	10.2 2,4-Dichlorophenoxyacetic acid: 39.6	liquid
62719-30	34.7	liquid
62719-31	5.4 2,4-Dichlorophenoxyacetic acid: 20.9	liquid
62719-57	17.1 Triclopyr: 32.5	liquid
62719-179	72.0	solid
62719-182	10.2	liquid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following 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.

3.____ 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%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

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.

9.____ 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).

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 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ 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.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ 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.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

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^3 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° C)
____ 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° 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

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

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ 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).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\underline{<}2$ or $\underline{>}11.5$.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ 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).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ 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.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In Notice (insert)

Attachment 7. Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame 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 Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - 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.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

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.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. 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.

j. 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).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
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.

Signature of Company's Authorized Representative	**Date**
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107,
2070-0057
Approval Expires
3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET