United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-96-006 March 1996

Reregistration Eligibility Decision (RED)

Desmedipham

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 desmedipham which includes the active ingredient ethyl m-hydroxycarbanilate carbanilate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, 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 ingredients 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 is due 90 days from the receipt of this letter. The second set of required responses is 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 Jeffrey Billingslea at (703) 308-8004.

Sincerely yours,

Lois Rossi, Division 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

Desmedipham

LIST B

CASE 2150

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DESMEDIPHAM REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Alan Halvorson	Economic Analysis Branch
James Saulman	Biological Analysis Branch
Thomas Harris	LUIS

Environmental Fate and Effects Risk Assessment

Stephanie Syslo	Environmental Risk Characterization Branch
Gail Maske	Environmental Fate and Groundwater Branch
Nick Mastrota	Environmental Risk Characterization Branch
William Effland	Environmental Risk Characterization Branch
David Wells	Environmental Risk Characterization Branch

Health Effects Risk Assessment

Arliene Aikens	Risk Characterization and Analysis Branch
Stephen Dapson	Toxicology Branch II
David Miller	Reregistration Support Chemistry Branch
Carol Lang	Occupational and Residential Exposure Branch
Brian Steinwand	Science Analysis Branch

Registration Support Risk Assessment

Karen Hicks	Registration Division Fungicide-herbicide Branch
Robert Taylor	Registration Division Fungicide-herbicide Branch

Risk Management

Richard Gebken	Accelerated Reregistration Branch

Office of Enforcement and Compliance:

Rick Colbert

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
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
FOB	Functional Observation Battery
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
LOEC	Lowest Observed Effect Concentration
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
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
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 © 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
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) addresses the pesticide ethyl m-hydroxy-carbanilate carbanilate (desmedipham) and the potential risks posed by the uses of all the currently registered products. Desmedipham, produced by AgrEvo USA Co., is a selective postemergence herbicide used to control various weeds in sugarbeets. It is also currently registered for special local need in one state for use on table beets and swiss chard for seed production.

The Agency has completed its review of the target database for desmedipham and has concluded that all currently registered uses as labeled and used as specified in this document will not pose unreasonable risks or adverse effects to humans or the environment. All currently registered pesticide uses of desmedipham are eligible for reregistration. However, the Agency is requiring additional data in the physical chemistry, residue chemistry, toxicology, environmental fate, and ecological effects disciplines to confirm this eligibility decision. Additionally, the Agency is requiring certain risk mitigation measures, including the use of personal protective equipment and aerial application drift management.

The Agency has determined that a preliminary classification of desmedipham as a group E chemical (non-carcinogenicity in humans) is appropriate. A Reference Dose (RfD) was established for chronic dietary exposure based on a parental toxicity endopont of concern in a rat reproduction study. The endpoint of concern for 1-day dietary exposure was based on developmental toxicity in rabbits. The Agency concludes that chronic and acute risks from dietary exposure to desmedipham are minimal.

Desmedipham has low to moderate acute mammalian toxicity. The short-term (1-7 days) occupational exposure endpoint of concern is based on developmental toxicity in rabbits. The intermediate-term (1 week to several months) occupational exposure endpoint of concern is based on parental toxicity in a rat reproduction study. Based on a dermal absorption study, dermal absorption is considered to be relatively low. The Agency concludes that occupational risks from exposure to desmedipham, mitigated by the use of personal protective equipment, are minimal.

The Agency has concluded that the risk to non target terrestrial and semiaquatic plants could not be fully assessed because of lack of testing using the typical end-use product (TEP). To be conservative, desmedipham should tentatively be assumed to pose risk to these plants through exposure from drift. The Agency is imposing additional Tier II studies for plant effects using a TEP and issuing guidance for aerial applications of desmedipham to reduce off-target spray drift and the potential environmental risks. The Agency has concluded that the use of desmedipham poses minimal risk of contamination of ground and surface water and to aquatic plants and animals. Also, acute risks to insects, birds and mammals are minimal. The chronic risk to birds is low to moderate and any effects are expected to be limited to local areas. The Agency also concludes that chronic risk to mammals is minimal.

Before reregistering the products containing desmedipham, the Agency is requiring that product specific data, revised Confidential Statements of Formula and revised labeling be

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

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" 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 desmedipham. The document consists of six sections. Section I is the introduction. Section II describes desmedipham, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for desmedipham . Section V discusses the reregistration requirements for desmedipham. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Desmedipham
- **Chemical Name:** Ethyl m-hydroxycarbanilate carbanilate
- **Chemical Family:** Carbanilate
- **CAS Registry Number:** CAS Reg. No. 13684-56-5
- **OPP Chemical Code:** 104801
- **Empirical Formula:** $C_{16}H_{16}N_2O_4$
- **Trade and Other Names:**
  3-((Ethoxycarbonyl)amino)phenyl N-phenylcarbamate,
  Carbamic acid, N-phenyl-, 3-((ethoxycarbonyl)amino)phenyl ester,
  Betanal-475,
  Betanex,
  EP 475,
  SN-475,
  SN-38107,
  Betamix 70 WP,
  Betanex 70 WP
- **Basic Manufacturer:** AgrEvo USA Co.
  Little Falls Centre One
  2711 Centerville Rd.
  Wilmington DE, 19808

B. Use Profile

Desmedipham is notable in that the area and distribution of its use is well defined. There is a Special Local Need registration in Washington for Swiss chard and table beets grown for seed which comprises an area of only 100 acres. The Federal registration is for sugarbeet production. This is concentrated in relatively small areas of the country, mostly in the northern Great Plains, Great Lakes region, Pacific Northwest, and California. About 150,000 to 200,000 acres are treated annually with desmedipham.

Type of Pesticide for Single Active Ingredient: HERBICIDE

Use Sites: TERRESTRIAL NON-FOOD CROP

Leafy and Stem Vegetables
* CHARD, SWISS (grown for seed)

Root Crop Vegetables
* TABLE BEETS (grown for seed)

TERRESTRIAL FOOD + FEED CROP

Sugar Crops
* SUGAR BEET

Target Pests for Desmedipham:

Weeds: Annual Sowthistle, Black Nightshade, Coast Fiddleneck, Common Chickweed, Common Lambsquarters, Common Ragweed, Groundcherry, London Rocket, Nettleleaf Goosefoot, Prostrate Pigweed, Purslane, Redroot Pigweed, Shepherdspurse, Wild Buckwheat, Wild Mustard.

Types/Formulations Registered:

TECHNICAL GRADE ACTIVE INGREDIENT: 97%

END USE PRODUCT FORMULATIONS
EMULSIFIABLE CONCENTRATE: 6%, 7%, 8%, 16%
WETTABLE POWDER: 35%, 70%

Methods and Rates of Application:

Types of Treatment: Band treatment; Broadcast

Equipment: Aircraft; Ground; Sprayer

Timing: Evening (for foliar applications)

C. Data Requirements

Data required to satisfy the reregistration database for desmedipham include studies on chemistry, ecological effects, environmental fate, toxicology, worker exposure, and residue chemistry. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

A Data Call-In under reregistration Phase IV was issued in April 1991, for desmedipham requiring additional chemistry, residue chemistry, toxicology, and ecological effects data to assess the potential for toxicity as a result of exposure to desmedipham. An additional Data Call-In was issued in September 1992, requiring data for the following guidelines based on the evaluation of submitted environmental fate data, persistence, use pattern and formulations of desmedipham:

71-4(a) Avian Reproduction-quail,
71-4(b) Avian Reproduction-duck.

This Reregistration Eligibility Decision reflects an assessment of all data and other available information before the Agency.

A Data Call-In was issued for desmedipham and many other pesticides in October 1995, as part of a post-application/reentry exposure requirement to satisfy the following guidelines:

132-1(a)	Foliar residue dissipation,
133-3	Dermal passive dosimetry exposure,
133-4	Inhalation passive dosimetry exposure.

These studies are considered outside of the target data requirements for reregistration. Once these data are submitted (due October 1997) the Agency will determine whether additional risk mitigation measures are appropriate for post-application exposures.

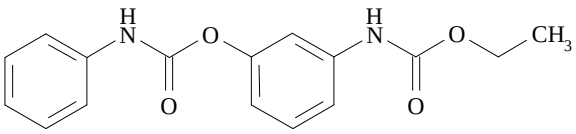
D. Regulatory History

Desmedipham was initially registered in the United States in November 1974, for use as a post-emergence herbicide. Currently there are 10 registered products containing desmedipham. There is also one Special Local Needs registration granted to the State of Washington (SLN WA95001900) for the table beet and Swiss chard seed production uses.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Desmedipham (ethyl-m-hydroxycarbanilate carbanilate) is a colorless to off-white crystalline solid with a melting point of 120° C. Technical desmedipham is nearly insoluble in water at 25° C, but is soluble in dichloromethane, ethyl acetate, methanol, and acetone. The molecular structure of desmedipham is:



Empirical Formula:	$C_{16}H_{16}N_2O_4$
Molecular Weight:	300.31
CAS Registry No.:	13684-56-5
Chemical Code:	104801

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for desmedipham is adequate to support the reregistration eligibility decision document.

a. Acute Toxicity

Table 1. Desmedipham Acute Toxicity

TEST (MRID)	RESULTS	CATEGORY	ACTIVE INGREDIENT (%)
Oral LD_{50}--Rat (00155581)	LD_{50} > 5000 mg/kg	IV	97.0
Dermal LD_{50}--Rat (00155582)	LD_{50} > 4000 mg/kg	III	97.0
Inhalation LC_{50}--Rat (41957102)	LC_{50} > 7.4 mg/L	IV	98.0
Eye irritation--Rabbit* (00155584)	Opacity and conjunctival irritation cleared by 72 hours	II	97.0
Dermal irritation--Rabbit* (00155583)	No irritation	IV	97.0
Dermal sensitization--Guinea Pig* (40312901)	A dermal sensitizer	N/A	98.0

* Not required for TGAI.

b. Subchronic Toxicity

1. In a 13-week oral toxicity study (MRID 40387102), technical grade desmedipham was fed to groups of 10 rats per sex at dose levels of 0, 300, 1200, or 4800 ppm in the diet for 13 weeks (equal to 0, 24, 97, and 415 mg/kg/day for males and 0, 27, 109, and 378 mg/kg/day for females, respectively).

Systemic toxicity was noted as lower body weight and body weight gains in males and females receiving the high dose as compared to the control during the 13-week test period. Body weights were also lower than control in the mid dose males during weeks 10 through 13. Food and water consumption were decreased in the high dose females. No effect was noted on mortality, clinical signs or on ophthalmologic examinations.

Absolute organ weights of the brain, heart, liver, kidneys, ovaries and adrenal glands were statistically significantly reduced in the high dose females. Absolute kidney weights were slightly decreased in the low and high dose males. Relative organ weights (to body weight) of the brain, heart, liver and kidney were slightly to moderately increased in both sexes in the high dose and mid dose females. Relative adrenal weights were slightly to moderately increased in both sexes in the high dose. Relative testes' weights were moderately increased in high dose males. The

toxicological significance of these organ weight changes is unknown, since there was no correlation between organ weight changes and histopathological observations.

Treatment related histopathological observations were noted in the spleen (hematopoiesis), thyroid glands (follicular hyperplasia), liver (hematopoiesis and pigmentation) and kidneys (pigmentation). The spleen was enlarged and dark red to black in color in all but one high dose male. Macrocytic normochromic anemia was observed in all treated animals. Dose related effects included methemoglobin formation, decreased erythrocyte counts, decreased hematocrit and hemoglobin concentration, and reticulocytosis. Hematological effects were seen in platelet and total leukocyte counts, mean corpuscular volume, mean corpuscular hemoglobin concentration, and Heinz body formation.

Treatment related effects on clinical chemistry parameters consisted of increased activities of aspartate and alanine aminotransferases, alkaline phosphatase and gamma-glutamyl transferase. Brain and plasma cholinesterase activities were reduced in mid and high dose females. Some minor effects were noted in levels of cholesterol, phosphorus, bilirubin and potassium. Dose related alterations in the plasma protein electrophoretic pattern in mid and high dose animals also occurred. The systemic toxicity LOEL is 24 mg/kg/day in males and 27 mg/kg/day in females based on effects on hematology and clinical chemistry parameters. The systemic toxicity NOEL is less than 24 mg/kg/day in males and less than 27 mg/kg/day in females.

2. In a 13-week oral (feeding) toxicity study (MRID 40387103), technical grade desmedipham was fed to groups of 25 male and female rats at dose levels of 0, 6, 30, 60 and 300 ppm in the diet for 13 weeks (equal to 0, 0.5, 2.6, 5.2 and 26.0 mg/kg/day for males and 0, 0.5, 2.7, 5.6 and 27.0 mg/kg/day for females, respectively).

Ten rats per sex per dose group were observed for an additional period (recovery) of 4 weeks to determine the reversibility of any parameter affected by treatment with the test compound. There was no effect of treatment on organ weights, body weight, food or water consumption, mortality, ophthalmologic examinations, gross pathology or histopathology.

Treatment related effects included increased methemoglobin formation throughout the treatment period in the high dose males and females. At weeks 16 or 17 of the recovery period, methemoglobin levels in the high dose females were similar to control but remained elevated in high dose males. Reticulocyte counts were increased at week 9 in high dose animals and at week 12 or 13 in high dose males. In addition, reticulocyte counts were slightly increased at week 16 or 17 of the recovery period in high dose animals. According to the investigators, the hematological effects of desmedipham reflected a slight oxidative injury to red blood cells, an effect that was reversible. Total thyroxine levels were slightly lower at week 12 or 13 for high dose animals and at week 16 or 17 of the recovery period in high dose males.

The systemic toxicity LOEL is 26 mg/kg/day in males and 27 mg/kg/day for females based on effects on hematology (increases in methemoglobin formation and reticulocyte counts)

and clinical chemistry (total thyroxine levels) parameters. The systemic toxicity NOEL is 5.2 mg/kg/day for males and 5.6 mg/kg/day for females.

In a 90-day dietary study (MRID 40387104), technical desmedipham was fed to groups of 4 beagle dogs per sex at dose levels of 0, 1, 5 or 150 ppm in the diet (equal to 0, 0.035, 0.17 and 4.97 mg/kg/day for males and 0, 0.035, 0.19 and 5.50 mg/kg/day for females respectively).

Treatment related increases in serum methemoglobin levels were observed at the high dose level. Pituitary cysts were found in 3 out of 4 high dose females. No other compound related effects were observed. The systemic toxicity LOEL is 4.97 mg/kg/day for males and 5.50 mg/kg/day for females and the systemic toxicity NOEL is 0.17 mg/kg/day for males and 0.19 mg/kg/day for females based on increases in serum methemoglobin levels.

3. In a 28-day feeding study (MRID 42045701) SPF-bred mice of the NMRI KFM-Han., outbred strain received 0, 100, 400, or 1600 ppm (equal to 0, 22, 91, and 416 mg/kg/day for males and 0, 26, 108, and 519 mg/kg/day for females, respectively) in the diet as a range finding study for the mouse carcinogenicity study.

No treatment related mortality or clinical observations were noted. There were slight differences in body weight gain in the mid and high dose males (9% and 13%, respectively) compared to control. There was an increase in food consumption and food efficiency in the high dose group during weeks 3 and 4 and overall in both sexes. The biological relevance of this observation is unclear.

Hematological observations were a dose related increase in Heinz body and methemoglobin formation in the mid and high dose groups. Other observations were a slight decrease in the erythrocyte count, hemoglobin concentration and hematocrit values in high dose males along with a slight reticulocytosis in high dose animals. Also observed were morphological changes in the erythrocytes as increased anisocytosis in mid dose males and high dose males and females and as increased polychromatophilia in high dose animals. The effects were referred to by the investigators as toxic hemolytic anemia. Further, spleen weights were increased in both males and females in the high dose group, supportive of the hematological observations.

The heart weights were increased in high dose animals (not absolute in males) and kidney weights were increased in high dose females only, probably not related to treatment. No treatment related macroscopic observations were noted. Microscopically there was a dose related increase in extra medullary hemopoiesis in the spleen, mainly in mid and high dose animals and bone marrow hyperplasia in high dose males. These observations were referred to by the investigators as reactive and compensatory processes in response to the hemolysis caused by the test compound. Other observations were singular in nature and not related to treatment.

The systemic toxicity LOEL is 91 mg/kg/day for males and 108 mg/kg/day for females based on hematological and related histopathological findings. The systemic toxicity NOEL is 22 mg/kg/day for males and 26 mg/kg/day for females.

4. In a 21-day dermal toxicity study (MRID 42124201), Betanex (16% desmedipham) was applied to the shaved skin of four groups of 10 male and 10 female rabbits each for 6 hours per day for 21 days at dosages of either 0, 60, 180, or 540 mg/kg body weight. A recovery group consisting of one-half of the animals from each group was treated an additional 2 days and was then observed treatment-free for 23 days.

No treatment related mortalities or clinical signs of toxicity occurred during the study. There was a dose-related increase in the incidence and severity of dermal lesions at the application site in the highest two dosage groups. No alterations in food consumption or body weight resulted from treatment. Hematology and clinical chemistry evaluations were not affected except for statistically significant decreases in thyroxine levels in the female rabbits in the highest two dosage groups.

The findings on gross necropsy and histopathology involved the dermal lesions. On gross examination, the lesions consisted of thickening of the skin, necroses, brown and red foci and nodules and eschar formation. Microscopically, there was a dose-related incidence of acanthosis, hyperkeratosis, dermal inflammatory cell infiltrates and epidermal ulceration (in the highest group only). The systemic toxicity LOEL is 180 mg/kg/day based on dermal lesions (gross and microscopic observations) and decreases in thyroxine levels. The systemic toxicity NOEL is 60 mg/kg/day.

c. Chronic and Carcinogenicity Toxicity

1. In a 2-year combined chronic toxicity/carcinogenicity study (MRID 40387107), desmedipham technical was administered to Wistar rats at dietary levels of 0, 60, 300, or 1500 ppm (equal to 0, 3.18, 15.71, and 79.90 mg/kg/day for males and 0, 3.86, 19.84, and 100.46 mg/kg/day for females, respectively). There were no effects of dosing on clinical signs or mortality. The mean body weights were persistently decreased in high-dose males and females with significant ($p < 0.05$) decreases at several study intervals; at study termination, the mean body weights in high-dose males and females were 4% and 13% lower than in controls, respectively. A dose-related hemolytic anemia was seen in both sexes. Methemoglobin formation was increased ($p < 0.05$) throughout the study in male and female mid and high dose groups. This was accompanied by an increase in Heinz bodies ($p < 0.05$) at all intervals of sampling in high-dose males and females.

Significant ($p < 0.05$) decreases were observed in erythrocyte counts, hemoglobin concentration, and hematocrit values in mid and high dose males and in high dose females. Reticulocyte counts were markedly increased in high-dose males and females throughout the study; slight but significant ($p < 0.05$) increases in reticulocyte counts were seen in most intervals in mid-dose males and females. Total bilirubin was slightly increased in high-dose groups at most intervals; the increases were significant ($p < 0.05$) in high-dose males at 12 months and in high-dose females at 12 and 24 months.

Mild effects on thyroid function were characterized by a decreased level of T4 in high-dose males and in mid- and high-dose females at both 12 and 24 months, as well as a slight decrease of T3 in mid- and high-dose females. Spleen weights (absolute and relative) were increased in high-dose males and females at 12 and 24 months. No increases were seen in the incidence of erythropoiesis and hemosiderosis in the spleen, but the severity increased with dosing. The incidence of hyperplastic changes in the thyroid was increased in dosed males, particularly at the high dose. Other histologic findings were considered to be spontaneous in origin. There was no increase in tumors noted.

The systemic toxicity LOEL is 15.71 mg/kg/day for males and 19.84 mg/kg/day for females based primarily on the anemia. The systemic toxicity NOEL is 3.18 mg/kg/day for males and 3.86 mg/kg/day in females.

2. In a 12-month oral toxicity study (feeding) (MRID 00156889), desmedipham was administered to beagle dogs for 1 year at dietary levels of 0, 300, 1500, and 5000 ppm (equal to 0, 9.6, 52.5, and 167.7 mg/kg/day for males and 0, 10.4, 57.4, and 200.7 mg/kg/day for females, respectively). For the first 28 days, the high-dose level was 7500 ppm and this was reduced to 5000 ppm because of weight loss and marked toxicity. Two dogs at the high dose were sacrificed moribund and one died. Mean weights in high-dose males recovered to the control level but mean weights in mid- and high-dose females were slightly decreased throughout the study.

There was a dose-related increase in methemoglobin in males and females which was significant ($p < 0.01$) in mid- and high-dose groups and an increase in Heinz bodies in the high-dose group. Red cell counts, hematocrit, and hemoglobin were decreased and mean corpuscular hemoglobin increased primarily in the high-dose groups. There was an erythrogenic response indicated by an increase in reticulocyte counts and morphologic changes of erythrocytes as well as an increase in erythrocyte precursors in the bone marrow of high-dose dogs. Several clinical chemistry parameters such as total bilirubin, cholesterol, alkaline phosphatase, lactic dehydrogenase and albumin/globulin ratio were affected in mid- and high-dose females. There was a decrease in serum triiodothyronine (T3) in dosed dogs and a decrease in thyroxine (T4) in mid- and high-dose females. This was accompanied by an increase in thyroid weights. There were increases in hematopoiesis in the spleen in high-dose dogs and accompanying increases in spleen weights. Hemosiderosis and cholestasis were increased in livers of high-dose dogs and liver weights were also increased. (See special study below).

The Systemic Toxicity LOEL is equal to or less than 9.6 mg/kg/day for males and equal to or less than 10.4 mg/kg/day for females based on moderate increases in methemoglobin in both sexes and an increase in hemosiderin deposition in the liver in low-dose females. The System Toxicity NOEL is less than 9.6 mg/kg/day for males and less than 10.4 mg/kg/day for females. Based on the results from a special study in dogs (MRID 42045702; see discussion below), the Agency RfD/QA Peer Review Committee (11/14/95) considered the threshold NOEL to be 150 ppm (equal to 5.1 mg/kg/day for males and 4.3 mg/kg/day for females) in the dog.

3. In a special study entitled *Determination of the No-Effect Level for Methemoglobin Production Following Desmedipham Technical Administration in the Dog (oral/feeding route)* (MRID 42045702), desmedipham technical was administered to beagle dogs at varying dose levels (150 to 500 ppm in one group; 75 ppm then 300 ppm then 0 ppm followed by 1500 ppm in another group). Higher dose levels of desmedipham technical, 500 and 1500 ppm, produced a "grey" urine. No other dose related clinical signs were noted. There was no apparent effect of treatment on the body weight gains or food consumption. Hematological parameters other than methemoglobin formation were unaffected by treatment. Some pathology was noted in the "high" dose group. The LOEL for the increase in methemoglobinemia in male dogs is 15.5 mg/kg/day (500 ppm) and in female dogs is 1.1 mg/kg/day (300 ppm) with the NOEL at 5.1 mg/kg/day (150 ppm) in males and 4.3 mg/kg/day (150 ppm) in females. This study must be considered with the chronic feeding study in the dog.

4. In a 104-week carcinogenicity study (MRID 40387106), desmedipham technical was fed to NMRI mice at dietary levels of 0, 30, 150, or 750 ppm (equal to 0, 4.2, 21.68, and 109.0 mg/kg/day for males and 0, 5.8, 30.75, and 145.0 mg/kg/day for females, respectively). Treatment-related signs of toxicity or clinical symptoms were not observed in the treated animals and the mortality incidence in males and females at all dietary levels was essentially similar. Males of both the interim sacrifice (12 months) and the high dose showed slightly reduced mean body weights. These reductions were not consistent and were not seen in females. Food consumption values in the interim sacrifice mid and high dose animals tended to be slightly increased during the treatment period. Hematology results revealed treatment-related Heinz body anemia in high dose males and females at weeks 52 and 104 accompanied by slight to moderate methemoglobin formation in high dose males and females at week 52. Other hematology parameters that differ significantly from controls were not considered of toxicological importance since they were not consistent over the intervals of sampling and were generally within the normal reference range.

Absolute and relative spleen weights were significantly increased ($p < 0.05$) in comparison with controls in high dose females after 52 weeks. Gross and histopathological findings did not indicate any toxic or carcinogenic significance. The systemic toxicity LOEL is 109 mg/kg/day for males and 145 mg/kg/day for females and the systemic toxicity NOEL 21.68 mg/kg/day for males and 30.75 mg/kg/day for females based on Heinz body anemia accompanied by methemoglobin formation in both sexes and an increase in absolute and relative (to body weight) spleen weights in females.

Desmedipham is classified as a Group E chemical (evidence of non-carcinogenity for humans). After submittal and review of additional requested confirmatory data regarding the historical incidence of the tumors noted and the number of animals examined, the group classification for desmedipham will be reevaluated.

d. Developmental Toxicity

1. In a developmental toxicity study (MRID 42045704 and 00156724), mated female Wistar rats were administered desmedipham technical via gavage at 0, 10, 100, or 1000 mg/kg/day during days 6-15 of gestation. Maternal toxicity was noted as reduced body weight gain and corrected body weight gain during the dosing and gestational periods and reduced food consumption during the dosing period in rats administered 1000 mg/kg/day. The maternal toxicity LOEL is 1000 mg/kg/day based on reduced body weight gains and corrected body weight gains and reduced food consumption. The maternal toxicity NOEL is 100 mg/kg/day. Developmental toxicity was manifested as reduced fetal body weight and an increased incidence of external (palatoschisis) and skeletal (sternebrae and vertebrae) anomalies in fetuses from animals administered 1000 mg/kg/day. The developmental toxicity LOEL is 1000 mg/kg/day based on the increased incidence of skeletal anomalies. The developmental toxicity NOEL is 100 mg/kg/day.

2. In a developmental toxicity study (MRID 00156725) Wistar/HAN albino rats (source: KFM) received by oral gavage either 0, 10, 100 or 500 mg/kg/day for gestation days 6 through 15. This study was conducted subsequent to study MRID 00156724 (above). Maternal toxicity was manifested as a reduction in body weight gain during the dosing period (gestation days 6-16) with a rebound in body weight gain following dosing (gestation day 16-21); a reduction in body weight gain for the overall treatment period (dosing plus post dosing period) and for corrected body weight gain. A reduction in food consumption was noted in the high dose group during the dosing period. There was an increase in methemoglobin formation on gestation day 16 in the treated groups (1.3, 1.6, 3.7, and 9.3% for the control, low, mid, and high dose groups, respectively). These values were statistically significant in the mid and high dose groups with an increasing trend noted at the low dose. There was also an increase in Heinz body formation in the high dose group.

The maternal toxicity LOEL is 100 mg/kg/day based on hematological findings. The maternal toxicity NOEL is 10 mg/kg day. The high dose fetuses had slightly reduced body weights as compared to the control. There was an increase in incompletely ossified sternebrae, and absent ossification of phalangeal nuclei, calcanea and cervical vertebrae in the high dose group. The developmental toxicity LOEL is 500 mg/kg/day and the developmental toxicity NOEL is 100 mg/kg/day based on the increase in fetal incidence of skeletal anomalies.

3. In a developmental toxicity study (MRID 41214706) Wistar/HAN albino rats (source: KFM) were exposed by the dermal route to either 0 or 1000 mg/kg/day (limit dose) of desmedipham for gestation days 6 through 15. Maternal toxicity was manifested as a slight reduction in body weight gain during the dosing period (gestation days 6-16), for the overall treatment period (dosing plus post dosing period) and for corrected body weight gain. No other treatment related observations were noted. The maternal toxicity LOEL is equal to 1000 mg/kg/day and the maternal toxicity NOEL is less than 1000 mg/kg day based on reduced body weight gain. No developmental toxicity was noted. The developmental toxicity LOEL is greater

than 1000 mg/kg/day and the developmental toxicity NOEL is equal to or greater than 1000 mg/kg/day.

4. In a developmental toxicity study (MRID 42045703 and 00132360), female rabbits were administered desmedipham technical via oral gavage at 0, 50, 150 or 450 mg/kg/day during days 6 through 27 of gestation. Maternal toxicity was evidenced by decreased body weight gain during the dosing and gestation periods and reduced corrected body weight gain during the dosing period in the 450 mg/kg/day dose group. The maternal toxicity LOEL is 450 mg/kg/day and the maternal toxicity NOEL is 150 mg/kg/day based on decreased body weight gain. Developmental toxicity was noted as a slight increase in litter and increased fetal incidence of left and right forelimb proximal phalangeal digit # 1 and medial phalangeal digit #1 and #4, and the increased litter and fetal incidence of left and right hindlimb medial phalangeal toe # 1, # 2, and #3 and reduced fetal body weights in litters from the 450 mg/kg/day dose group. The developmental toxicity LOEL is 450 mg/kg/day and the developmental toxicity NOEL is 150 mg/kg/day based on increased incidence of skeletal anomalies and reduced fetal body weights.

e. Reproductive Toxicity

In a 2-generation reproduction study (MRID 40387105), Wistar rats were fed diets containing desmedipham technical at levels of 0, 50, 250, or 1250 ppm (approximately 0, 4, 20, or 110 mg/kg/day, respectively) for two consecutive generations. Significant reductions in parental body weights at the high-dose level and hemolytic anemia accompanied by significant increases in splenic weights and compensatory functioning of the thyroid at the mid- and high-dose levels were observed. The LOEL for parental systemic toxicity is 20 mg/kg/day and the NOEL for parental systemic toxicity is 4 mg/kg/day based on hemolytic anemia accompanied by significant increases in splenic weights and compensatory functioning of the thyroid.

No specific reproductive toxicity was noted; however, developmental toxicity was noted as reductions in lactational body weights of pups at the high dose level. The developmental/ off-spring systemic toxicity LOEL is 110 mg/kg/day and the developmental/offspring systemic toxicity NOEL is 20 mg/kg/day. The LOEL for reproductive toxicity is greater than 110 mg/kg/day and the NOEL for reproductive toxicity NOEL is equal to or greater than 110 mg/kg/day.

f. Mutagenicity

In a *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay (MRID 41607005), the mutagenic potential of eight concentrations of desmedipham, ranging from 10.0 to 5000.0 μg/plate, was tested in the plate incorporation test using the *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 along with *Escherichia coli* strain WP2. Two separate experiments were performed with triplicate plates, with and without activation, and with negative, solvent and positive controls. Evidence of toxicity in the number of revertants was seen at the higher concentrations of the test substance. There was no significant, reproducible and/or dose-dependent increase in the number of revertants observed in any of the strains, with or

without metabolic activation. In an unscheduled DNA synthesis assay (UDS) in primary rat hepatocytes (MRID 41214707), desmedipham technical (98% a.i., Batch 320033) was negative for UDS in primary rat hepatocytes treated with the test material at doses up to 25.2 μg/mL. At 50.4 μg/mL, hepatocytes were not scored because of poor cell morphology. Higher concentrations ($\geq$101 μg/mL) were excessively cytotoxic.

In a mouse micronucleus assay (MRID 00156886), Desmedipham Technical (98.3% a.i., Batch 320033) was negative for micronucleus induction in the bone marrow cells of male or female NMRI mice at 24, 487, or 72 hours after oral gavage administration of 5000 mg/kg (the limit dose) desmedipham technical. No deaths or signs of target organ toxicity were seen at any harvest time; sedation was the only clinical sign observed. In view of the negative results, the response of the positive control validated the experiment. It was, therefore, concluded that desmedipham technical did not induce a genotoxic effect.

In a mouse lymphoma assay (MRID 00156887), Desmedipham Technical (98% a.i., Batch 320033) was positive in two independent mouse lymphoma forward mutation assays conducted with 6.3-200 μg/mL (initial assay) and 20-120 μg/mL assay (confirmatory assay) in the presence and absence of S9 activation. In the initial assay, increases in the mutation frequency (MF) and in the number of mutants per plate were observed at the highest clonable level (100 μg/mL +/- S9) and also at 50 μg/mL +S9. In the confirmatory assay, desmedipham technical induced dose-related increases in the MF that ranged from 1.5 to 5.4 fold higher than controls at 80 and 100 μg/mL -S9, respectively. By contrast, mutagenic activity was detected over the entire range of assayed concentrations in the presence of S9 with fold-increases of 1.4 at the low dose (20 μg/mL) and 9.5 at the highest cloned level (100 μg/mL).

In an *in vitro* human lymphocytes assay (MRID 00156888), Desmedipham Technical (98% a.i., Batch 320033) was negative for the induction of structural aberrations in human lymphocytes treated in vitro with 10, 50, or 100 μg/mL (+/- S9) desmedipham technical. The test material was not cytotoxic at any dose but was insoluble at 125 μg/mL +/- S9.

g. Metabolism

In a metabolism study in the rat (MRID 41607006), disposition and metabolism of phenyl carbamate ^{14}C-desmedipham and ethyl phenyl carbamate ^{14}C-desmedipham was investigated in male and female rats at a low oral dose (5 mg/kg). Absorption of desmedipham appeared rapid but incomplete. Urine represented the major route for excretion of desmedipham derived radioactivity, with 68-84% excreted in 24 hours by this route for both labeled compounds. In feces, between 10-15% was excreted in the first 24 hours for both labels. Tissue levels at study termination (96 hours post-dose) were negligible for both phenyl-labeled and ethyl phenyl carbamate labeled desmedipham, except for blood and plasma in rats treated with phenyl-labeled desmedipham, where measurable amounts of radioactivity were found.

In rats administered phenyl labeled desmedipham (^{14}C-desmedipham (phenyl carbamate label), Radiochemical Purity: > 97.0%, Specific Activity: 59.1 μCi/mg), the major metabolite

identified in urine by TLC and HPLC was 4-acetamidophenol, with minor amounts of 4-aminophenol, 2-aminophenol, 2-acetamidophenol, and parent desmedipham. The major fecal metabolite detected from administration of phenyl labeled desmedipham was 4-acetamidophenol, with smaller amounts of 4-aminophenol and unchanged desmedipham. Several polar compounds were also detected which were not resolved by the separation techniques employed.

In rats given ethyl phenyl carbamate labeled desmedipham (^{14}C-desmedipham (ethyl phenyl carbamate label), Radiochemical Purity: > 99.7%, Specific Activity: 61.6 μCi/mg), the major urinary metabolite detected was ethyl-N-(3-hydroxyphenyl) carbamate, with smaller amounts of 3-acetamidophenol and 3-aminophenol. Analysis of fecal homogenates showed a similar pattern of metabolites as for urine. For both the phenyl labeled and ethyl phenyl carbamate labeled test material, there did not appear to be any sex differences in urinary metabolites from administration of phenyl labeled desmedipham. However, this cannot be stated with certainty as the metabolite data were not presented in quantitative fashion (i.e. percent administered dose). A scheme for metabolism of desmedipham was proposed based on the data presented in this study. This study was classified as supplemental.

In a second metabolism study in the rat (MRID 42880001; 42880002), disposition and metabolism of phenyl carbamate (PC) labeled ^{14}C-desmedipham and ethyl phenyl carbamate (EPC) labelled ^{14}C-desmedipham was investigated in male and female rats at a low oral dose (5 mg/kg, EPC labelled desmedipham only), repeated low oral dose (5 mg/kg x 14 days), and a single high dose (1000 mg/kg). Absorption of desmedipham appeared rapid but incomplete, and was decreased at the high dose level. Urine represented the major route for excretion of both PC and EPC labelled desmedipham derived radioactivity, with between 67-83% excreted by 30 hours post-dose. In feces, between 7-20% was excreted in the first 30 hours for both labels at the low dose. At the 1000 mg/kg dose, urinary excretion was decreased to between 32-44% of the administered dose, while fecal excretion of radioactivity was significantly increased for both labels (between 50-56% of administered dose). Distribution data showed significant amounts of residual radioactivity in several tissues for both PC and EPC labelled desmedipham at the 1000 mg/kg dose level. Blood and well-perfused tissues showed the highest levels of residual radioactivity, and values were higher for PC labelled desmedipham vs EPC labelled desmedipham.

In rats administered phenyl labeled desmedipham (^{14}C-desmedipham (phenyl carbamate label), Radiochemical Purity: > 98.0%, Specific Activity: 59.1 μCi/mg), the major metabolite detected in urine at both the 5 mg/kg and 1000 mg/kg dose level and identified by TLC and HPLC analysis was 4-acetamidophenol, with minor amounts of 4-aminophenol, 3-aminophenol and 3-acetamidophenol. The major fecal metabolite detected from administration of PC labelled desmedipham at 5 mg/kg and 1000 mg/kg was phenylmethyl carbamate in both male and female rats. Parent desmedipham was also present in significant percentage at the 1000 mg/kg dose level.

In rats given EPC labelled desmedipham (^{14}C-desmedipham (ethyl phenyl carbamate label), Radiochemical Purity: > 98.0%, Specific Activity: 17.2 μCi/mg), the major urinary metabolite detected at 5 mg/kg and 1000 mg/kg was ethyl-N-(3-hydroxyphenyl) carbamate, with smaller amounts of 3-acetamidophenol and 3-aminophenol. An unknown metabolite comprising between

4.2-6.2% of the administered radioactivity in EPC dosed rats was identified as N-(3-hydroxy-phenyl) 1-hydroxyethyl carbamate. Analysis of fecal fiber extracts showed the presence of both ethyl-N-(3-hydroxyphenyl) carbamate and parent desmedipham, while aqueous supernatants of fecal extracts showed minor amounts (< 1% of the dose) of several previously identified metabolites. For both the phenyl labeled and ethyl phenyl carbamate labeled test material, sex differences in metabolism appeared to be minor. From the data presented, a revised scheme for metabolism of desmedipham was provided. Metabolite data for the single low dose of PC labelled desmedipham was not provided, although the Agency had requested additional data before upgrading this study to satisfy the §85-1 data requirement. The data in this study partially satisfy the data requirements for §85-1.

h. Reference Dose

The Agency RfD Committee recommended that a RfD for this chemical be based on a reproductive toxicity study in rats with a parental toxicity NOEL of 4 mg/kg/day (50 ppm). Effects seen were significant reduction of body weight, hemolytic anemia accompanied by significant increase in spleen weights and thyroid compensatory function at the next higher dose of 20 mg/kg/day (250 ppm), the middle dose level tested, and higher dose levels. An uncertainty factor (UF) of 100 was applied to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD is 0.04 mg/kg/day.

i. Cancer Classification

The Cancer Classification assigned to desmedipham is tentatively classified as a "Group E" chemical, based on evidence of noncarcinogenicity. Confirmation of this classification will be made upon receipt and evaluation of requested confirmatory data addressing historical control data on the background incidence of tumors seen and the registrant's response to other issues with respect to the number of animals examined in the rat study. (MRID 40387107)

WHO/JMPR Status

Desmedipham has not been reviewed by the Food and Agriculture/World Health Organization (FAO/WHO) joint meeting on pesticide residues (JMPR).

j. Dermal Absorption

In a dermal absorption study (MRID 41957101), groups of male Wistar rats were exposed to single dermal doses of 0.01, 0.1, 1.0, 10.0 mg/kg ^{14}C desmedipham for 0.5, 1, 2, 4, and 10 hours. Urine, feces, and blood were collected up to 120 hours post dosing. Elimination of ^{14}C desmedipham derived radioactivity was minor via urine and feces. The percentage of an administered dose of desmedipham absorbed decreased with increasing dose, but the absolute amount of desmedipham absorbed increased in a linear fashion with increasing dose. Levels of desmedipham derived radioactivity in the carcass and blood were insignificant at all doses tested, but the amount of radioactivity found at the application site was increased at the highest dose,

indicating retention of desmedipham in the dermis or viable epidermis. The level of dermal absorption was considered to be 5.4 % at 10 hours.

k. Toxicological Endpoints of Concern

The Toxicological Endpoint Selection Committee (8/24/95) of the Agency's Office of Pesticide Programs determined the following:

- An acute (1 day) dietary risk assessment and a short term (1 to 7 days) occupational/residential risk assessment are required. The developmental NOEL is 150 mg/kg/day based on developmental toxicity in rabbits; the developmental LOEL is 450 mg/kg/day based on incidences of skeletal anomalies and reduced fetal body weights observed in a rabbit study. (MRIDs 42045703 and 00132360)

Discussion: The developmental NOEL is 150 mg/kg/day and the developmental LOEL is 450 mg/kg/day based on incidences of skeletal anomalies and reduced fetal body weights. Although a developmental study in Wistar rats demonstrated a NOEL of 100 mg/kg/day, the LOEL was 1000 mg/kg/day based on external and skeletal anomalies in fetuses. This rat study was not chosen as the primary study for endpoint selection, since the large spacing between the doses makes it difficult to extrapolate to meaningful results. The NOEL, although lower than that seen in the rabbit developmental study selected, is considered to be an artifact of dose selection and probably underestimates the actual threshold for adverse effects significantly. It does, however, support the observations in the rabbit study above.

- An intermediate term (1 week to several months) occupational/residential risk assessment is required. The NOEL is 4 mg/kg/day based on multi-generation reproduction study data in the rat. The LOEL is 20 mg/kg/day, based on reduced body weight, hemolytic anemia, significant increases in spleen weights and compensatory thyroid function in the rat. (MRID 40387105)

2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues of desmedipham *per se* have been established at 0.2 ppm in/on sugar beet roots and tops [*Source: 40 CFR § 180.353*; no tolerances exist for residues of desmedipham in animal commodities and no food/feed additive tolerances have been established. A tolerance for the use on table beets and Swiss chard grown for seed is not required. The Agency has determined that the residue to be regulated in plants and animals is desmedipham *per se*.

The current analytical method in PAM, Vol. II may not be adequate for the enforcement of tolerances for residues of desmedipham. AgrEvo has proposed an HPLC UV/VIS method to

be the primary enforcement method used for the determination of residues of desmedipham in or on sugar beets. Additional data have been required before this method can be incorporated into PAM, Vol II as an enforcement method.

Plant Metabolism GLN 171-4 (a):

The qualitative nature of the residue in plants is adequately understood. The metabolism of desmedipham in plants mirrors that of phenmedipham as the two compounds are structurally similar. The sugar beet metabolism study conducted with phenmedipham is considered adequate: sugar beet leaves from plants grown in nutrient solution were treated with radiolabeled phenmedipham by foliar application or hypocotyl injection. Phenmedipham and its methyl-N-(3-hydroxy-phenyl)carbamate hydrolysis product (MHPC) in the leaves comprised ~18% and 3% of the total applied radioactivity, respectively. In addition, conjugated O- and N-glucosides of the MHPC metabolite and phenmedipham represented ~32% and 24% of the applied activity, respectively. (MRIDs 00041862, 40274901, 41214710)

The Agency has concluded that the AgrEvo submitted metabolism study for phenmedipham is adequate for desmedipham, and that phenmedipham and desmedipham should be regulated in the same manner and that the residue of concern is desmedipham per se.

Animal Metabolism GLN 171-4 (b):

The nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies reflecting oral dosing. The Agency has determined that the residue to be regulated in animals is desmedipham per se. (MRIDs 00098591, 41998603, 42371301, 42687401, 42822701)

Residue Analytical Methods - Plants and Animals GLN 171-4 and (d):

The residue analytical methods requirement is not fulfilled. However, for the purposes of the risk assessment, the current analytical method discussed below is adequate for data collection on residues of desmedipham in/on sugar beets.

The Agency will consider the HPLC UV/VIS method (Method Desmedipham/R75, also referred to as the "desmedipham-specific method") used for the determination of residues of desmedipham in or on sugar beets to be the proposed primary analytical enforcement method. Submitted method validation data from AgrEvo and an independent laboratory validation indicated that recoveries of desmedipham from sugar beet roots and tops using this method were adequate. The Agency tentatively accepts the proposed analytical method as a primary enforcement method, provided data pertaining to the potential interferences from the related propham (IPC) and phenmedipham pesticides, as well as additional raw data are submitted. If this data for the primary method is determined to be adequate, after submission of acceptable data and a successful EPA method validation trial, then the Agency will not require the submission of a confirmatory method. Radiovalidation of the desmedipham-specific method is still outstanding.

The FDA multi-residue testing data has been forwarded to FDA for evaluation. The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix I) does not report recoveries for desmedipham using any of the PAM I multiresidue methods.

Enforcement analytical methods for residues in animal commodities are not required since tolerances are not needed (see GDLN 171-4(j)). (MRIDs 00076669, 41998604, 42921801, 42921802, 42921803, 00041859)

Storage Stability GLN 171-4 (e):

Adequate storage stability data are required to support any required field trials (see GLN 171-4(k). The available data indicate that residues of desmedipham are stable in/on sugar beet tops and roots stored at -21°C for up to 8 months. An outstanding study which appreciably exceeds the storage period would require that concurrent storage stability studies be performed. (MRID 00041860)

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs GLN 171-4 (j):

Sugar beet commodities are not listed as poultry feed items on the Updated Livestock Feeds Table for Subdivision "O" dated 4/26/94. Therefore, tolerances for residues in poultry and eggs are not required.

The administered dose in the submitted ruminant metabolism study represented ~ 1x the maximum expected dietary burden (including the proposed 15 ppm tolerance for sugar beet tops), and desmedipham residues in all tissues were < 0.01 ppm. Therefore, the Agency considers a cattle feeding study is not required, and no tolerances for residues in meat and milk need be established (see CFR §180.6(a)(3).

Magnitude of the Residue in Plants GLN 171-4 (k):

Review of available data indicates that residue trials were conducted in nine states using application rates that exceeded the single and seasonal application rates registered at that time. In addition, samples were collected at a 90 day PHI. The current PHI is 75 days. Treated tops and roots bore desmedipham residues at < 0.2 ppm. The residue data were supported by submitted storage stability data. Additional data reviews indicated that after single applications of desmedipham (at 0.5 to 4 lb ai/A and PHIs of 60-152 days) in the major sugar beet producing states, apparent residues ranged from 0.01-0.12 ppm in the roots and 0.02-0.15 ppm in the tops. Following correction for control samples, net residues were typically < 0.02 ppm. The Agency concluded that the proposed use will result in, at most, trace residues of desmedipham on sugar beet roots and tops. However, as control values occasionally exceed 0.1 ppm, the existing tolerance of 0.2 ppm (sugarbeet roots) was determined to be appropriate.

Samples were analyzed using a method similar to the current PAM II enforcement method. Subsequently, additional 6(a)(2) field trial data submitted by the registrant indicated higher than expected desmedipham residues in sugar beet tops harvested 75 days after the last of two applications. In this submission, applications were made one week apart, each at 0.975 lb ai/A. The field trials were conducted in MI, MN, ND and CA using the EC and WP formulations. Desmedipham residues were determined to be < 0.05-13.86 ppm in/on eight sugar beet top samples, by using the desmedipham specific method. The registrant submitted a petition for a desmedipham tolerance amendment for residues in/on sugar beet tops at 15 ppm (AgrEvo letter 12/3/92). The established 0.2 ppm tolerance for sugar beet roots appears to be acceptable at this time. (MRIDs PP# 4F1459, 00116379, 00076668, 00041865, 00066110, 00070105, 00116710, 00049456, 42516501, 42921801, 42921802, 42921803) However, additional confirmatory field crop data for sugar beet tops has been requested from the registrant to substantiate the residue tolerances for sugar beet tops at 15 ppm for desmedipham. Upon receipt of these data EPA will determine whether the current tolerance is adequate or needs to be revised.

Magnitude of the Residue in Processed Food/Feed GLN 171-4 (l):

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for sugar beets. The submitted processing study is adequate: no food/feed additive tolerances or Section 701 (maximum residue limits) as necessary. (MRID 42112301)

Confined Rotational Crops GLN 165-1:

For the purposes of risk assessment, the nature of the residues in rotational crops is adequately understood. The available confined rotational crop study is adequate, provided the dates of sample extraction and analysis for each crop matrix as well as supporting storage stability data reflecting the storage intervals and conditions of samples from the study are submitted.

Limited and/or extensive field rotational crop studies are not required because residues of the regulated parent were predominately found at < 0.01 ppm in/on rotational crop commodities. Therefore, rotational crop restrictions are not necessary and no plant-back intervals need be prescribed. (MRID 42909601)

b. Magnitude of the Residue in Drinking Water

A Maximum Contaminant Level (MCL) or a Drinking Water Lifetime Health Advisory Level (HAL) has not been established for desmedipham (EPA, Office of Water). Desmedipham is currently not regulated under the Safe Drinking Water Act (SDWA). Rapid environmental degradation of desmedipham in surface water is expected to occur from hydrolysis and microbial processes. Desmedipham residues in surface water were not detected in sugar beet agricultural production areas (CA, WA, MN), when monitored by multi-residue test methods (see Sec. II.C.2.c. (2)). Based on these results and because desmedipham has a low potential to leach from

soil to ground water, the Agency does not expect the current registered uses of desmedipham result in residues of desmedipham in drinking water.

c. Occupational and Residential Exposure

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

(1) Handler Exposure

There is potential short and intermediate-term occupational exposure to mixers, loaders, applicators, and flaggers associated with application of desmedipham products to sugar beets. These potential exposure scenarios are: (1) mixer/loader exposure for mixing liquid aerial application; (2) mixer/loader exposure for mixing liquid ground boom treatment application; (3) mixer/loader exposure for mixing wettable powder for aerial application; (4) mixer/loader exposure for mixing wettable powder for ground boom treatment application; (5) applicator exposure for aerial (liquid application); (6) applicator exposure for ground boom tractor equipment; and (7) flagger exposure during flagging (liquid applications). There are no residential uses of desmedipham, therefore a residential exposure/risk assessment is not required.

Some of these workers are exposed to desmedipham more than 7 days per year (reasonable worst-case estimate). Therefore, the exposure and risk assessments must include both short-term (less than 7 days per year) and intermediate-term (7 or more days per year) exposure scenarios. Short-term and intermediate-term exposure scenarios descriptions are presented in Table 2. The Agency relied on exposure data from its Pesticide Handlers Exposure Database (PHED). The limits of this database are defined in Table 5.

In accordance with the existing use patterns, it is not expected that occupational exposures would occur for more than 90 days, resulting in chronic worker exposure. A chronic exposure assessment is not required since chronic exposure is not expected.

(2) Post Application Exposure

Post-application exposures may occur to agricultural workers following applications to sugar beets during routine crop-production tasks, such as hoeing and thinning. No desmedipham specific data are available for assessment of post-application handler exposures to desmedipham containing registered products.

3. Risk Assessment

a. Dietary

A desmedipham tolerance of 0.2 ppm in/on the raw agricultural commodity(RAC) sugar beets (roots and tops) is published in 40 CFR 180.353. The Agency has determined that an acute (1 day) dietary risk assessment is appropriate for desmedipham because the toxicology endpoints for desmedipham include developmental toxicity discussed above.

The RfD used in the analysis of dietary exposure is 0.04 mg/kg/bwt/day, based on a NOEL of 4.0 mg/kg/day (LOEL 20 mg/kg/day) from a 2-generation rat reproduction study (MRID 40387105) which demonstrated a significant increase in spleen weights and compensatory thyroid function as an endpoint. An uncertainty factor of 100 was applied.

This dietary risk assessment assumes tolerance level desmedipham residues of 0.2 ppm tolerance in sugar beets (roots) and 100 percent crop treatment, as the worst case assumption. Anticipated residue data were not needed for this risk assessment. Although the registrant has proposed to raise the tolerance for sugarbeet tops to 15 ppm, sugar beet tops are not a human food item. This is because humans do not eat sugarbeet tops, and sugarbeet tops fed to animals do not result in residues of concern in meat or milk. Therefore, this was not included in the dietary analysis.

Acute Dietary Risk

An acute dietary risk analysis was conducted for the dietary subgroup, females (13 + years), as this group represents women of child bearing age. The computed MOE is 50,000 for this subgroup. When the MOE is determined to be 100 or higher, the Agency does not regard there to be human health risks of concern. Therefore, from an acute dietary exposure to residues of desmedipham in sugar beets (0.2 ppm) the Agency believes there is an adequate margin of exposure to the toxicological endpoint of concern (developmental effects).

Chronic Dietary Risk

A chronic dietary risk assessment of exposures to residues of desmedipham is also appropriate, since the toxicological endpoint of concern is reproduction effects. This chronic risk analysis was performed using the present tolerance level of 0.2 ppm desmedipham in/on sugar beet (roots) and 100 percent crop treated, to estimate the TMRC for the general population and 22 subgroups (age, sex, ethnicity, season, and region of the U.S.).

The TMRC is 0.000066 mg/kg/day for the general population using the established tolerance of 0.2 ppm for the RAC sugar beets. The subgroup with the highest TMRC is children (1-6 years) with a TMRC of 0.000164 mg/kg/day or 0.41% of the RfD. The Agency concludes this level of risk does not represent a potential level of concern for any exposed population, either general or subgroup.

b. Occupational and Residential

Desmedipham is classified as acute toxicity category II for eye irritation, category III for dermal toxicity and is a dermal sensitizer. Acute oral, inhalation and dermal irritation are toxicity category IV. The toxicity endpoint for short term (1 to 7 days) occupational risk assessment is a NOEL of 150 mg/kg/day, based on the developmental toxicity study in rabbits (acute toxicity endpoint) with correction for dermal absorption. The endpoint for intermediate term (1 week to several months) occupational exposure risk assessment is a multi-generation reproduction study in rats with a NOEL of 4 mg/kg/day and a LOEL of 20 mg/kg/day. The dermal absorption rate for desmedipham is 5.4 percent at 10 hours. (MRID 40387105, 42045703, 00132360)

Handler Risk

For short and intermediate term risk from occupational exposure, the Agency estimates risk in terms of the margin of exposure (MOE). The following equations were used to compute the desmedipham MOEs:

$$MOE = \frac{NOEL}{Maximum\ Daily\ Exposure}$$

$$Short\text{-}Term\ MOE = \frac{150\ mg/kg/day}{Maximum\ Daily\ Dose}$$

$$Intermediate\text{-}Term\ MOE = \frac{4\ mg/kg/day}{Maximum\ Daily\ Dose}$$

Risk from Short-Term Exposure

Short-term exposures under the scenarios cited in Table 2, assuming workers wear baseline PPE protection (long-sleeved shirt, long pants, shoes and socks), result in MOEs above 100 except for mixers and loaders of wettable powder formulations for aerial applications. The MOE for this exposure scenario is 83. See Table 3, column titled "Baseline Total MOE." The addition of chemical resistant gloves to the PPE requirements for this scenario results in an MOE of 375.

Risk from Intermediate-Term Exposure

a.) Intermediate term exposures for handlers and flaggers are presented in Table 4. The applicator and fogger risks are acceptable with MOEs greater than 100. However all of the mixer/loader scenarios for exposures with baseline protection result in MOEs below 100 (column titled "Baseline Total MOE"). The risk

associated with mixer/loader exposure scenarios (except mixers and loaders for wettable powder formulations supporting aerial applications) may be adequately reduced (i.e., result in MOEs above 100; see column titled "Total MOE") with the addition of personal protective equipment as follows.

- Mixers/loaders of emulsifiable concentrate formulations (see scenarios 1a and 1b, Table 4) - wear chemical-resistant gloves in addition to baseline protection;

- Mixers/loaders of wettable powder formulations who are supporting ground applications (see scenario 2b, Table 4) - wear dust/mist filtering respirator and chemical-resistant gloves in addition to baseline protection;

b.) For mixers/loaders of wettable powder formulations who are supporting aerial applications, scenario 2a, the use of double layer clothing, chemical resistant gloves, and a dust/mist respirator would only raise the MOE to 40 (Table 4, column "Total MOE"). The Agency estimates the use of engineering controls in the form of water-soluble product packaging and single layer clothing will result in an MOE of 444. Reduction of the application rates to 0.5 pound active ingredient per acre, assuming aerial applications of up to 350 acres per day, would negate the need for engineering controls. Other risk mitigation measures were considered, such as limiting product users to no more than five days of exposure per growing season. However, the Agency believes such use-limitations would not be practical or enforceable.

Post-Application Risk

Specific desmedipham post-application exposure data are not available. However, the Agency notes the toxicology endpoint of most concern is an intermediate-term (1 week to several months) endpoint and that the current desmedipham registration is for early-season use on sugar beets. Early season use should present minimal risk because foliar contact would be low. Foliage area would be small at this time. The Agency therefore concludes that health risks to handlers from post-application exposures will not pose a significant risk. The current REI (restricted entry interval) is 24 hours, and PPE is required for workers who enter the treated area before 24 hours.

Table 2. Short-Term and Intermediate-Term Occupational Exposure Scenarios

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Maximum Label Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
Mixer/Loader Exposure							
Mixing Liquid Aerial Application (1a)	2.9	1.2	1.26	350	1278.9	0.53	1279.4
Mixing Liquid Ground boom Treatment Application (1b)				80	292.3	0.12	292.42
Mixing Wettable Powder for Aerial Application (2a)	3.7	43.4	1.26	350	1631.7	19.1	1650.8
Mixing Wettable Powder for Ground boom Treatment Application (2b)				80	373.0	4.37	377.37
Applicator Exposure							
Aerial (liquid application) (3)	0.05	0.3	1.26	350	22.1	0.13	22.2
Ground boom Tractor (4)	0.01	0.7	1.26	80	1.01	0.07	1.08
Flagger							
Flagging (liquid applications) (5)	0.01	0.2	1.26	350	4.4	0.09	4.5

[a] Long pants, long sleeve shirts, no gloves, open mixing/loading, open cockpit, open cab tractor.

[b] No respirator

[c] Label Reg Nos. 45639-160, 45639-86, 45639-155

[d] 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.

[e] Daily dermal exposure (mg/day) = Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated

[f] Daily inhalation exposure (mg/day) = Exposure (ug/lb ai) * (1mg/1000ug) conversion * Max. Appl Rate (lb ai/A) * Max. Treated

[g] Daily total exposure (mg/day) = Daily dermal exposure + Daily inhalation exposure

Table 3. Short-Term Handler Exposure, Mitigation, and Risk

Exposure Scenario (Scen. #)	Baseline Daily Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Total Absorbed Dose (mg/kg/day)[b]	Baseline Dermal MOE[c]	Baseline Total MOE[d]	Risk Mitigation Measure					
					Additional PPE[e]					
					Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Dermal Absorbed Dose (mg/kg/day)[a]	Daily Total Absorbed Dose (mg/kg/day)[b]	Dermal MOE	Total MOE
Mixer/Loader Risk										
Mixing Liquid Aerial Application (1a)	1.2	1.2	125	125	N/A	N/A	N/A	N/A	N/A	N/A
Mixing Liquid Ground boom Treatment Application (1b)	0.263	0.265	570	566	N/A	N/A	N/A	N/A	N/A	N/A
Mixing Wettable Powder for Aerial Application (2a)	1.5	1.8	100	83	0.2	43.4 (no respirator)	0.08	0.40	1,875	375
Mixing Wettable Powder for Ground-boom Treatment Application (2b)	0.336	0.409	446	370	N/A	N/A	N/A	N/A	N/A	N/A
Applicator Risk										
Aerial (liquid Application) (3)	0.02	0.02	7,500	7,500	N/A	N/A	N/A	N/A	N/A	N/A
Ground boom Tractor (4)	0.0009	0.002	166,667	75,000	N/A	N/A	N/A	N/A	N/A	N/A
Flagger Risk										
Flagging (liquid applications) (5)	0.004	0.006	37,500	25,000	N/A	N/A	N/A	N/A	N/A	N/A

[a] Daily absorbed dermal dose = (daily dermal exposure * dermal absorption rate 0.054)/60 kg

[b] Baseline absorbed total dose = [(daily dermal exposure * dermal absorption rate 0.054) + (daily inhalation exposure)]/60 kg

[c] Dermal MOE = NOEL (short-term NOEL = 150 mg/kg/day) / absorbed daily dermal dose

[d] Total MOE = NOEL (short-term NOEL = 150 mg/kg/day) / absorbed daily total dose

[e] Scenario 2a: Additional PPE = Single layer clothing and chemical resistant gloves.

N/A Not applicable since previous MOE was over 100.

Table 4. Intermediate-Term Handler Exposure, Mitigation, and Risk (Maximum PPE Used)

Exposure Scenario (Scen. #)	Baseline Daily Dermal Absorbed Dose (mg/kg/day)[a]	Baseline Total Absorbed Dose (mg/kg/day)[b]	Baseline Dermal MOE[c]	Baseline Total MOE[d]	Risk Mitigation Measure					
					Additional PPE[e]					
					Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Dermal Absorbed Dose (mg/kg/day)[a]	Daily Total Absorbed Dose (mg/kg/day)[b]	Dermal MOE[c]	Total MOE[d]
Mixer/Loader Risk										
Mixing Liquid Aerial Application (1a)	1.2	1.2	3	3	0.04	1.2 (no respirator)	0.02	0.0288	200	139
Mixing Liquid Ground boom Treatment Application (1b)	0.263	0.265	15	15	0.04	1.2 (no respirator)	0.0036	0.0056	1111	714
Mixing Wettable Powder for Aerial Application (2a)	1.5	1.8	3	2	0.1	8.7 (dust/mist respirator)	0.04	0.1	100	40
Mixing Wettable Powder for Ground boom Treatment Application (2b)	0.336	0.409	12	10	0.2	8.7 (dust/mist respirator)	0.018	0.033	222	121
Applicator Risk										
Aerial (liquid Application) (3)	0.02	0.02	200	200	N/A	N/A	N/A	N/A	N/A	N/A
Ground boom Tractor (4)	0.0009	0.002	4444	2000	N/A	N/A	N/A	N/A	N/A	N/A
Flagger Risk										
Flagging (liquid applications) (5)	0.004	0.006	1000	667	N/A	N/A	N/A	N/A	N/A	N/A

[a] Daily dermal absorbed dose = (daily dermal exposure * dermal absorption rate 0.054) / 60 kg

[b] Baseline Total Absorbed Dose = [(daily dermal exposure * dermal absorption rate 0.054) + (daily inhalation exposure)]/60 kg

[c] Dermal MOE = NOEL (intermediate-term NOEL = 4 mg/kg/day)/ daily dermal absorbed dose

[d] Total MOE = NOEL (intermediate-term NOEL = 4 mg/kg/day) / daily total absorbed dose

[e] Additional PPE:

Scenario 1a = single layer clothing and chemical-resistant gloves ;
Scenario 1b = single layer clothing and chemical resistant gloves;
Scenario 2a = double layer clothing, chemical-resistant gloves and a dust/mist respirator;
Scenario 2b = single layer clothing, chemical-resistant gloves and a dust/mist respirator.

N/A Not applicable since previous MOE was over 100.

Table 5. Description of Desmedipham Exposure Scenarios for Risk Calculations (Tables 2, 3,and 4)

Exposure Scenario (Number) Data Source PHED V1.1	PPE[a]		Engineering Controls[b]	Standard Assumptions[c] (8-hr work day)	Comments[d]
	Clothing	Equipment			
Mixer/Loader Exposure					
Mixing Liquid (1a and 1b)	Single layer clothing, chemical resistant gloves.	Open mixing liquids	N/A	80 to 350 acres	**Baseline:** Dermal and inhalation acceptable grades. Dermal = 53 to 122 replicates; Inhalation = 85 replicates; High confidence in dermal and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates; Inhalation = 85 replicates; High confidence in dermal and inhalation data. PHED data used for baseline and Max PPE, no PFs (protection factor) were necessary.
Mixing Wettable Powder (2a and 2b)	2a) short-term risk: single layer clothing, chemical resistant gloves, and for intermediate-term risk: coveralls over single layer clothing, chemical resistant gloves, and a dust/mist respirator	Open mixing wettable powder	For aerial mixing/loading , intermed-term risk: Water soluble packets, single layer clothing, no gloves.	2a) 350 acres	**Baseline:** Dermal and inhalation acceptable grades. Dermal = 7 to 45 replicates; Inhalation = 44 replicates; Low confidence in dermal data; Medium confidence inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 22 to 45 replicates; Inhalation = 44 replicates; Medium confidence in dermal and inhalation data. **Engineering Control:** Dermal grades acceptable; inhalation all grades. Dermal = 5 to 15 replicates. Inhalation = 15 replicates. PHED data used for baseline and engineering controls no PFs were necessary. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 80% PF for the addition of dust/mist respirator.
	2b) single layer clothing, chemical resistant gloves, and a dust/mist respirator			2b) 80 acre	
Applicator Exposure					
Aerial equipment (liquids) (3)	Coveralls over long sleeved shirt and long pants; no gloves.	Aircraft; open cockpit	N/A	800 acres	**Baseline:** Dermal grades A, B, C; inhalation all grades. Dermal = 1 to 17 replicates; Inhalation = 17 replicates. Low confidence for dermal and inhalation data. PHED data used for baseline, no PFs were necessary.
Ground boom (4)	N/A	N/A	N/A	80 acres	**Baseline:** Dermal and inhalation acceptable grades. Dermal = 23 to 33 replicates; Inhalation = 22 replicates; High confidence in dermal and inhalation data. PHED data used for baseline, no PFs were necessary.
Flagger					
Liquids (5)	N/A	N/A	N/A	800 acres	**Baseline**: Dermal and inhalation grades acceptable. Dermal = 16 to 18 replicates; Inhalation = 18 replicates. High confidence in dermal data and inhalation data. PHED data used for baseline values, no PFs were necessary.

[a] Clothing represents the baseline exposure estimates used in Tables 2, 3, and 4. Single layer clothing is long sleeved shirt, long pants, shoes and socks.

[b] Engineering Controls: water -soluble packets, single layer clothing, no gloves.

[c] Standard Assumptions based on an 8-hour work day as estimated by the Agency.

[d] "Acceptable grades," as defined by Agency guidance for meeting Subdivision U Guidelines are grades A and B. All grades that do not meet Agency's criteria are listed individually. PF is protection factor.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of desmedipham to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Table 6. Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} (mg/kg)	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	98.3	> 2,000	41607004	Practically nontoxic	Yes

Table 7. Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	98.2	> 5,000	00114112	Practically nontoxic	Yes
Mallard	98.2	> 5,000	00114111	Practically nontoxic	Yes
Northern Bobwhite	"Technical"	> 10,000	00159177	Practically nontoxic	No, Supplemental

These findings indicate that desmedipham is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled (GLN 71-1, MRID 41607004; GLN 71-2, 00114111 and 00114112).

(2) Birds, Chronic

Avian reproduction studies are required when the persistence, bioaccumulation, or multiple applications of the pesticide indicate that birds may be exposed repeatedly or continuously, or the mammalian reproduction tests indicate a reproductive hazard. Avian reproduction studies are required for desmedipham because it may be applied more than once per growing season.

Table 8. Avian Reproduction Findings

Species	% A.I.	NOEC (ppm)	LOEC (ppm)	Endpoints Affected	MRID	Fulfills Guideline Requirement
Northern Bobwhite	97.8	450	2500	Number of eggs laid and male body weight	43544901	Yes
Mallard Duck	97.8	90	450	Egg shell thickness, viable embryos per eggs set, male body weight	43544902	Yes

Avian reproductive studies indicate that eggshell thinning could occur at dietary concentrations above 90 ppm. A 7.5% reduction in egg shell thickness was observed in mallard ducks fed a diet of 450 ppm desmedipham compared to ducks fed a control diet. This represents a statistically significant difference. Also, the percent of viable embryos was slightly reduced from 93% in the control group to 86% in the 450 ppm group. Even though this reduction was not statistically significant, it was thought to be treatment related. The guideline requirements are fulfilled (GLN 72-4, MRIDs 43544901 and 43544902).

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies (including acute and subacute testing) and such factors as intended use pattern and pertinent environmental fate characteristics. In most cases, including desmedipham, data from the available mammalian studies which are used for human health risk assessment and are discussed above in Section B.1. can be used to estimate the toxicity to wild mammalian species.

The Agency concluded from the available mammalian data that the technical grade active ingredient (TGAI) of desmedipham is practically nontoxic to the rat (LD_{50} of > 5000 mg/kg) on an acute oral basis (MRID 00155581). Typical end-use products (TEPs) also are practically nontoxic to the rat (LD_{50} of > 5000 mg/kg for 70% and 35% desmedipham) mammals (MRIDs 42032004 and 42032404). The Agency infers from these conclusions that desmedipham may also be practically non-toxic to wild mammalian species.

Chronic and subchronic feeding studies indicated that dietary concentrations of desmedipham of 60 ppm (approximately 5.4 mg/kg/day) or less caused no significant effects. Concentrations between 250 and 300 ppm (approximately 20 and 26 mg/kg/day) caused effects on the blood, including increased levels of methemoglobin and hemolytic anemia (MRID 40387103 and 40387105). A decrease in splenic weight was also observed at the 250 ppm level in rats (MRID 40387105). The ecological significance of these effects on wild mammals is not known. In a 2-generation rat reproduction study (MRID 40387105), reductions in body weights of adults and pups were observed at a concentration of 1250 ppm (approximately 100 mg/kg/d). The NOEL for these gross effects, which are more likely to be ecologically significant, is 250 ppm or 20 mg/kg/day.

Several studies with mammals have shown that desmedipham causes decreased levels of thyroid hormones. This appears to be due to compensatory function of the thyroid in response to effects on the blood. This effect is reversible and is not judged to be of significance to wild mammals. Desmedipham does not appear to have a direct toxic effect on the thyroid gland.

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. Because sugar beets is not a crop that is normally associated with high exposure to bees, it is not expected that honey bees will be exposed to desmedipham. However, the following nontarget insect toxicity data are available.

Table 9. Nontarget Insect Acute Contact Toxicity Findings

Species	% A.I.	LD_{50} (ug a.i./bee)	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	97.5	> 50[a]	41711402	Practically nontoxic	Yes

[a] This study also found that the acute oral toxicity of desmedipham to the honey bee is > 50 ug a.i./bee.

There is sufficient information to characterize desmedipham as practically nontoxic to bees. The guideline requirement is fulfilled (GLN 141-1, MRID 41711402).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of desmedipham to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies; one study with a coldwater species (preferably the rainbow trout), and the other with a warm water species (preferably the bluegill sunfish).

Table 10. Freshwater Fish Acute Toxicity Findings (96 hr)

Species	% A.I.	LC_{50} (ppm)	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	98.4	1.7	00116714	Moderately toxic	Yes
Bluegill sunfish	98.4	6.0	00116713	Moderately toxic	Yes

The results of the 96-hour acute toxicity studies indicate that desmedipham is moderately toxic to fish. The guideline requirements are fulfilled (GLN 72-1, 00116713, 00116714).

Fish early life-stage, fish life-cycle or aquatic invertebrate studies have not been required for desmedipham because it appears to have low toxicity to aquatic organisms, it is not expected

to be continuously or recurrently present in water, and it is generally not very persistent in water (see Section C.2. below).

(2) Freshwater Invertebrates

The minimum testing required to assess the toxicity of desmedipham to freshwater invertebrates is a freshwater aquatic invertebrate acute toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Table 11. Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (mg a.i./L)	MRID NO.	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	96	1.88	00116712	Moderately Toxic	Yes

There is sufficient information to characterize desmedipham as moderately toxic on an acute basis to aquatic invertebrates. The guideline requirement is fulfilled (GLN 72-2, MRID No. 00116712).

Aquatic invertebrate life-cycle studies have not been required for desmedipham because it appears to have low toxicity to aquatic organisms, it is not expected to be continuously or recurrently present in water, and it is generally not very persistent in water.

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Use of desmedipham on sugar beets and Swiss chard is not expected to result in significant exposure to marine or estuarine environments. There are therefore no data requirements under this category.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) are generally required for herbicides with terrestrial non-residential use patterns to assess risk to nontarget plants. The vegetative vigor study is specifically required for chemicals which may move off-site through volatilization (vapor pressure $\geq 10^{-5}$ mm Hg at 25°C) or drift (applied aerially or through irrigation), and/or which may have endangered or threatened plant species associated with the site of application. The seedling emergence study is required for chemicals with a solubility greater than 10 ppm, or when it is applied aerially or through irrigation. These tests are required for

desmedipham because it is an agricultural herbicide that can be aerially applied and because it may affect endangered plant species which are associated with the areas where sugar beets are grown.

Tier I plant tests are screening tests to evaluate the affects of the maximum application rate on plants. If the maximum rate results in greater than a 25% effect compared to the control plants, Tier II plant tests are required. Tier II tests use a series of test levels to measure the dose response. Regression analysis is used to derive EC_{25} values, which are defined as the estimated levels at which 25% effects, compared to control plants, are anticipated.

Results of reviewed terrestrial plant toxicity data (Tier I) on technical desmedipham are listed below:

Table 12. Tier I Nontarget Terrestrial Plant Toxicity Findings (Exposure = 1.26 lb a.i./A)

Study Type	MRID No.	Species	% A.I	Response	Fulfills Guideline Requirement
Seed Germination	41711401	Soybean, lettuce, carrot, tomato, cucumber, radish, corn, oat, wheat, and onion	98	Not significant	Yes
Seedling Emergence	41774101	Soybean, carrot, cucumber, corn, oat, and wheat	98	Not significant	Yes
		Lettuce	98	60% reduction in fresh wt.	Yes
		Tomato	98	25% reduction in fresh wt.	Yes
		Radish	98	20% reduction in fresh wt.	Yes
		Onion	98	40% reduction in fresh wt.	Yes
Vegetative Vigor	41816401	Soybean, carrot, corn, oat, wheat, and onion	98	Not significant	Yes
		Radish	98	20% reduction in fresh wt.	Yes
		Lettuce	98	39% reduction in fresh wt.	Yes
		Tomato	98	Chlorosis	Yes
		Cucumber	98	Chlorosis	Yes

Based on responses in the above tier I data, a tier II vegetative vigor study using technical grade desmedipham (TGAI) was required for lettuce and a tier II seedling emergence study with TGAI was required for tomato, onion, and lettuce. Tier II seedling emergence and vegetative vigor tests with a typical end-use product (TEP) were also required for tomato, onion, lettuce, corn, soybean, and radish along with four of the most sensitive species listed on the label. Results of reviewed tier II terrestrial plant toxicity data on technical desmedipham for the most sensitive species are listed below:

Table 13. Tier II Nontarget Terrestrial Plant Toxicity Findings

Study Type	MRID No. Author/Year	% A.I.	Plant Type	Species	NOEL (lb a.i./A)	EC_{25} (lb a.i./A)	Fulfills Guideline Requirement
Seedling Emergence (TGAI)	42366302	98	Monocot	Onion	0.30	0.58	Partially[1]
			Dicot	Lettuce	0.30	0.40	
			Dicot	Tomato	0.15	0.31	
Vegetative Vigor (TGAI)	42366301	98	Dicot	Lettuce	1.22	> 1.22	Partially[1]

[1] Seedling emergence and vegetative vigor testing with a TEP is required to fulfill these guidelines.

The results in Table 13 show that when desmedipham is applied without adjuvants, exposure levels of 0.31 lb a.i./A or greater can cause significant detrimental effects on the germination and emergence of certain plants. The results from the vegetative vigor test indicate that desmedipham applied as the TGAI is not toxic at normal use rates. (NOEL of 1.22 lb/A, compared to the maximum label rate of 1.26 lb ai/A). The Agency believes that the adjutants normally present in the TEPs must be present for desmedipham to express toxicity to plants. Therefore, testing with a TEP is needed to estimate the toxicity during normal use of desmedipham on the foliage of nontarget terrestrial and semi-aquatic plants. The guideline requirements are only partially fulfilled (GLN 123-1(a), 123-1(b), MRIDs 42366301 and 42366302).

(2) Aquatic

Aquatic plant testing is required for any herbicide which has terrestrial non-residential uses and may move off-site by runoff (solubility > 10 ppm in water) or by drift (aerial or irrigation applications), is applied directly to aquatic use sites, or may affect endangered plant species. This testing is required for desmedipham because it is an agricultural herbicide which may be applied aerially and may effect endangered plant species which are associated with the sugar beet site. Testing is required with the following species: *Kirchneria subcapitata*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Results of reviewed tier I and II aquatic plant toxicity data on technical desmedipham are listed below:

Table 14. Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	EC_{50} (mg a.i./L)	MRID No.	Fulfills Guideline Requirement
Navicula pelliculosa (Freshwater diatom), Tier 2	98	0.044[a]	43053503	Yes
Lemna gibba, Tier 1	98	> 0.33[a]	43053505	Yes
Kirchneria subcapitata, Tier 2	98	0.19[a]	43053501	Yes
Skeletonema costatum, Tier 1	98	> 0.3[a]	43053504	Yes
Anabaena flos-aquae, Tier 1	98	> 0.22[a]	43053502	Yes

[a]Based on estimated 5-day mean concentrations.

The results also indicate that mean 5-day exposure levels of desmedipham at 0.044 mg a.i./L or greater concentrations can cause significant detrimental effects on the growth and reproduction of certain single-celled aquatic plants. The guideline requirements are fulfilled (GLN 122-2, MRIDs 43053502, 43053504, and 43053505; GLN 123-2, MRIDs 43053501 and 43053503).

2. Environmental Fate

Although the environmental fate database is not complete, there is sufficient acceptable and supplemental environmental fate information for the Agency to conclude that desmedipham will not persist in the environment. The primary degradation pathway for desmedipham is hydrolysis to ethyl-(3-hydroxyphenyl) carbamate (EHPC) and aniline, with further degradation by microbial processes to CO_2. Photodegradation, volatilization, and bioaccumulation in fish do not appear to contribute significantly to the dissipation of desmedipham. Desmedipham and EHPC have a low potential to leach to ground water in most soils. It is expected that desmedipham residues which reach surface water by either spray drift or runoff will be rapidly degraded.

The following additional confirmatory information has been requested to perform a more comprehensive environmental fate assessment:

- The material balances during hydrolysis of desmedipham at pHs 5 and 7 (GLN 161-1);
- Pedological characteristics of the test soils used during the aerobic soil metabolism (GLN 162-1), anaerobic aquatic metabolism (GLN 162-3), and the column leaching (GDLN 163-1) studies.
- Stability during frozen storage of the field samples of the terrestrial field dissipation study (GLN 164-1).

If the confirmatory information is acceptable, these studies can be upgraded to acceptable and the data requirements will be fulfilled. Data to characterize desmedipham's spray drift potential from aerial and ground applications have been recently submitted by the industry Spray Drift Task Force. The Agency has not evaluated these data at the drafting of this document, but will do so in the near future.

a. Environmental Fate Assessment

The primary degradation pathway for desmedipham is hydrolysis to ethyl-(3-hydroxyphenyl) carbamate (EHPC) and aniline, with a half-life at pH 7 of 17-20 hours; at pH 9, the half-life is 7-10 minutes. Hydrolysis of desmedipham is slower at lower pH, which is characteristic of chemicals containing ester linkages. EHPC is then further degraded by microbial processes to CO_2. Information available in the open literature indicates that aniline is rapidly degraded by microorganisms to CO_2 and is also directly incorporated into bound residues (Verschueren, 1977; Government of Canada, 1994). Desmedipham photodegrades slowly in

water and on soil (half-lives > 100 hours), which indicates that, in comparison to hydrolysis, photodegradation will not be a major degradation process in neutral to alkaline environments. Adsorption/desorption data for desmedipham could not be obtained using batch equilibrium methods due to the rapid hydrolysis of desmedipham to EHPC at pHs ≥5. Column leaching studies indicated that desmedipham and its transformation product EHPC do not leach readily. Following 45 days of continuous irrigation, ≤3% of the applied radioactivity was detected in the leachate of treated soil columns. In addition, greater than 95% of the radioactivity applied remained in the top 5-6 cm of the columns. In laboratory studies, desmedipham was seen to bioaccumulate to a small extent in bluegill sunfish (maximum bioconcentration factors of 20X, 98X, and 159X for fillet, whole fish, and viscera, respectively); however, residues were depurated rapidly (> 90% by 7 days). Supplemental information from field dissipation studies indicates that the DT_{50} (the time it takes for 50% of the applied material to dissipate) of desmedipham when applied to sugar beets in California was 7 days; supplemental information from a North Dakota study site indicates an even shorter half-life on alkaline soils (estimated < 1 day on soil of pH ≥ 7.3).

Based on these data, the Agency concludes that desmedipham has a low potential to leach to ground water in most soils. Data support a finding that desmedipham would not persist in neutral to alkaline surface waters which would typically be found in areas of sugar beet production. It may contaminate surface water from spray drift associated with ground or aerial application. Desmedipham will adsorb to soil particles and may be transported by surface runoff to surface water bodies on entrained sediment. However, rapid degradation by abiotic hydrolysis and microbial-mediated metabolism should result in low concentrations in surface waters. Multi-residue monitoring data in several states with sugar beet production (California, Washington, and Minnesota) did not report the presence of desmedipham in surface waters.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

The rate of hydrolysis of desmedipham is pH dependent, with rapid hydrolysis occurring under alkaline conditions. A confirmed half-life of 7-10 minutes was reported for pH 9 buffered aqueous solutions; supplemental information from unacceptable hydrolysis studies provided half-lives of 1417 to 1897 hours (59 to 79 days) at pH 5 and 17 to 20 hours at pH 7. The hydrolysis products, aniline and ethyl N-(3-hydroxyphenyl) carbamate (EHPC), formed in equimolar amounts at pH 9. After 50 minutes at pH 9 (at which time hydrolysis of desmedipham was essentially complete), aniline and EHPC did not appear to degrade. The guideline requirement is partially fulfilled (GLN 161-1 [pH 9], MRID 00142740).

The unacceptable hydrolysis studies conducted at pHs 5 and 7 may be upgradeable if the registrant provides acceptable material balances for those studies.

Photodegradation

Photodegradation in water: Desmedipham, at a concentration of 8 ppm in pH 3.8 buffered aqueous solution, photodegraded with a half-life of 10 hours when irradiated for 355 hours with a Hg-arc vapor lamp which had a light intensity approximately an order of magnitude greater than that of sunlight in the 290 to 320 nm wavelength range. Desmedipham did not degrade in the dark control (no light exposure) samples, indicating that desmedipham was stable to hydrolysis at pH 3.8. The transformation product EHPC was present at approximately 10% of the applied after 10 hours of irradiation; other minor photoproducts were ethyl N-(3-hydroxy-4-phenyl carbamylphenyl) carbamate, and ethyl N-(2-phenylcarbamyl-5-hydroxyphenyl) carbamate, each at less than 1%. Concentrations of EHPC increased with increasing time of exposure; it did not appear to photodegrade (radioactivity in other HPLC fractions did not increase).

The Agency does not currently accept photodegradation studies performed using a Hg vapor lamp because the emission spectrum is not similar to that of natural sunlight. In this study, samples at pH 3.8 were irradiated continuously with light of at least an order of magnitude greater intensity than natural sunlight at the wavelengths (< 300 nm) at which desmedipham can photodegrade. Although the conditions of the study show that desmedipham can photodegrade in water, the rate of photodegradation is expected to be much slower than that of the primary mechanism of degradation (hydrolysis) under natural conditions. It is not expected that photodegradation in water will contribute significantly to the dissipation of desmedipham in the environment. The guideline requirement is fulfilled (GLN 161-2, MRIDs 00098607 and 41446101).

Photodegradation on soil: Aminophenyl ring-labelled ^{14}C-desmedipham and aniline ring-labelled ^{14}C-desmedipham photodegraded under a xenon arc lamp with calculated half-lives ranging from 110 to 160 hours. Sandy loam soil films were exposed to light of an intensity approximately 3 times that of summer solar irradiation at noon at 50°N. In the dark control samples, desmedipham degraded with a half-life of greater than 500 hours in the aminophenol ring-labelled samples; degradation in the aniline ring-labelled samples was < 10% after 238 hours of irradiation. The major non-volatile transformation product identified in extracts of irradiated soil samples was EHPC, which is a known hydrolysis product. Maximum concentrations of EHPC were 7.4% after 488 hours of irradiation of aminophenyl labelled ^{14}C-desmedipham and 2.9% after 238 hours of irradiation of aniline ring-labelled ^{14}C-desmedipham. The only volatile transformation product was carbon dioxide; maximum concentrations were 26.4 to 28.8%. The guideline requirement is fulfilled (GLN 161-3, MRID 00098608).

Volatilization into the Atmosphere and subsequent photodegradation: No data were reviewed for photodegradation in air (GLN 161-4). The requirement for this environmental fate study was waived due to the low vapor pressure (3×10^{-9} Torr) of technical desmedipham (GLN 63-9, MRID 41937501). The low vapor pressure and the small Henry's Law constant (which is an indication of the low tendency for the material to volatilize from water; estimated to be 1.69×10^{-10} atm-m^3 mol^{-1}) indicate that would not be a significant route of dissipation for desmedipham.

Aerobic Soil Metabolism

Supplemental information indicates that desmedipham degraded with a calculated half-life of 7.7 days when applied at a rate of 2.9 ppm to German Standard Soil 2.3 (described by the study author as a sandy loam soil) which was incubated aerobically at 21°C. The estimated DT_{90} (the time required from 90% of the applied material to degrade) was 29.1 days. The transformation product EHPC reached a maximum of 4.5% (≈0.09 ppm) of applied radioactivity at day 14 post-treatment, and decreased to 0.9% of the applied by 100 days post-treatment. Several other non-volatile transformation products were detected by TLC during the testing period; however, none were present at > 2.7% of the applied. The level of evolved $^{14}CO_2$ steadily increased during the testing period. The percentage of evolved $^{14}CO_2$ reached 15.4% by day 30 post-treatment and a maximum of 29.1% by day 100 post-treatment. Other volatiles were not discernible in any of the volatile traps during the testing period. Bound residues increased from 1.1% of applied radioactivity at day O to a maximum of 61.7% of applied radioactivity at day 71 post-treatment. There was a slight decrease to 59.1% by day 100. The bound soil residues were further characterized into fulvic acid, humic acid, and humin fractions; the amounts of applied radioactivity in the various fractions stabilized between days 30 and 100, and were 14-17%, 19-23%, and 21-26% of the applied, respectively.

It is recommended that soils typical of the use sites in the U.S. be used in aerobic soil metabolism studies. If other non-domestic soils are used, those soils must be comparable to U.S. soils. The soil used in this study was a German soil (Standard soil 2.3), but the registrant did not provide pedological characteristics for that soil (including but not limited to clay mineralogy, Great Soil Group classification, vegetation, climatological conditions, etc.). Because the Agency cannot evaluate whether this soil is comparable to a U.S. soil, the study is not acceptable at this time. However, the study may be upgradeable to acceptable if the registrant provides adequate information on the pedological characteristics of the German Standard soil and its characteristics are substantially similar to a U.S. soil in which sugar beets are grown. The guideline requirement is not fulfilled (GLN 162-1, MRID 41998601).

Anaerobic aquatic metabolism

Supplemental information from an unacceptable study indicates that desmedipham hydrolyzed rapidly (< 2 hours) to EHPC when added to an anaerobic aquatic system. Therefore, the study authors were unable to determine an exact half-life for desmedipham under anaerobic conditions. The observed rapid hydrolysis of desmedipham under the conditions of the study is consistent with other information reviewed by the Agency (MRID 00142740) and reported above.

Supplemental information from an unacceptable study indicates that EHPC degraded with a half-life of 211.9 days when applied as desmedipham to an anaerobic German sediment. At 2 hours and 2 days post-treatment, 15.3% and 8.9% of applied radioactivity, respectively, remained as desmedipham. EHPC increased to concentrations of 74.7% and 87.7% at days 2 and 15 post-treatment, respectively, and decreased to 50% by the termination of the study (100 days post-treatment). No further breakdown products and very little CO_2 (total = 4.1% of applied

radioactivity) were discernible during the testing period. Therefore EHPC is assumed to be stable to degradation under anaerobic conditions.

This study is not acceptable at this time due to deficiencies in the study, but may be upgradeable to acceptable if confirmatory data are submitted by the registrant. The guideline requirement is not fulfilled. (GDLN 162-3, MRID 41998601)

(2) Mobility

Adsorption/desorption studies

Adsorption/desorption data for desmedipham could not be obtained using the batch equilibrium method due to the rapid hydrolysis of desmedipham to EHPC at pHs $\geq$5. However, information on the mobility of desmedipham could be obtained from column leaching studies.

Aged/unaged column leaching studies

Supplemental information indicates that desmedipham and its transformation product EHPC were relatively immobile when ^{14}C-desmedipham (labelled in each ring) was applied to German soil columns irrigated with water at a rate of 25 mL/day (total of 1125 mL over 45 days). Following the 45 days of continuous irrigation, $\leq$3% of applied radioactivity was detected in the leachate of the treated soil columns. In addition, greater than 95% of the radioactivity applied remained in the top 5-6 cm of the columns; roughly half of this was extractable with methanol and was comprised of both desmedipham and EHPC. $^{14}CO_2$ produced during the 30-day aging period prior to leaching reached 15.4% and 4.1% of applied radioactive in the aminophenoxy- and phenyl-labelled desmedipham treated columns, respectively.

Supplemental mobility data have shown similar results. In unacceptable aged soil column studies using German soils, desmedipham residues did not leach. Soil TLC mobility studies are not acceptable at this time but do provide some supplemental data. The mobility of desmedipham applied to thin layers of soil on glass plates that were then eluted with water was compared to pesticides of known mobility applied to the same plates. K_ds were then calculated from the R_f's and the soil/water partition coefficients for selected pesticides; these calculated K_ds ranged from 100 to 158 ml/g, which would indicate that desmedipham was immobile. The USDA/Soil Conservation Service (SCS) database reports a K_{oc} for desmedipham of 1500 (Wauchope et al., 1992).

At this time, soils information to upgrade the column leaching study is still required. The guideline requirement is not fulfilled. (GLN 163-1; MRIDs 41214709, 42281403, 42124202, 41214708).

Volatility studies

No laboratory volatility (GLN 163-2) or field volatility (GLN 163-1) studies were reviewed for desmedipham. The requirement for these environmental fate studies was waived due to the low vapor pressure (3×10^{-9} Torr) of technical desmedipham (GLN 63-9, MRID 41937501). The low vapor pressure and the small Henry's Law constant (which is an indication of the tendency for the material to volatilize from water; estimated to be 1.69×10^{-10} atm-m^3 mol^{-1}) indicate that volatilization from soil or water would not be a significant route of dissipation for desmedipham.

(3) Accumulation

Bioaccumulation in Fish:

Results from accumulation in fish studies are used to estimate the bioconcentration potential of the parent pesticide under controlled laboratory conditions. Bluegill sunfish exposed to ^{14}C-desmedipham (labelled in the aminophenol ring only) at a concentration of 0.056 mg/L for 10 days, reached maximum bioconcentration factors of 20X, 98X, and 159X for fillet, whole fish, and viscera, respectively. During a 7-day depuration period 90%, 91%, and 93% depuration was reported for fillet, whole fish, and viscera, respectively. During the testing period the test fish showed no ill effects from the desmedipham-treated water. Very little parent desmedipham was detected in fish tissues (< 1%); approximately 80% of the residues found in the fish tissues were EHPC and N-(3-hydroxyphenyl) acetamide, both free and as conjugates (probably glucuronides). It is recommended that each ring of a double ring compound be radiolabelled and be used in separate bioaccumulation in fish studies in order to fully understand a pesticide's metabolic pathway.

Desmedipham contains an aminophenol ring and an aniline ring; acceptable bioaccumulation data for desmedipham labelled in the aminophenol ring were reported in this study. The potential for the aniline ring to bioaccumulate in fish tissues can be inferred from its solubility and its octanol-water partition coefficient. A combination of a high water solubility (34,000 mg/L; Verschueren, 1977) and a low tendency to partition into organic solvents (0.8:1.0, n-octanol:water; Chiou, et al., 1982) would predict little or no bioaccumulation in fish. In laboratory tests, aniline does not appear to accumulate in aquatic biota (Government of Canada, 1994). Therefore, no further data for the bioaccumulation in fish of desmedipham radiolabelled in the aniline ring are needed at this time. The guideline requirement is fulfilled (GLN 164-5; MRID 42710101).

(4) Field Dissipation

Supplemental information from an unacceptable field dissipation study conducted in 1989 indicates that desmedipham dissipated with a registrant-calculated half-life of 30 days when applied twice in 7 days (total application 2.19 lb a.i./A as Betanex EC) to sugar beets planted on loamy sand soil in the spring of 1989 in Fresno, California. The maximum mean concentration

of desmedipham in the 0- to 3-inch depth was 0.95 ppm at 1 day post-treatment (the second application date was designated by the study author as time 0); mean concentrations decreased to 0.22 and 0.07 ppm by 28 days and 2 months post-treatment, respectively.

Data were also reported for a second site in Northwood, North Dakota treated in 1989; however, the data from this site were variable and inconsistent. This may have been due to contamination of the test site, which was indicated by the presence of apparent residues of desmedipham and EHPC in soil samples taken from the untreated control plots at that site. In addition, since no samples were taken from the treatment plots prior to application, it could not be determined if those plots also contained apparent residues. Therefore, a detailed conclusion as to the dissipation or potential for leaching of desmedipham under field conditions at this site was not possible. The study author estimated an apparent DT_{50} of 0.7 days; however, the registrant did not calculate a half-life because the data were too variable. At soil depths down to 18 inches, reported levels of both desmedipham and EHPC were greater than the detection limit (0.005 ppm) at all sampling intervals up to 7 days following the second application; however, levels in the control samples were also greater than above the detection limit for that time interval. It is therefore not possible to determine whether detections of desmedipham at those depths were due to movement of residues or contamination of the site. The rapid disappearance of desmedipham in North Dakota compared to that observed in California could be due to differences in soil pH; pHs were 7.3 and 6.4 at the North Dakota and California sites, respectively.

The portion of the study conducted in North Dakota is unacceptable because of the apparent contamination of the test soils and cannot be upgraded with the submission of additional data.

The portion of the study conducted in California is not acceptable at this time because the stability of desmedipham residues during frozen storage was not provided. Soil samples were stored for up to 18 months before analysis. Because desmedipham hydrolyzes rapidly at neutral to alkaline pHs, there is a possibility that any desmedipham residues in the test soils at time of sampling may have degraded during storage.

However, the study may be upgradeable to acceptable if the registrant provides information that shows that desmedipham is stable during a period of frozen storage of up to 18 months. The guideline requirement is not fulfilled (GLN 164-1, 42180501).

(5) Spray Drift

No desmedipham-specific studies were reviewed. Droplet size spectrum (GLN 201-1) and drift field evaluation (GLN 202-1) studies were required for desmedipham, since the different products may be applied by aircraft and it is estimated that there will be detrimental effects to non-target organisms due to drift. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including

application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1996 EPA plans to evaluate these studies. In the interim and for this assessment of desmedipham the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The estimated drift rates at 100 feet down wind of the treated sites are 1% of the applied spray volume from ground applications and 5% from aerial applications. After its review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks from the application of desmedipham products to sugar beets.

c. Water Resources

(1) Ground Water

The Agency found no indication that desmedipham would exceed any ground water LOC endpoints. Although desmedipham exceeded one of the persistence triggers (calculated field dissipation half-life), hydrolysis data indicate that desmedipham will hydrolyze rapidly in neutral to alkaline pH soils. In addition, the high K_d and K_{oc} values demonstrate that desmedipham will bind strongly to soil organic matter and is not mobile. Based on the data available, desmedipham does not meet sufficient ground water triggers. The Agency has no reports of sampling for desmedipham in ground water (Hoheisel, et al., 1992). The Agency concludes that desmedipham has a low potential to leach to ground water in most soils.

(2) Surface Water

Transport of desmedipham would be limited in surface runoff events for alkaline (pH 8-9) aqueous environments due to its rapid hydrolysis (Section C.2.). However, if surface runoff from acidic (< pH 7) environments should occur within a few days of the time of application, an undetermined fraction of the applied may be available to runoff. The solubility (7 ppm) and the intermediate K_{oc} (1500 from (United States Department of Agriculture/ Agricultural Research Service) database; and estimated K_ds of 100-150 ml/g) of desmedipham indicate it could move both in the dissolved phase and as sorbed residues to eroding soil. The soil may be transported and deposited as sediment in streams, rivers, lakes and ponds during runoff events.

In neutral to alkaline receiving surface water bodies (rivers, streams, lakes, etc.), desmedipham will hydrolyze fairly rapidly. However, in acidic waters, desmedipham may persist and distribute itself between the dissolved phase and that sorbed on suspended sediments. The transformation product EHPC may persist in the anaerobic water/sediment environment associated with bottom sediments. Volatilization of desmedipham from surface waters is not considered an important route of dissipation based on the low Henry's Law constant (1.69×10^{-10} atm-m^3 mol^{-1}, estimated). Based on the bioconcentration factors, which ranged from 20X to 159X, and depuration of > 90% in 7 days, desmedipham should not significantly bioaccumulate.

3. Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. When an LOC is exceeded by the RQ, it indicates that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if a particular LOC has been exceeded, a risk quotient must be derived and compared to that LOC. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

- EC_{25} for terrestrial plants,
- EC_{50} for aquatic plants and invertebrates,
- LC_{50} for fish and birds, and
- LD_{50} for birds and mammals.

The chronic test results are the NOEL (sometimes referred to as the no-observed-effect concentration or NOEC) for avian and mammal reproduction studies, and either the NOEL or the MATC (maximum allowable toxicant concentration) for chronic aquatic studies. The MATC is defined as the geometric mean of the NOEL and the LOEL (sometimes referred to as the low-observed-effect concentration or LOEC).

When the risk quotient exceeds the LOC for a particular category, potential risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOCs.

Table 15. Levels of Concern (LOC) and associated Risk Presumption

IF THE	LOC	PRESUMPTION
Mammals, Birds		
acute RQ >	0.5	Acute risk
acute RQ >	0.2	Risk that may be mitigated through restricted use
acute RQ >	0.1	Endangered species may be affected acutely
chronic RQ >	1	Chronic risk, endangered species may be affected chronically,
Fish, Aquatic invertebrates		
acute RQ >	0.5	Acute risk
acute RQ >	0.1	Risk that may be mitigated through restricted use
acute RQ >	0.05	Endangered species may be affected acutely
chronic RQ >	1	Chronic risk, endangered species may be affected chronically
Plants		
RQ >	1	Risk
RQ >	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

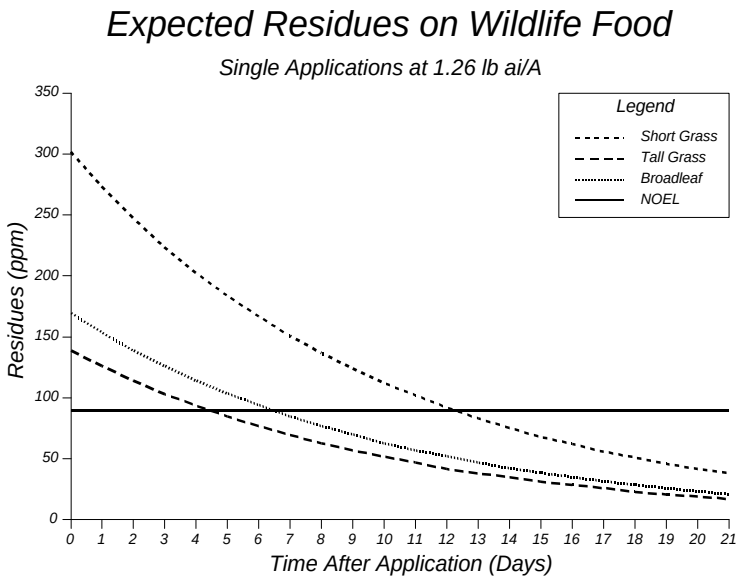
(a) Birds

Pesticide residues found on avian dietary food items following application were compared to LC_{50} values to predict hazard for birds. The Agency estimated the day 0 residues on vegetation based on the work of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). Maximum residues on vegetative food items were estimated using a program for calculating daily estimated residues based on repeated applications and first-order kinetics at an assumed rate (Lee, n.d.). For the purpose of determining acute exposure, the maximum residues of desmedipham are expected to occur immediately after the second of two applications. Based on label information, the use rate per application was assumed to be 0.98 lb ai/A, one-half of the maximum per growing season rate of 1.96 lb ai/A. The interapplication interval is assumed to be 7 days, during which time the residues from the first application would partially degrade. Based on the half-life for aerobic soil metabolism (7.7 days) and soil photolysis (6.6 days), the half-life of the overall degradation of desmedipham on vegetation was estimated to be approximately 7 days. This half-life may over-estimate persistence since a supplemental study of hydrolysis at pH 7.0 suggested a half-life of only 17-22 h. The estimated peak residues (i.e. EECs) on selected avian dietary food items, and their corresponding RQs, are given in the table below:

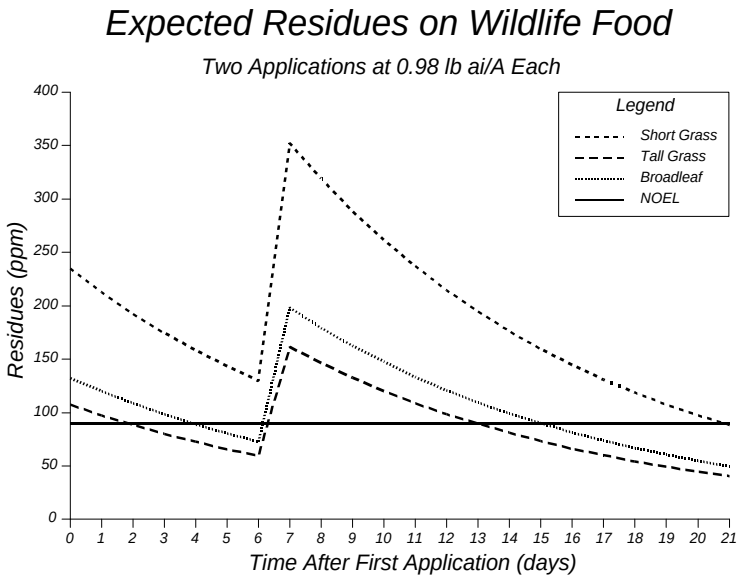
Table 16. Estimated Environmental Concentrations and Dietary Risk Quotients for Birds (Based on LC_{50} > 5000 ppm)

Food items	EEC (ppm)	RQ
Short Grasses	353	< 0.071
Tall Grasses	162	< 0.032
Broadleaved Plants and Insects	198	< 0.040
Fruits and Pods	22.1	< 0.0044

Because of the low acute toxicity of desmedipham to birds, the risk quotients for use of desmedipham are very low. No RQ exceeds the LOC for high risk to birds (1) or the LOC for possible effects to endangered species (0.1). Therefore, the use of desmedipham is expected to pose negligible acute risk to endangered and nonendangered species of birds.



The chronic toxicity of desmedipham is considerably greater than the acute toxicity. The NOEL for egg shell thinning in birds is 90 ppm. The same program (Lee, n.d.) was used to estimate expected residues on wildlife food items over time following a single and two repeated applications. As for acute exposure, desmedipham was assumed to degrade on vegetation with a half-life of 7 days. The graph above depicts the predicted residues on plants, relative to the NOEL, following a single application. When the residue levels exceed the NOEL, the RQ is greater than the LOC of 1, indicating risk of reproduction impairment. The predicted plant residues exceed the NOEL for 4, 6, and 12 days on tall grass, broadleafs, and short grass, respectively. Predicted residue levels are always less than the LOEL of 450 ppm. Thus, a single application of desmedipham at the maximum label rate is predicted to result in exposures to birds for 4 to 12 days that are between the level demonstrated to cause egg shell thinning (the LOEL) and the level demonstrated to be safe (the NOEL). The Agency concludes that desmedipham may pose a chronic risk to birds at this application rate.



A similar situation occurs when desmedipham is applied twice at a rate of 0.98 lb ai/A each application, with an interapplication interval of 7 days. This rate is one-half the maximum rate allowed per growing season. The following graph shows the expected residues on wildlife food relative to the NOEL. The residues on short grass exceed the NOEL for a full 21 days, and residues on tall grass and broadleafs exceed the NOEL for two short intervals that range from approximately 2 to 9 days. Residues never exceed the LOEL of 450 ppm. As before, the Agency concludes that desmedipham may pose a chronic risk to birds at this application rate.

(b) Mammals

Small mammal acute hazard is addressed using the acute oral LD_{50} value from the rat study described above (Section III.B), converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50}\ X\ body\ weight\ (g)}{food\ consumed\ per\ day\ (g)}$$

Estimated mammalian LC_{50} values for three species of small mammals are presented below:

Table 17. Estimated Small Mammal Dietary Exposure in PPMs (Based on an LD_{50} > 5000 mg/kg)

Small Mammal	Body Weight (g)	Percent of Weight Eaten Per Day	Food Consumed Per Day (g)	Estimated LC_{50} (ppm)
Meadow vole	46	61 %	28.1	> 8200
Adult field mouse	13	16 %	2.1	> 31,000
Least shrew	5	110 %	5.5	> 4550

The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The risk quotients are calculated by dividing the EECs residues by the estimated LC_{50}s. The table below shows the risk quotients for peak exposures following single and multiple application:

Table 18. Mammalian Dietary Risk Quotients

Species and Diet	Application Rate (lb ai/A)	Maximum EEC[1] in food item (ppm)	Risk Quotient
Meadow vole consuming short grasses	1.26 (single application)	302	< 0.037
	0.98 (two applications)	348	< 0.043
Adult field mouse consuming seeds	1.26 (single application)	18.9	< 0.00061
	0.98 (two applications)	21.7	< 0.00070
Least shrew consuming insects	1.26 (single application)	170	< 0.037
	0.98 (two applications)	194	< 0.043

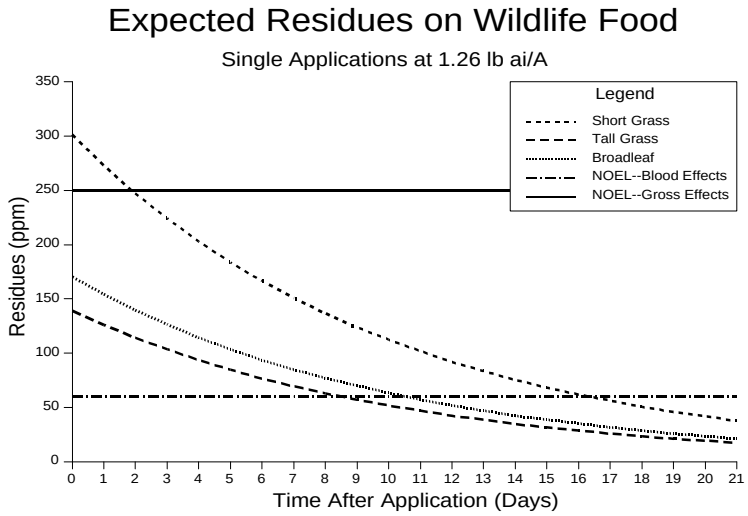
[1] Based on Hoeger and Kenaga (1972) with modifications by Fletcher et al. (1994).

The acute mammalian risk quotients for use of desmedipham are very low. None exceed the LOC for risk to mammals (1) or the LOC for possible effects to endangered species (0.1). Therefore, the use of desmedipham at the above application rate and based on the acute oral toxicity of desmedipham to the rat is expected to pose negligible acute risk to endangered and nonendanged species of mammals.

Mammals also may suffer subchronic or chronic effects, depending on the chronic toxicity of the chemical and the degree and duration of exposure to the organism. The toxicity to wild mammals is probably best represented by subchronic and reproductive toxicity studies with the laboratory rat, as described in sections B.1.b. and B.1.e.) respectively. A subchronic feeding study yielded a NOEL of 60 ppm and an LOEL of 300 ppm (MRID 40387102). These values are based on changes observed in the blood which may or may not have ecological significance to the survival and reproduction of wild mammals. A 2-generation reproduction study found similar blood effects at similar dietary concentrations (NOEL = 50 ppm, LOEL = 250 ppm).(MRID 40387105) Gross effects which are likely to have ecological significance (e.g. decreased weight of parents and pups) were only observed at a dietary concentration of 1250 ppm. The NOEL for these gross effects was 250 ppm.

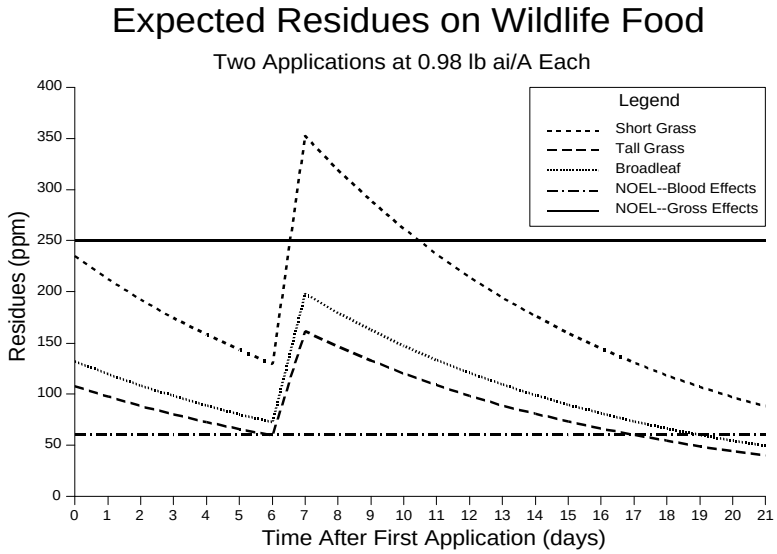
Estimates of desmedipham residues in mammalian food are identical to those estimated previously for avian food. Day 0 estimates were based on the work of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994), and the change in residues over time was estimated

using the program described above [Section 3.a.(1)(a)]. The graph below shows the estimated residues after a single application at the rate of 1.26 lb ai/A, relative to the two NOEL values discussed above (60 ppm and 250 ppm).



Residues exceed the NOEL for minor blood effects (60 ppm) for 8 to 16 days. The residues do not exceed the higher NOEL of 250 ppm except for the first two days of residues on short grass.

Predicted residues on plants for two repeated applications of 0.98 lb ai/A, separated by an interval of 7 days, are depicted in the graph below.



Plant residues are generally greater than the NOEL for minor blood effects for 17 days or longer. Furthermore, the residues on short grass also exceed the LOEL of 250 ppm for approximately 4 days. The NOEL for gross effects is exceeded only by residues on short grass for a duration of approximately 4 days. These residues remain well below the LOEL for gross effects (1250 ppm). Two applications result in a higher exposure than a single application.

The overall risk of significant chronic effects to mammals from the current use of desmedipham is presumed to be minimal, as described in the risk characterization section (C.3.c.).

(c) Insects

Since desmedipham was found to be practically nontoxic to honey bees, no detrimental effects on honey bees are expected.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: The Agency calculated generic EECs using the GENeric Expected Environmental Concentration Program (GENEEC). These generic EECs are designed as a coarse screen and estimate expected concentrations from a few basic chemical parameters and pesticide product label application information.

GENEEC is a model designed to mimic a PRZM-EXAMS simulation. It uses a chemical's soil/water partition coefficient and various degradation and metabolic half-life values to estimate runoff from a 10-hectare field into a 1-hectare by 2-meter deep pond. GENEEC calculates generic estimated environmental concentration (GEEC) values that are used for both acute and chronic risk assessments. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, and degradation of the pesticide within the water body. It also accounts for direct deposition of spray drift onto the water body.

Table 19. The following values were used for input into the GENEEC Program:

Chemical Characteristic	Value
Soil Organic Carbon Partitioning Coefficient	1500
Soil Aerobic Metabolic Half-life	7.7 days
Hydrolysis Half-life	22 h
Photolysis Half-life (at pH 7)	10 h
Water Solubility	7 ppm

The soil organic carbon partitioning coefficient was obtained from the USDA/SCS database. Other values were obtained from studies submitted to the Agency and are discussed in the Environmental Fate section of this chapter (section C.2). The hydrolysis and photolysis half-lives are based on supplemental data. For scenarios with two applications, the interval between applications was assumed to be 7 days. Spray drift at 100 feet downwind is assumed to be 1% of the application rate for ground applications and 5% of the application rate for aerial applications. (A. Jones, pers. comm.)

Table 20. Estimated Environmental Concentrations (Eecs) for

Crop	Application Method	Application Rate (lbs a.i./A)	Number of Applications (Interval)	Peak GEEC (ppb)	4-day GEEC (ppb)	21-day EEC (ppb)	56-day EEC (P.B.)
Sugar Beet	Aerial	0.98[a]	2 (7 days)	14.5	6.65	1.32	0.50
Sugar Beet	Ground	0.98[a]	2 (7 days)	14.1	6.23	1.24	0.46
Sugar Beet	Aerial	1.26	1	9.64	4.26	0.85	0.32
Sugar Beet	Ground	1.26	1	9.77	4.29	0.85	0.32

[a] This rate is one half of the maximum rate allowed per growing season.

The greatest aquatic environmental concentration of desmedipham is predicted to be 14.5 ppb.. This is the concentration predicted after the second of two aerial applications at 0.98 lb ai/A.. Concentrations are predicted to dissipate fairly rapidly. Less than half of the peak concentration should remain after 4 days, and less than one-tenth should remain after 21 days.

(a) Freshwater Fish

Using the highest peak EECs (aerial and ground applications, two per year), acute RQs were calculated for the bluegill and rainbow trout, based on their respective 96-hr LC_{50}s.

Table 21. Acute Risk Quotients (RQ) for Freshwater Fish

Crop and Application Method	Application Rate (lb ai/A per application)	Peak GEEC[a] (ppb)	Species	96-hr LC_{50} (ppb)	Acute RQ
Sugar Beets, Aerial	0.98	14.5	Bluegill	6000	0.0024
			Rainbow trout	1700	0.0086
Sugar Beets, Ground	0.98	14.1	Bluegill	6000	0.0024
			Rainbow trout	1700	0.0083

[a] The peak GEEC is the highest expected concentration after two equal applications of desmedipham separated by an interval of 7 days.

The RQs for acute risk are all well below the LOCs for presuming risk and possible effects on endangered species. Use of desmedipham is thus predicted to have little or no acute effects on freshwater fish.

Due to desmedipham's relatively low acute toxicity to fish and its low persistence in water (Section C.2.), testing for chronic effects on fish have not been required. The Agency presumes the chronic risk to freshwater fish is minimal.

(b) Freshwater Invertebrates

Acute RQs for *Daphnia magna* were calculated using the same peak EECs as above and the *Daphnia magna* 96-hr LC_{50}.

Table 22. Acute Risk Quotients (RQ) for Freshwater Invertebrates

Crop and Application Method	Application Rate (lb ai/A per application)	Peak GEEC[a] (ppb)	Species	96-hr LC_{50} (ppb)	Acute RQ
Sugar Beets, Aerial	0.98	14.5	*Daphnia magna*	1880	0.0077
Sugar Beets, Ground	0.98	14.1	*Daphnia magna*	1880	0.0075

[a] The peak GEEC is the highest expected concentration after two applications of desmedipham separated by an interval of 7 days.

The RQs for acute risk are all well below the LOCs for presuming risk and possible effects on endangered species. Use of desmedipham is thus predicted to have little or no acute effects on freshwater invertebrates.

Due to desmedipham's relatively low acute toxicity and its low persistence in water (Section C.2.), testing for chronic effects on invertebrates has not been required. The Agency presumes the chronic risk to freshwater invertebrates is minimal.

(c) Estuarine and Marine Animals

Use of desmedipham is not expected to pose a risk to estuarine and marine habitats because it is not generally used in areas associated with marine and estuarine habitats.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

The Agency performs separate risk assessments for two categories of nontarget plants, terrestrial and semi-aquatic. Non-target terrestrial plants inhabit non-aquatic areas which are generally well drained. Non-target semi-aquatic plants inhabit low-lying areas that are usually wet, although they may be dry during certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment.

To estimate the exposure to non-target terrestrial and semi-aquatic plants, the Agency must calculate pesticide loading from runoff, spray drift, and volatilization. Exposure from runoff differs between plant types, in that terrestrial plants are assumed to be subjected to sheet runoff, whereas semi-aquatic plants are assumed to be subjected to channelized runoff. Because of the low vapor pressure (3×10^{-9} Torr) of technical desmedipham (GLN 63-9, MRID 41937501), volatilization is not considered to significantly contribute to exposure.

Ground Applications

Runoff: The Agency assumes that runoff will expose nontarget plants to a fixed percentage of the application rate. Since the water solubility of desmedipham at 20°C is 7.0 ppm, the percent runoff is assumed to be 1% based on the water solubility of the active ingredient. (Table 25.)

Table 23. Assumed percentages of application rate that may expose nontarget plants through runoff.

Water Solubility	% Runoff Assumed
< 10 ppm	1%
10 - 100 ppm	2%
> 100 ppm	5%

The Agency recognizes that runoff potential is not strictly a function of solubility. Because of the rapid hydrolysis of desmedipham in neutral to alkaline water, exposure to plants from runoff will probably be less than that predicted by this model. The conclusions of this model will therefore be conservative (i.e., over-protective).

For non-target terrestrial plants, the Agency assumes a scenario in which plants are exposed from sheet runoff. A treated site of 1 acre is assumed to drain into an adjacent area of 1 acre where terrestrial plants may be impacted. The runoff loading (lb ai) for sheet runoff is calculated with the following formula:

$$\textit{Runoff Loading (lb ai)} = \text{max. } \textit{appl. rate (lb ai/A)} \; X \; 1\% \; \textit{runoff} \; X \; 1 \; \textit{acre}$$

In the scenario used for non-target semi-aquatic plants, exposure from runoff is assumed to be from channelized runoff. A treated site of 10 acres is assumed to drain into a low lying area of 1 acre where semi-aquatic plants may be impacted. Like terrestrial nontarget plants, the percentage of runoff is based upon water solubility. The runoff loading (lb ai) for channelized runoff is calculated with the following formula:

$$Runoff\ Loading\ (lb\ ai) = \text{max. } appl.\ rate\ (lb\ ai/A)\ X\ 1\%\ runoff\ X\ 10\ acre$$

Spray drift: For application with ground equipment, exposure from spray drift is assumed to be 1% of the application rate. The drift loading (lb ai) impacting a 1-acre site adjacent to a 1-acre treated site is calculated as follows:

$$Drift\ Loading\ (lb\ ai) = \text{max. } appl.\ rate\ (lb\ ai/A)\ X\ 1\%\ runoff\ X\ 1\ acre$$

The drift loading rate is divided by the vegetative vigor EC_{25} to calculate a risk quotient for spray drift on vegetation. In addition, the total loading rate is divided by the seedling emergence EC_{25} to calculate risk quotients for exposure to emerging seedling of terrestrial and semi-aquatic plants. The total loading rate, or the total lb ai potentially impacting a 1-acre site, is the sum of the runoff loading and drift loading. Because of the greater assumed drainage area, the runoff loading from channelized runoff (for semi-aquatic plants) will be ten times greater than that from sheet runoff (for terrestrial plants).

The predicted loading rates from ground applications of desmedipham at the maximum use rate of 1.26 lb ai/A are summarized in Table 26.

Table 24. Predicted loading rates from ground applications.

Type of Exposure	Loading Rate (lb ai/A)
Sheet runoff	0.0126
Channelized runoff	0.126
Spray drift	0.0126

Aerial Applications

Runoff: Exposure due to runoff following aerial applications is calculated in the same manner as for unincorporated ground applications, except that a correction for application efficiency is required. Application efficiency, that is, how much of what is applied actually hits the target site, is less for aerial application since much of what is sprayed drifts away from the site. The Agency assumes the application efficiency to the treated site to be 60%. The runoff loading (lb ai) for sheet runoff is calculated as follows:

$$Runoff\ loading\ (lb\ ai) = \text{max. } appl.\ rate\ (lb\ ai/A)\ X\ 60\%\ appl.\ efficiency\ X\ 1\%\ runoff\ X\ 1\ acre$$

The runoff loading (lb ai) for channelized runoff is calculated as follows:

Runoff loading (*lb ai*) = max. *appl. rate* (*lb ai*/*A*) *X* 60% *appl. efficiency X* 1% *runoff X* 10 *acre*

Spray drift: Some of what drifts from the site following aerial application settles relatively quickly in immediately adjacent areas; the Agency estimates the drift at 100 feet downwind of the site will be 5% of the application rate. The loading from spray drift from aerial application is calculated as follows:

Drift loading (*lb ai*) = max. *appl. rate* (*lb ai*/*A*) *X* 60% *appl. efficiency X* 5% *runoff X* 1 *acre*

As with ground applications, the total loading rate for aerial applications is the sum of the runoff loading and drift loading. The runoff loading rate for sheet runoff is used in the sum for terrestrial plants whereas the runoff loading rate for channelized runoff is used in the sum for semi-aquatic plants.

The predicted loading rates from aerial applications of desmedipham at the maximum use rate of 1.26 lb ai/A are summarized in Table 27.

Table 25. Predicted loading rates from aerial applications

Type of Exposure	Loading Rate (lb ai/A)
Sheet runoff	0.00756
Channelized runoff	0.0756
Spray drift	0.0630

Risk Quotients

Risk quotients for terrestrial and semi-aquatic plants are derived by dividing an exposure estimate, in terms of a loading rate (lb ai/A), by an EC_{25}, also expressed in terms of lb ai/A. The total loading rate (runoff plus spray drift) is used with the EC_{25} of the most sensitive species in the seedling emergence study to determine the risk quotient for exposure to seedlings. The loading from spray drift alone is used with the EC_{25} value of the most sensitive species in the vegetative vigor study to determine the risk quotient for exposure to foliage.

The summarized information for terrestrial and semi-aquatic non-target plants is presented in Table 26.

Table 26. Exposure and Risk Quotients for Terrestrial and Semi-aquatic Plants

Use Site & Rate	Type of Plants	Exposure Scenario	Exposure (lb ai/A)	EC_{25} (lb ai/A)	Risk Quotient
Ground, 1.26 lb ai/A	Terrestrial	Sheet runoff + spray drift (1%)	0.025	0.31 (Seedling emergence)	0.081
	Semi-aquatic	Channelized runoff + spray drift (1%)	0.14	0.31 (Seedling emergence)	0.45
	Terrestrial and semi-aquatic	Spray drift (1%)	0.013	--[a] (Vegetative vigor)	--
Aerial, 1.26 lb ai/A	Terrestrial	Sheet runoff + spray drift (5%)	0.071	0.31 (Seedling emergence)	0.23
	Semi-aquatic	Channelized runoff + spray drift (5%)	0.14	0.31 (Seedling emergence)	0.45
	Terrestrial and semi-aquatic	Spray drift (5%)	0.063	--[a] (Vegetative vigor)	--

[a] The Agency does not believe that the toxicity values determined from the vegetative vigor tests with the TGAI represent the toxicity of desmedipham when plants are exposed to spray drift of formulated product. This toxicity value should be derived from a TEP vegetative vigor study, which has not yet been submitted to the Agency.

As shown in the above table, the risk assessment for terrestrial and semi-aquatic plants is incomplete (i.e., missing spray drift component) because data from TEP studies are lacking. TEP studies are needed because desmedipham end-use products are expected to show enhanced activity on plant foliage due to the addition of adjuvants. These adjuvants are important for the proper wetting of foliage and absorption of the active ingredient into plant tissue. Risk resulting from exposure of spray drift on foliage cannot be quantitatively assessed until these TEP data are obtained. Since desmedipham is used to control emerged weeds, it is assumed that exposure from spray drift poses some risk to nontarget plants.

Risk for exposure to emerging seedlings resulting from a combination of runoff and spray drift were assessed using data from TGAI studies. The Agency has more confidence in using desmedipham TGAI data for assessing risk to seedlings than for emerged vegetative because adjuvants are expected to affect the activity of desmedipham less when it is applied to soil than when it is applied to foliage. Nevertheless, the certainty of the risk assessment is still reduced by not having TEP data.

None of the risk quotients for emerging seedlings exceed 1, the LOC for presuming risk. This indicates that exposure of desmedipham from runoff and spray drift will have minimal risk to the germination and emergence of seedlings.

Threatened and endangered plants: Risk quotients for threatened and endangered plants are calculated using NOELs rather than EC_{25}s.

Table 27. Exposure and Risk Quotients for Endangered Terrestrial and Semi-aquatic Plants

Use Site & Rate	Type of Plants	Exposure Scenario	Exposure (lb ai/A)	NOEC (lb ai/A)	Risk Quotient
Ground, 1.26 lb ai/A	Terrestrial	Sheet runoff + spray drift (1%)	0.025	0.15 (Seedling emergence)	0.17
	Semi-aquatic	Channelized runoff + spray drift (1%)	0.14	0.15 (Seedling emergence)	0.93
	Terrestrial and semi-aquatic	Spray drift (1%)	0.013	--[a] (Vegetative vigor)	--
Aerial, 1.26 lb ai/A	Terrestrial	Sheet runoff + spray drift (5%)	0.071	0.15 (Seedling emergence)	0.47
	Semi-aquatic	Channelized runoff + spray drift (5%)	0.14	0.15 (Seedling emergence)	0.93
	Terrestrial and semi-aquatic	Spray drift (5%)	0.063	--[a] (Vegetative vigor)	--

[a] The Agency does not have confidence that the toxicity value determined from the vegetative vigor tests with the TGAI represent the toxicity of desmedipham in formulations when plants are exposed via spray drift. This toxicity value should be derived from a TEP vegetative vigor study, which has not yet been submitted to the Agency.

None of risk quotients for emerging seedlings exceed the LOC of 1. This assessment indicates that exposure to desmedipham from runoff and spray drift will not effect seedlings of endangered or threatened plants. However, as explained above, this risk assessment is incomplete because of the lack of TEP toxicity data. The potential for desmedipham to effect endangered or threatened plants via spray drift cannot be quantitatively assessed at this time. However, since desmedipham is used to control emerged weeds, it is assumed that spray drift from aerial applications could harm endangered or threatened plants.

(b) Aquatic Plants

The scenario used to estimate exposure to nontarget aquatic plants assumes a 1-ha by 2-meter deep pond that receives drainage from a 10-ha treated site. Exposure is assumed to occur through both runoff and spray drift from the treated site. Generic EEC's (GEEC's) were estimated by the GENEEC Program (see section C.3.a.2).

Risk quotients are calculated for aquatic plants by dividing the peak GEEC by the aquatic plant EC_{50} values. A risk quotient for aquatic vascular plants is based on the EC_{50} for duckweed (*Lemna gibba*). A risk quotient for nonvascular aquatic plants is based on the EC_{50} of the most sensitive algal or diatom species tested. For desmedipham, the most sensitive nonvascular plant tested was a freshwater diatom (*Navicula pelliculosa*).

Table 28. Acute Risk Quotients (RQ) for Aquatic Plants

Crop and Application Method	Application Rate (lb ai/A per application)	Peak GEEC[a] (ppb)	Type of Plant	EC_{50} (ppb)	Acute RQ
Sugar Beets, Aerial	0.98	14.5	Vascular (*Lemna gibba*)	> 330	< 0.044
			Algae or Diatom	44	0.33
Sugar Beets, Ground	0.98	14.1	Vascular (*Lemna gibba*)	> 330	< 0.042
			Algae or Diatom	44	0.32

[a] The peak GEEC is the highest expected concentration after two applications of desmedipham separated by an interval of 7 days.

None of the risk quotients exceed 1, the LOC for presuming risk. Thus, concentrations of desmedipham in water are predicted to have minimal effects of nontarget aquatic plants. Also, desmedipham concentrations in water are not expected to affect endangered species of aquatic plants. As with terrestrial plants, drift of TEP possibly may have adverse effects to aquatic plants if it contacts foliage above the water.

(4) Endangered Species

The risk assessment indicates that use of desmedipham may affect endangered species of terrestrial vertebrates (birds, mammals, reptiles, and amphibians). (Birds and mammals are used as surrogates for reptiles and amphibians). Chronic effects on these species are possible. Foliar contact of spray drift of desmedipham may also affect nontarget terrestrial plants, as well as macrophytes and emerged aquatic plants. Use of desmedipham should not cause effects on endangered fish, insects, or aquatic invertebrates.

When the Endangered Species Protection Program becomes final, limitations in the use of desmedipham may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

4. Water Resources Risk Implications for Human Health

Desmedipham is currently not regulated under the Safe Drinking Water Act (SDWA). The Agency's Office of Water has not established a Maximum Contaminanant Level (MCL) for a Drinking Water Lifetime Health Advisory Level (HAL) for desmedipham.

a. Ground Water

The Agency has no reports of sampling for desmedipham in ground water. Chemical and physical data indicate that desmedipham will hydrolyze rapidly in neutral to alkaline soils. In addition, the high estimated K_d and K_{oc} values demonstrate that desmedipham will bind strongly to soil organic matter and is not mobile. The Agency concludes that desmedipham has a low

potential to leach to ground water on most soils and there is a low human health risk in regard to ground water resources.

b. Surface Water

Desmedipham degrades rapidly via neutral to alkaline hydrolysis; therefore, it is non-persistent in neutral to alkaline surface waters which would be typically occur in most areas of sugar beet production. Desmedipham could be transported to surface water bodies during application by means of spray drift. Desmedipham will adsorb to soil particles and could be transported by surface runoff to surface water bodies on entrained sediment. However, rapid degradation by abiotic hydrolysis and microbial-mediated metabolism will result in low concentrations in surface waters. Currently available multi-residue monitoring data for states associated with sugar beet production (CA, WA, MN) did not report the presence of desmedipham in surface waters.

Desmedipham is tentatively classified as a Group E chemical (evidence of non-carcinogenicity for humans; Section B.1.c.) and also does not have Acute Toxicity concerns with regard to human health (Table 2, section B.1.a.). The RfD for desmedipham is 0.04 mg/kg/day (section B.1.i.).

5. Environmental Risk Characterization

Based on available data, desmedipham is expected to have minimal effects on the quality of ground water. The Agency has no reports of sampling for desmedipham in ground water. Chemical and physical data indicate that desmedipham binds strongly to soil organic matter and is not mobile. The Agency concluded that desmedipham has a low potential to leach to ground water in most soils.

The environmental impact from residues of desmedipham on surface water is expected to be negligible. Desmedipham may reach surface water, primarily via spray drift and suspended particles in runoff to which desmedipham is absorbed. However, in most areas where sugar beets are grown, rapid degradation by abiotic hydrolysis and microbial-mediated metabolism should result in relatively low concentrations in surface water. Also, the toxicity of desmedipham to aquatic organisms is relatively low. The Agency concluded from its risk assessment negligible risk to endangered and nonendangered aquatic organisms (fish, invertebrates, and plants), with the exception of aquatic plants with foliage above the water which may be affected by spray drift.

The Agency concluded negligible risk from the risk assessment for desmedipham exposure to seeds and to emerging seedlings from the chemical in the soil, but this assessment was incomplete because testing with a TEP was lacking. Without a complete risk assessment, a tentative conclusion was made that desmedipham could harm terrestrial and semiaquatic plants that are exposed to drift.

Because desmedipham was shown to be practically nontoxic to honey bees, the Agency concludes that the risk to honey bees will be minimal. The risk characterization for other terrestrial animals is less certain. Acute risk screens indicated that acute exposure to residues of desmedipham will result in little or no mortality to birds or mammals. With high confidence, the Agency can conclude that the acute risk of desmedipham to endangered and nonendangered terrestrial animals is minimal.

However, the chronic risk screens indicated that chronic risks may exist in that exposure to desmedipham has the potential to cause some minor blood effects in mammals (MRID 40387103). Whether these blood effects are of ecological significance to wild mammals is not known. Exposure appears to be too little and for too short of duration to cause gross effects in the survival and reproduction of wild mammals. The risk from exposure to desmedipham residues should be limited to minor sublethal effects that are temporary and may not be ecologically significant. The risk of serious chronic effects on the reproduction and survival of mammals is minimal.

For birds, the risk screen indicated a possible risk of reproductive effects, but as discussed below, the Agency concludes that this risk is low to moderate. Because the chronic RQ for birds exceeded the LOC, an analysis of the certainties and uncertainties in the risk assessment and of the extent and significance of the risk was conducted. One uncertainty is due to the fact that only two species were tested. The risk assessment used the results from the more sensitive of the two species tested. However, because variation in sensitivity between species to pesticides tends to be great, it is likely that other species are more sensitive. The risk to these other species could be greater than that predicted.

Furthermore, on a per weight basis, food consumed by birds in the wild generally contains more water, fewer calories, and less nutrition than does the feed consumed by birds in laboratory tests. Therefore, birds in the wild must consume a greater quantity of food to meet their nutritional requirements. For the same concentration of active ingredient in the diet, birds in the field will ingest a larger dose (mass per body weight) than the birds in the laboratory tests. If these factors were known and taken into account, the predicted risk may have been greater.

On the other hand, conservative assumptions were made in estimating residue levels. For example, residues are based on maximum application rates, which may be greater than those typically used. Residue on each type of food item was assumed to be equal to the highest level of the possible range of levels predicted from field trials. That is, the estimated residues approach the maximum likely to occur (Hoerger and Kenaga, 1972; Fletcher et al, 1994).

Also, it is uncertain where the threshold is at which significant reproductive effects begin to occur. Based on chronic test results from the most sensitive species, this threshold is predicted to lie somewhere between the NOEL (90 ppm) and LOEL (450 ppm), but the precise level is unknown. Estimated environmental concentrations of desmedipham lie between the LOEL and the NOEL. Even if the environmental concentrations of desmedipham were precisely known, all that can be concluded is that the environmental concentrations probably are near the threshold.

The duration of the exposure is also in question. Greater durations of exposure correspond with a greater risk and extent of detrimental effects. The longer residues remain at levels that may cause effects (i.e. levels greater than the NOEL), the greater the likelihood that wild organisms will move into the treated areas and be exposed. For desmedipham, the duration of exposure that exceeds the NOEL is predicted to be 21 days for short grass that receives two applications of desmedipham spaced seven days apart. For other types of foliage with two applications, and for all foliage types with a single application, the durations of exposure was characterized as 4 to 12 days. Overall, the estimated duration of exposure is relatively short compared to the duration of the avian reproductive tests.

The assumed persistence of residues on wildlife food was conservative, i.e. at the upper end of the range of the different degradation rates reported in the environmental fate studies. The half-life selected for estimating dissipation of residues on food items (approximately 7 days) was consistent with the half-lives determined in the field dissipation and aerobic soil metabolism studies (Section 2.b.). Under some conditions, the rate of degradation may be faster (hydrolysis half-life at pH 7 was 17-22 hours), which would result in a quicker decline of residues, and risk, to levels below the LOC for chronic effects.

In the statements concerning the duration of exposure, birds were assumed to consume only those food items containing the maximum predicted concentration of desmedipham during the entire period. While the test organisms were fed only on the contaminated food, wild organisms, and especially birds, may move about, feeding in an opportunistic manner from a variety of sites. In the chronic risk assessment, the assumption is made that birds would be returning to the treated fields every day to feed. This is considered unlikely because sugar beet fields are not believed to be favorable feeding areas for birds. Most birds will likely feed part of the time in uncontaminated areas, thereby reducing the level of chronic risk.

Another consideration is the extent of exposure. The EECs used to assess risk to birds were based on direct application to the food items in the treated field. Therefore, the birds would have to be feeding in the treated field itself to be exposed to these levels. Residues on avian food items off the treated site generally result from drift from the treatment area. Residues on food items would only be a small percentage of those that occur within the treated field (currently assumed to be 1% if treatment is by ground equipment and 5% if by aerial equipment). Chronic risk to birds feeding in this area would be negligible. Although these marginal regions probably comprise less area than the fields themselves, they probably comprise a more favorable habitat that will be used more extensively for feeding. These regions would likely contain more plant foods than areas in the field where weeds are controlled by tilling. Also, most of the weeds in the field should be killed by action of desmedipham and other herbicides that are applied. This dead and dying vegetation may be less attractive to birds than the green vegetation that would occur in the field margins.

Finally, the timing of exposure is important in considering the potential for desmedipham to cause reproductive effects in birds. The reproductive effects observed in laboratory tests (eggshell thinning and reduced viability of embryos) would be expected only in wild birds that are

exposed during the period of breeding and egg laying. The field dissipation tests give an indication of the typical timing application of, and hence exposure to, desmedipham on sugar beet fields. These studies were done in actual fields of sugar beets under typical growing conditions. Applications in these tests were made in May and mid-June in California and North Dakota, respectively. Timing of the breeding and egg laying of some relevant species are reported below:

Table 29. Timing of Breeding in Selected Bird Species

Species	Begin	Peak	End	Location
Canada Goose	Early March	Late March		Oregon, Washington, California,
	Mid-March	Late March - April	May	Montana
	Early April	Mid-April	Early May	Idaho
Mallard Duck		May		California, Utah, Montana, South Dakota, New York, Vermont
	Early April	Early May	Mid-July	North Dakota
Northern Bobwhite	April	Mid-May - July	September	Illinois
American Robin	Early April	Mid-April	Late April	Illinois

Source: Environmental Protection Agency, 1993. Wildlife Exposure Factors Handbook, Volume I of II. Document number EPA/600/R-93/187a. Washington, DC 20460.

Reproduction of Canada geese should not be affected since applications of desmedipham are made in areas where sugar beets are grown after the end of the breeding season. For the mallard, applications generally occur after the peak of breeding, but the period of exposure does overlap with the later part of the breeding season. There will also be overlap for species whose breeding season continues into the summer, such as the northern bobwhite and passerines that have multiple clutches. However, unlike ducks and geese, these species generally do not feed extensively on grass. Their diet is usually composed of some combination of seeds, fruit, or invertebrates, which are food items predicted to contain considerably less residues than short grass. This reduces the level of risk to these species.

The Agency concludes that the use of desmedipham poses some risk to birds in that it may cause impairment of reproduction of some species. The risk characterization suggests that the level of risk is moderate to low. Risk appears to be limited to situations of exceptionally high exposure. At the local level, some effects may be possible in a few cases when sensitive birds feed heavily for a continued time within treated fields. The mallard duck is an example of a species which may be susceptible. Chronic effects, however, are not expected to be widespread or extensive. Also, as the use of desmedipham is concentrated in a few relatively small areas of the country, the impact to the environment will be limited to the local level. The impact on the overall environment on national or regional scales is not likely to be significant.

Risk Characterization Conclusions

The Agency's following risk characterization conclusions are based on the weight-of-the-evidence after consideration of all the information reviewed by the Agency on desmedipham and wildlife behavior. It also takes into account the assumptions made during the risk assessment process.

The following are concluded with relatively high certainty:

- Ground water and surface water contamination is of minimal concern.
- Risk to aquatic plants and animals is minimal.
- Acute risk to insects, birds, and mammals is minimal.

Certainty is not as high in the following conclusions:

- The chronic risk to mammals is minimal.
- A chronic risk to birds exists but is characterized as low to moderate. Effects are expected to be limited in extent, and the impact to the environment should be significant only on the local level.

Risk to terrestrial and semiaquatic plants could not be assessed because of lack of testing using the TEP. To be conservative, desmedipham should tentatively be assumed to pose risk to these plants through exposure from drift.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing desmedipham as an active ingredient. 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 desmedipham. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of desmedipham, 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 desmedipham and to determine that desmedipham can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all currently registered products containing desmedipham as the active ingredient are eligible for reregistration. The reregistration of these 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, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of desmedipham 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 desmedipham, if

new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient desmedipham, the Agency has sufficient information on the health effects of desmedipham and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that desmedipham products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing desmedipham for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Worker Protection

The Worker Protection Standard (WPS)

2. Scope of the WPS

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (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 the 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 all registered uses of desmedipham are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

a. Compliance With the WPS

Any product whose labeling can be reasonably interpreted to permit 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, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products 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, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

b. Personal Protective Equipment/Engineering Controls for Handlers

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

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

    - In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most 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 the 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.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required to mitigate risk, then long-sleeve shirts, long pants, socks, and shoes are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

c. Occupational-Use Products

EPA has determined that regulatory action on desmedipham must be taken to adequately mitigate risks to certain handlers. EPA will establish active-ingredient-based minimum PPE requirements for certain occupational handlers.

The MOEs for dermal exposure are of concern for occupational mixers/loaders. EPA is requiring active-ingredient-based protection for handlers of desmedipham in these exposure situations. Specifically, EPA is requiring chemical-resistant gloves for all mixers and loaders. In addition, a dust/mist respirator will be required for mixers/loaders of wettable powder formulations who are supporting groundboom applications. To adequately mitigate risks to mixers/loaders of wettable powder formulations who are supporting aerial applications, EPA is requiring engineering controls -- the product must be formulated in water-soluble packaging, or application rates must be limited to no more than 0.5 lb/a.i. on no more than 350 acres/day.

d. Homeowner-Use Products

There are no homeowner uses of desmedipham.

3. Post-Application/Entry Restrictions

a. Occupational-Use Products (WPS Uses)

(1) Restricted-Entry Interval:

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

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

The WPS REI in effect until now was 24 hours. This was an interim REI placed on desmedipham products by PR Notice 93-7 based on data which indicated that desmedipham is in toxicity category II for eye irritation potential.

During the reregistration process, EPA determined that the 24-hour REI established under the WPS should be retained for all occupational-use products that contain desmedipham and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this decision is that desmedipham is categorized as toxicity category II for eye irritation potential. EPA has determined that no additional regulatory action (beyond the 24-hour REI) must be taken to mitigate post-application exposures/risks.

(2) Early-Entry PPE:

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient. In any case, the minimum early-entry PPE allowed by the WPS is coveralls, chemical-resistant gloves, socks, and shoes.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since EPA has determined that no additional regulatory action must be taken due to the adverse effects of desmedipham, it is establishing PPE for dermal protection on the basis of the acute toxicity of the active ingredient. Desmedipham is classified as toxicity category III for acute dermal toxicity and toxicity category IV for skin irritation potential, therefore, the minimum early-entry PPE allowed by the WPS is required. Since desmedipham is classified as toxicity category II for eye irritation potential, protective eyewear is required.

4. WPS Notification Statement

Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."

EPA has determined that double notification is not required for desmedipham end-use products.

5. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing desmedipham. See specific labeling statements are described in the next section.

6. Dietary Exposure Assessment

For the purposes of risk assessment, adequate plant metabolism and magnitude of the residue data are available for sugar beets. The Agency used the established 0.2 ppm tolerance for sugar beet roots for risk assessment.

The qualitative nature of the residue in animals is adequately understood. As sugar beet commodities are not fed to poultry, no tolerances are required for poultry meat and eggs. The Agency has determined under section 180.6(a)(3) of the Code of Federal Regulations, that there is no reasonable expectation of finite residues for ruminant commodities and that no tolerances on meat, milk, poultry, or eggs will be required. The Agency used the proposed 15 ppm tolerance level for sugar beet tops when calculating the theoretical maximum dietary intake of beef and dairy cattle for purposes of determining that tolerances for meat and milk are not needed.

7. Tolerance Reassessment

The tolerances listed in 40 CFR §180.353 are for residues of desmedipham *per se* in/on sugar beets (roots and tops). No tolerances exist for residues of desmedipham in animal commodities, and no food/feed additive tolerances have been established.

AgrEvo has proposed raising the established tolerance for sugar beet tops from 0.2 ppm to 15 ppm based on preliminary field trial data submitted under section 6(a)(2) of FIFRA. The Agency is requesting that additional confirmatory field trial data for sugar beet tops be submitted to reassess the existing 0.2 ppm tolerance for sugar beet tops and whether the proposed tolerance of 15 ppm in sugar beet tops should be adopted.

Table 30. Tolerance Reassessment Summary for Desmedipham.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.353:			
Sugar beets (roots and tops)	0.2	To be determined	Additional residue data are required for roots and tops. Sugar beets, roots Sugar beets, tops

8. Restricted Use Classification

No restricted use classification is required for desmedipham and all currently registered uses..

9. Reference Dose

The Agency RfD Committee recommends that an RfD for this chemical be based on a reproductive toxicity study in rats with a parental toxicity NOEL of 4 mg/kg/day (50 ppm). Significant reduction of body weight, hemolytic anemia accompanied by significant increase in spleen weights and thyroid compensatory function were seen at the next higher dose of 20 mg/kg/day (250 ppm), the middle dose level tested, and higher dose levels. An uncertainty factor (UF) of 100 was applied to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD is 0.04 mg/kg/day.

10. 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 a description of the Endangered Species Program in the Federal Register and have available voluntary 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 document. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

11. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, the Agency 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.

V. ACTIONS REQUIRED OF 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 desmedipham for the above eligible uses has been reviewed and determined to be substantially complete. The following confirmatory

data has been requested from AgrEvo to upgrade the following supplemental submissions to guideline acceptable.

61-1	Product Identity and Disclosure of Ingredients
62-2	Certification of Ingredient Limits
62-3	Analytical Methods to Verify the Certified Limits
83-1(a)	Chronic Feeding Toxicity - Rodent
85-1	General Metabolism
123-1(a)	Seed Germination/Seedling Emergence
123-1(b)	Vegetative Vigor
161-1	Hydrolysis
162-1	Aerobic Soil Metabolism
162-3	Anaerobic Aquatic Metabolism
164-1	Terrestrial Field Dissipation
165-1	Rotational Crops (Confined)
171-4 (c/d)	Residue Analytical Methods
171-4 (k)	Magnitude of the Residue in Plants - Sugar Beets, roots - Sugar Beets, tops

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 herbicide used for use in sugar beets."

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 support of such use(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 support of such use(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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria 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.

Additional studies are being required for seedling emergence testing (GDLN 123-1a) and a vegetative vigbor test (GDLN 123-1b), using a typical end-use product (TEP). Results from Tier II nontarget terrestrial plant toxicity studies utilizing the desmedipham technical (TGAI) showed no detrimenal effects to the vegetative vigor of the most sensitive species (lettuce) when applied at a rate near the maximum label rate. This result implies that the adjuvants normally present in the TEPs must be present for the desmedipham to express toxicity to plants. Confirmatory testing utilizing a TEP containing these adjuvants is thus required.

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain desmedipham, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain desmedipham, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

Minimum (Baseline) PPE/Engineering Control Requirements

The minimum (baseline) PPE for all occupational uses of desmedipham end-use products is:

For emulsifiable concentrate formulations[1]:

"Mixers and loaders must wear:

[1] For the glove statement, use the statement established for desmedipham through the instructions in Supplement Three of PR Notice 93-7.

--long-sleeved shirt and long pants,
--chemical-resistant gloves,
--shoes plus socks. "

For wettable powder formulations[1]:

"Mixers and loaders must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves,
--shoes plus socks.
--dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

If the formulation is produced in water-soluble packaging, the respirator equipment may be reduced as specified in the WPS. Also, registrants may modify the labels of their wettable powder formulations to limit sugar beet aeriel applications to 0.5 pounds AI per acre and 350 acres per day rather than reformulating to water-soluble packets.

Determining PPE Requirements for End-use Product Labels

The PPE that will be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

For **sole-active-ingredient** end-use products that contain desmedipham the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain desmedipham the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all desmedipham end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

-- coveralls,
-- chemical-resistant gloves,
-- shoes plus socks,
-- protective eyewear.

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing desmedipham that are intended primarily for occupational use.

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 Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

1. Registrant: select this if coveralls are required for pesticide handlers on the end-use product label:

> "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrant: select this always:

> "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions 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."

Skin Sensitizer Statement

> "This product may cause skin sensitization reactions in some people."

2. Labeling Requirements for End-Use Products

Spray Drift Labeling

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 Information.

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 produces 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

Avoid applications 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 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 from the sensitive areas).

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 desmedipham 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 REPORT

Case 2150[Desmidipham] Chemical 104801[Desmedipham (ethyl m-hydroxycarbanilate carbanilate)ester]

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
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
SUGAR BEET				Use Group: TERRESTRIAL FOOD+FEED CROP									
Band treatment, Foliar, Sprayer	EC	NA	.375 lb A	*	NS	NS	.6525 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.96 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	.6094 lb A	*	NS	NS	.975 lb	NS	5	1			C46, C92, H01(75)
	EC	NA	.375 lb A	*	NS	NS	.975 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.99375 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	1.219 lb A	*	NS	NS	1.95 lb	NS	5	1			C46, C92, CAG, CAU, H01(75)
	WP	NA	.63 lb A	*	NS	NS	.98 lb	NS	7	NS			C46, CAU, H01(75)
	WP	NA	1.26 lb A	*	NS	NS	1.96 lb	NS	7	1			C46, C92, H01(75)
Broadcast, Evening, Aircraft	EC	NA	.05625 lb A	*	NS	NS	.6525 lb	NS	7	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.2484 lb A	*	NS	NS	.96 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	EC	NA	.08125 lb A	*	NS	NS	.975 lb	NS	5	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.24375 lb A	*	NS	NS	.975 lb	NS	7	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.2484 lb A	*	NS	NS	.99375 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	EC	NA	.1625 lb A	*	NS	NS	1.95 lb	NS	5	1	AZ, 013		C46, C92, CAG, CAU, H01(75)
	WP	NA	.315 lb A	*	NS	NS	.98 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	WP	NA	.63 lb A	*	NS	NS	1.96 lb	NS	7	1	AZ, 013		C46, C92, H01(75)

APPENDIX A REPORT

Case 2150[Desmidipham] Chemical 104801[Desmedipham (ethyl m-hydroxycarbanilate carbanilate)ester]

USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

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
SUGAR BEET (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Broadcast, Evening, Ground	EC	NA	.05625 lb A	*	NS	NS	.6525 lb	NS	7	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.2484 lb A	*	NS	NS	.96 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	EC	NA	.08125 lb A	*	NS	NS	.975 lb	NS	5	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.24375 lb A	*	NS	NS	.975 lb	NS	7	1	AZ, 013		C46, C92, H01(75)
	EC	NA	.2484 lb A	*	NS	NS	.99375 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	EC	NA	.1625 lb A	*	NS	NS	1.95 lb	NS	5	1			C46, C92, CAG, CAU, H01(75)
	WP	NA	.315 lb A	*	NS	NS	.98 lb	NS	7	NS	AZ, 013		C46, CAU, H01(75)
	WP	NA	.63 lb A	*	NS	NS	1.96 lb	NS	7	1	AZ, 013		C46, C92, H01(75)
Broadcast, Foliar, Aircraft	EC	NA	.375 lb A	*	NS	NS	.6525 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.96 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	.6094 lb A	*	NS	NS	.975 lb	NS	5	1			C46, C92, H01(75)
	EC	NA	.375 lb A	*	NS	NS	.975 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.99375 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	1.219 lb A	*	NS	NS	1.95 lb	NS	5	1			C46, C92, CAG, CAU, H01(75)
	WP	NA	.63 lb A	*	NS	NS	.98 lb	NS	7	NS			C46, CAU, H01(75)
	WP	NA	1.26 lb A	*	NS	NS	1.96 lb	NS	7	1			C46, C92, H01(75)

APPENDIX A REPORT

Case 2150[Desmidipham] Chemical 104801[Desmedipham (ethyl m-hydroxycarbanilate carbanilate)ester]

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 Max. Tex. Dose	# 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
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SUGAR BEET (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Broadcast, Foliar, Ground	EC	NA	.375 lb A	*	NS	NS	.6525 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.96 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	.6094 lb A	*	NS	NS	.975 lb	NS	5	1			C46, C92, H01(75)
	EC	NA	.375 lb A	*	NS	NS	.975 lb	NS	7	1			C46, C92, H01(75)
	EC	NA	.3809 lb A	*	NS	NS	.99375 lb	NS	7	NS			C46, CAU, H01(75)
	EC	NA	1.219 lb A	*	NS	NS	1.95 lb	NS	5	1			C46, C92, CAG, CAU, H01(75)
	WP	NA	.63 lb A	*	NS	NS	.98 lb	NS	7	NS			C46, CAU, H01(75)
	WP	NA	1.26 lb A	*	NS	NS	1.96 lb	NS	7	1			C46, C92, H01(75)
NON-FOOD/NON-FEED													
BEETS (for seed crop only)				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast, Postemergence, Low volume ground sprayer	EC	NA	.24375 lb A	*	2	NS	NS	NS	30	NS	WA, 013		C14, C92
					Geo.013: For use only within Western Washington.								
CHARD, SWISS (for seed crop only)				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast, Postemergence, Low volume ground sprayer	EC	NA	.24375 lb A	*	2	NS	NS	NS	30	NS	WA, 013		C14, C92
					Geo.013: See above								

APPENDIX A REPORT

Case 2150[Desmidipham] Chemical 104801[Desmedipham (ethyl m-hydroxycarbanilate carbanilate)ester]
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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

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)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
WP	: WETTABLE POWDER

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
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A REPORT

Case 2150[Desmidipham] Chemical 104801[Desmedipham (ethyl m-hydroxycarbanilate carbanilate)ester]

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USE LIMITATIONS CODES
C14 : Grown for seed only.
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAG : Do not apply where runoff is likely to occur.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
013 : Other
AZ : Arizona
WA : Washington

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case desmedipham covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to desmedipham 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 desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	AB	41607001*
61-2A	**Start. Mat. & Mnfg. Process**	AB	41607001, 42281401
61-2B	**Formation of Impurities**	AB	41607001
62-1	**Preliminary Analysis**	AB	41607002
62-2	**Certification of limits**	AB	41607002*
62-3	**Analytical Method**	AB	41607002*
63-2	**Color**	AB	41607003
63-3	**Physical State**	AB	41607003
63-4	**Odor**	AB	41607003
63-5	**Melting Point**	AB	41607003
63-6	**Boiling Point**	AB	N/A
63-7	**Density**	AB	41607003
63-8	**Solubility**	AB	41214701, 41607003
63-9	**Vapor Pressure**	AB	41937501
63-10	**Dissociation Constant**	AB	41607003

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

Data Supporting Guideline Requirements for the Reregistration of desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	**Octanol/Water Partition**	AB	41214703
63-12	**pH**	AB	N/A
63-13	**Stability**	AB	41607003,42281402, 43406001
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	AB	41607004
71-2A	**Avian Dietary - Quail**	AB	00114112, 00159177*
71-2B	**Avian Dietary - Duck**	AB	00114111
71-4A	**Avian Reproduction - Quail**	AB	43544901
71-4B	**Avian Reproduction - Duck**	AB	43544902
72-1A	**Fish Toxicity Bluegill**	AB	00116713
72-1C	**Fish Toxicity Rainbow Trout**	AB	00116714
72-2A	**Invertebrate Toxicity**	AB	00116712
122-1A	**Seed Germination/Seedling Emergence**	AB	41774101, 41711401
122-1B	**Vegetative Vigor**	AB	41816401, 41711401
122-2	**Aquatic Plant Growth**	AB	WAIVED
123-1A	**Seed Germination/Seedling Emergence**	AB	42366302*
123-1B	**Vegetative Vigor**	AB	42366301* 41816401

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

Data Supporting Guideline Requirements for the Reregistration of desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
123-2	**Aquatic Plant Growth**	AB	43053501, 43053502, 43053503, 43053504, 43053505
141-1	**Honey Bee Acute Contact**	AB	41711402
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	AB	00155581
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	AB	00155582
81-3	**Acute Inhalation Toxicity - Rat**	AB	41957102
81-4	**Primary Eye Irritation - Rabbit**	AB	00155584
81-5	**Primary Dermal Irritation - Rabbit**	AB	00155583
81-6	**Dermal Sensitization - Guinea Pig**	AB	41692901, 41415401, 41214704, 41214705, 40312901
82-1A	**90-Day Feeding - Rodent**	AB	40387102, 40387103, 42045701
82-1B	**90-Day Feeding - Non-rodent**	AB	40387104
82-2	**21-Day Dermal - Rabbit/Rat**	AB	41957101, 42124201
83-1A	**Chronic Feeding Toxicity - Rodent**	AB	40387107*
83-1B	**Chronic Feeding Toxicity -Non Rodent**	AB	42045702, 40387104 00156889
83-2A	**Oncogenicity - Rat**	AB	40387107*

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

Data Supporting Guideline Requirements for the Reregistration of desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
83-2B	**Oncogenicity - Mouse**	AB	42045701, 40387106
83-3A	**Developmental Toxicity - Rat**	AB	42045704, 41214706 00156724, 00156725
83-3B	**Developmental Toxicity - Rabbit**	AB	42045703,00156889, 00132360
83-4	**2-Generation Reproduction - Rat**	AB	40387105
84-2A	**Gene Mutation (Ames Test)**	AB	41607005, 41214707, 00156887
84-2B	**Structural Chromosomal Aberration**	AB	00156886, 00156888
84-4	**Other Genotoxic Effects**	AB	41214707
85-1	**General Metabolism**	AB	42880001*, 42880002*, 41607006*
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	AB	41607001
161-1	**Hydrolysis**	AB	00148330, 00148331*
161-2	**Photodegradation - Water**	AB	41780401, 41446101, 00098607
161-3	**Photodegradation - Soil**	AB	00098608
161-4	**Photodegradation - Air**	AB	WAIVED
162-1	**Aerobic Soil Metabolism**	AB	41998601*
162-3	**Anaerobic Aquatic Metabolism**	AB	41998602*, 00142740*
163-1	**Leaching/Adsorption/Desorption**	AB	42281403*, 42124202*, 41214708*, 41214709*

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

Data Supporting Guideline Requirements for the Reregistration of desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
163-2	**Volatility - Lab**	AB	WAIVED
164-1	**Terrestrial Field Dissipation**	AB	42180501*
165-1	**Confined Rotational Crop**	AB	42909601*
165-2	**Field Rotational Crop**	AB	WAIVED
165-4	**Bioaccumulation in Fish**	AB	42710101
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	AB	00041862, 40274901, 41214710*
171-4B	**Nature of Residue - Livestock**	AB	00098591, 41998603, 42371301,42687401, 42822701
171-4C	**Residue Analytical Method - Plants**	AB	00076669*, 41998604*, 42921801*, 42921802*, 42921803*, 00041859*
171-4D	**Residue Analytical Method - Animal**	AB	00076669*, 41998604*, 42921801*, 42921802*, 42921803*, 00041859*
171-4E	**Storage Stability**	AB	00041860

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

Data Supporting Guideline Requirements for the Reregistration of desmedipham

REQUIREMENT		USE PATTERN	CITATION(S)
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	AB	Guideline four poultry and eggs was waived, No tolerances established
171-4K	**Crop Field Trials**	AB	
	- Sugar Beets, roots		PP# 4F1459, 00116379*, 00076668*, 00041865*, 00066110*, 00070105*, 00116710*, 00049456*
	- Sugar Beets, tops		PP#4F145913, 00116379*, 00076668*, 00041865*, 00066110*, 00070105*, 00116710*, 00049456*, 42516501*
171-4L	**Magnitude of the Residues in Processed Food/Feed**		
	- Sugar Beets	AB	42112301, No tolerances established

* Studies submitted for this guideline have been classified as supplemental, and additional data is required by the registrant to upgrade these studies to guideline acceptable.

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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(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific 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 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific 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, Data Call-In Response Form, as well as 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 03-31-96).

This Notice is divided into six sections and six 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 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional 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 Attachment 3, Requirements Status and Registrant's Response Form, within the time frames 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 (tel: 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 160.3(a)(6)].

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for 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

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 chose 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. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

1. 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 the Data Call-In Response Form. If you choose this option, this is the only form 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.

2. 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 of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on 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.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 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 -- 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.

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. 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 -- 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. 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 -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. 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 your 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 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 burdens 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 will normally 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(j) " '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(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also 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 are usually 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 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 should also 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 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.

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, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

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 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.

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:

   a. 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 Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. 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 would generally 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 must also 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 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 (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for 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 Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

DESMEDIPHAM DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jeffrey Billingslea at (703) 308-8004.

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

Jeffrey Billingslea
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: **DESMEDIPHAM**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **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.

Item 7a. 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**." 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. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

This page is replaced with the sample DCI part A from the Agency PSDCI module.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the 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. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). 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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA 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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. 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 also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. 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 (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If 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 EPA 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)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). 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 and Registrant's Response" Form indicating 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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

This page is replaced with the Product Specific DCI Part B page 1

This page is replaced with the Product Specific DCI Part B page 2

This page is replaced with the Product Specific DCI Part B page 3

This page is replaced with the Product Specific DCI Part B page 4

EPA'S BATCHING OF DESMEDIPHAM PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

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 desmedipham as the active ingredient, the Agency has batched products which can be considered similar 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. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

In the batching process, the Agency reviewed the following products:

- Desmedipham Technical [97.0% a.i.) (Id. No. 45639-85)]
- Betanex [16% a.i.) (Id. No. 45639-86)]
- Betamix Herbicide [(8.0% a.i.) (Id. No. 45639-87)]
- Betanex 70 WP [(70.0% a.i.) (Id. No. 45639-155)]
- Betamix 70WP [(35.0% a.i.) (Id. No. 45639-156)]
- NA 305 [(6.0% a.i.) (Id. No. 45639-158)]
- Betamix Progress [(7.0% a.i.) (45639-159)]
- CQ 1451 [(6.0% a.i.) (45639-160)]
- NA 307 [(7.0% a.i.) (45639-162)]
- Betamix Herbicide [(8.0% a.i.) (WA95001900)]

There are no acute tox data requirements for Desmedipham Technical (45639-85).

The following products: NA 305 (45639-158); Betamix Progress (45639-159); CQ 1451 (45639-160); and NA 307 (45639-162) are in the same batch and there are acceptable data available within PRS to categorize their acute toxicity.

Also, there are acceptable data available within PRS to categorize the acute toxicity of Betanex 70WP (45639-155) and Betamix 70WP (45639-156).

However, PRS requests that acute toxicity testing on Betamix (45639-87) or (45639-87 EPA SLN Reg. No. WA-950019) be provided for review. The results should be acceptable to support Betanex Herbicide (45639-86).

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

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.

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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	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

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)

The following is a list of available documents for desmedipham that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jeffrey Billingslea at (703)-308-8004.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for desmedipham.

The following documents are part of the Administrative Record for desmedipham and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria