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Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-05-007
March 2005

Reregistration Eligibility Decision for Phenmedipham

Reregistration Eligibility Decision (RED) for Phenmedipham

List A

Case No. 0277

Approved by: _____

Debra Edwards, Ph.D., Director
Special Review and Reregistration Division

Date: March 31, 2005

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Glossary of Terms and Abbreviations

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIRST	Tier I Surface Water Computer Model
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
GLN	Guideline Number
IR	Index Reservoir
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
μg/g	Micrograms per Gram
μg/L	Micrograms per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MHPC	N-(3-hydroxyphenyl)-methylcarbamate
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion

PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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Executive Summary

EPA has completed its risk assessments and is issuing its reregistration eligibility determination and tolerance reassessment decision for the pesticide phenmedipham. The risk assessments, which are summarized below, are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. Exposure to MHPC, the primary degradate of phenmedipham, is also considered in the assessment.

Phenmedipham is a broadleaf herbicide used on sugar beets, spinach, and garden (table) beets. It is also used on Swiss chard grown for seed. Currently, there are no labeled residential uses or non-agricultural uses. In addition, the Agency considered a petition from IR-4 for use of phenmedipham on fresh market spinach, with a proposal to increase the spinach tolerance from 0.5 ppm to 4.0 ppm. Phenmedipham was first registered in 1970. Approximately 200,000 pounds of phenmedipham active ingredient are applied annually. Over 98% of the total pounds of phenmedipham are applied to sugar beet crops.

The Food Quality Protection Act (FQPA) of 1996 requires EPA to consider aggregate risks from non-occupational sources of pesticide exposure, potential increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. FQPA also requires the Agency to determine that "a reasonable certainty of no harm" would result from exposure to each pesticide. When a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed.

Although the Agency bridged data from desmedipham to complete the risk assessments, and desmedipham has a similar structure and mode of action in plants, the Agency has no information indicating phenmedipham shares a common mechanism of toxicity with desmedipham or any other substances. Moreover, phenmedipham does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this reregistration eligibility decision and tolerance reassessment, EPA is assuming that phenmedipham does not share a mechanism of toxicity with other compounds. Although phenmedipham is a carbamate, it is not a cholinesterase inhibitor. In the future, if additional information suggests phenmedipham share a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

Dietary Risk - Food

EPA's dietary risk analysis evaluated only chronic exposure for phenmedipham. Based on the low hazard profile of phenmedipham, acute risk is not of concern, and is not assessed. Chronic dietary (food) risk estimates are less than 100% of the chronic Population Adjusted Dose (cPAD) for the general U.S. population and all population subgroups. Because risk from dietary sources does not exceed the Agency's level of concern, no measures are necessary to mitigate chronic dietary risk from food-based exposures. Moreover, the Agency has determined that phenmedipham is not likely to be carcinogenic to humans; therefore, no chronic (cancer) risk assessment was conducted.

Dietary Risk - Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. Tier 1 modeling was conducted to determine estimated concentrations of phenmedipham *per se* and its primary degradate MHPC. The modeling assessment indicates that exposure to phenmedipham from groundwater and surface water sources of drinking water is low.

Residential Risk

There are currently no registered residential uses of phenmedipham; therefore, no residential risk assessment was conducted and no mitigation measures are warranted.

Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways), as well as exposures from non-occupational (i.e. residential) sources, if applicable. In the case of phenmedipham, the aggregate assessment only considers food and drinking water exposures, because no residential uses are registered. Based on the low toxicity profile for phenmedipham, acute aggregate exposure is not a risk concern and was not assessed.

The chronic aggregate risk assessment addresses exposure to phenmedipham *per se* and the degradate, MHPC, in both food and drinking water. Based on screening-level drinking water model estimates, chronic aggregate dietary risk estimates for all population subgroups are less than 1% of the cPAD. Because, chronic aggregate risk is below EPA's level of concern, no mitigation measures are necessary to address combined chronic food and drinking water risks.

Occupational Risk

Occupational risk associated with phenmedipham has been assessed for handler exposure at the time of application and for post-application (reentry) exposure. Combined dermal and inhalation exposures were assessed for mixer/loaders and applicators. Risk estimates indicate that with the use of baseline personal protective equipment (PPE) with chemical-resistant gloves, as currently required, all exposure scenarios for mixer/loaders and applicators are well below the Agency's level of concern (LOC). In addition, all post-application exposure scenarios are below the Agency's LOC at day zero (12 hours after application).

Ecological Risk

Based on currently labeled uses, phenmedipham applications did not result in risk quotient (RQ) exceedances for any terrestrial or aquatic organism risk. Thus, phenmedipham does not pose any ecological risks of concern.

Endangered Species "No Effects" Finding

The Agency has reviewed data and other information for phenmedipham and its degradates and concludes that this herbicide does not warrant action under the Endangered

Species Act because EPA's screening level assessment shows 'no effect' on listed species or their critical habitat (RQ values were below the level of concern for endangered species). This determination was derived from the evaluation of relevant toxicity tests that were conducted on aquatic and terrestrial organisms, as well as, aquatic and terrestrial plants.

Summary of Labeling Changes

End-use product labels must be amended to include a 120-day plant back interval for cereal grains. Alternatively, if the registrant wishes to support a 30-day plant back interval for cereal grains, data from limited field rotational crop studies are required.

Upon approval of the proposed new use on fresh market spinach, end-use product labels with uses for spinach must be amended to change the current pre-harvest interval (PHI) from 40 days to 21 days.

Tolerance Reassessment

There are four tolerances for phenmedipham currently listed in 40 CFR §180.278 that are reassessed. Submitted studies show residues of phenmedipham in sugar beet dried pulp and molasses; therefore, the Agency is recommending establishing tolerances for these commodities at 0.5 ppm and 0.2 ppm, respectively. In addition, IR-4 had submitted studies proposing to raise the spinach tolerance from 0.5 to 4.0 ppm.

Regulatory Decision

The Agency has determined that phenmedipham is eligible for reregistration provided that label restrictions and amendments are made as outlined in Chapter IV and the Labeling Changes Summary Table. The Agency is issuing this Reregistration Eligibility Decision (RED) document for phenmedipham, and will publish a Notice of Availability in the Federal Register. This RED document includes guidance and requested time frames for making any necessary label changes for products containing phenmedipham. The Agency will be providing a final 60-day public comment period for stakeholders to respond to the phenmedipham risk management decision. If substantive information is received during the comment period that indicates that any of the Agency's estimates need to be refined and that risk mitigation is warranted, appropriate modifications will be made at that time. If no substantive comments are received, the RED described herein will be considered final.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 3, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to phenmedipham and any other substances. Moreover, phenmedipham does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA is assuming that phenmedipham does not share a common mechanism of toxicity with other compounds. Although the Agency bridged data from desmedipham to complete the risk assessments, and desmedipham has a similar structure and mode of action in plants, a cumulative assessment was

not conducted because a common mechanism of toxicity has not been established. It should be noted that, although phenmedipham is a carbamate, it is not a cholinesterase inhibitor. In the future, if additional information suggests phenmedipham shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

This document presents EPA's human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for phenmedipham. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the human health and environmental effects risk assessments based on data and other information received. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The risk assessments and other supporting documents for phenmedipham are available in the Public Docket, under docket number OPP-2004-0384, and on the Agency's web page, http://www.epa.gov/edockets/.

II. Chemical Overview

A. Regulatory History

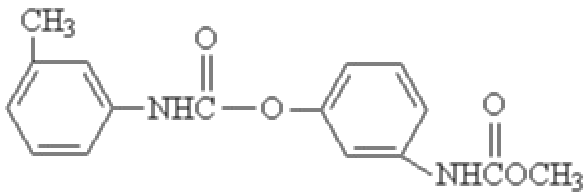
Phenmedipham was first registered in the United States in 1970 to Nor-Am Chemical Company (Schering Ag). The progression of the registrant's ownership of the phenmedipham registration is as follows:

- In 1994 Nor-AM Chemical merged with Hoechst-Roussel Agri-Vet Company to form AgrEvo USA
- In 1999, the AgrEvo USA Company merged with Rhone-Poulenc Ag Company to form Aventis CropScience
- In 2001, Bayer purchased the CropScience business from Aventis to form Bayer CropScience, LP
- In 2004, AgValue-DP, LLC, registered for a technical and 3 end-use products

Phenmedipham is used as an herbicide. Phenmedipham is a List A reregistration chemical, and was the subject of a "Guidance for the Reregistration of Pesticide Products Containing Phenmedipham" (Registration Standard), dated March 30, 1987. This document summarized regulatory conclusions on the available data on phenmedipham at that time, and specified the additional data that was required for reregistration purposes. Subsequent to the Generic Data Call-In (GDCI) issued in the Registration Standard, additional GDCIs were issued in October 1995 and August 2000. The GDCI issued in 1995 required data from foliar residue dissipation, dermal, and inhalation studies. The 2000 GDCI required various studies on ecological toxicity and chronic toxicity. Numerous submissions of data have been received since the Registration Standard document was issued.

B. Chemical Identification

PHENMEDIPHAM:



Common Name:	Phenmedipham
Trade Names:	Betamix®, Progress®, Spin Aid®, Phen®
Chemical Name:	3-methoxycarbonylaminophenyl-3-methylcarbanilate

Chemical Family: Bis-carbamate

Case Number: 0277

CAS Registry Number: 13684-63-4

OPP Chemical Code: 098701

Molecular Weight: 300.34 g/mol

Empirical Formula: $C_{16}H_{16}N_2O_4$

Basic Manufacturer: Bayer CropScience, LP
AgValue-DP, LLC

Technical phenmedipham (3-methoxycarbonylaminophenyl-3-methylcarbanilate) is a colorless and odorless crystal with a melting point of 143°C. Phenmedipham remains stable for three years below 28°C. Phenmedipham is not very soluble in water (3.1 ppm in pH 4 buffered solution), and is moderately soluble in most organic solvents (methanol, toluene, acetone, and ethyl acetate). The vapor pressure of phenmedipham is 9.75×10^{-12} mm Hg at 25°C.

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of phenmedipham eligible for reregistration is contained in Appendix A.

Type of Pesticide: Herbicide

Target Organism: Broadleaf weeds.

Mode of Action: Phenmedipham is a photosynthesis inhibitor and acts by disrupting CO_2 fixation and the production of intermediary energy components – ATP and $NADPH_2$.

Use Sites:

Food: Sugar beets, garden (table) beets, and spinach.
Non-Food: Swiss chard for seed production.
Residential: No registered residential uses.
Public Health: No public health uses.

Use Classification: General use

Formulation Types: Technical (95% - 97%) and Emulsifiable Concentrate (EC)

Table 1 lists current technical and end-use formulations.

Table 1. Formulations of Phenmedipham		
Formulation	**Registration No.**	**Active Ingredient(s)**
Technical	264-618	97.0% phenmedipham
	75240-1	95.0% phenmedipham
Emulsifiable Concentration	264-616, 75240-4	15.9% phenmedipham
	264-816	15.0% phenmedipham, 15.0% desmedipham, 15.0% ethofumesate
	264-621, 75240-5, WA000013	8.0% phenmedipham, 8.0% desmedipham
	264-815	13.1% phenmedipham, 10.2% desmedipham, 15.9% ethofumesate
	264-632, 75240-6	7.0% phenmedipham, 7.0% desmedipham, 7.0% ethofumesate
	264-631	6.0% phenmedipham, 6.0% desmedipham, 6.0% ethofumesate
	264-633	6.0% phenmedipham, 6.0% desmedipham, 6.0% ethofumesate

Application Methods: Phenmedipham can be applied as a broadcast or spray treatment with ground, aerial, or sprayer equipment.

Application Rates: The maximum labeled phenmedipham rate for use on sugar beets is 1.012 and 0.975 pounds of active ingredient per acre (lbs ai/A) on spinach and garden beets, respectively.

Application Timing: Foliar applications of phenmedipham are made postemergence.

D. Estimated Usage of Pesticide

Based on Agency data, the average total domestic usage of phenmedipham was approximately 200,000 pounds annually. The predominant usage is on sugar beets (over 98% of total pounds of phenmedipham), with the greatest usage in North Dakota and Minnesota. Approximately 75% of sugar beets are treated with phenmedipham, 5% spinach is treated (processing only), and 5% garden (table) beets are treated annually.

III. Summary of Phenmedipham Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents, and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for phenmedipham. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2004-0384 and may also be accessed through the Agency's website at http://www.epa.gov/edockets/. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2004-0384. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

- *Phenmedipham: Human Health Risk Assessment,* February 28, 2005
- *Phenmedipham: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document,* February 28, 2005
- *Phenmedipham: Summary of Analytical Chemistry and Residue Data for Reregistration Eligibility Decision (RED) Document,* February 28, 2005
- *Phenmedipham: Summary of Product Chemistry Data for Reregistration Eligibility Decision (RED) Document,* February 28, 2005
- *Phenmedipham. Chronic Dietary Exposure Assessment for the Reregistration Decision (RED) Document,* February 28, 2005
- *Phenmedipham: Report of the Cancer Assessment Review Committee,* January 12, 2005
- *EFED RED Chapter for Phenmedipham,* March 31, 2005
- *Tier I Estimated Drinking Water Concentrations of Phenmedipham and its Degradate (MHPC) for use in Human Health Risk Assessment,* August 4, 2004
- *Characterization of the Span of Time Between Planting and Harvesting as "Season" versus "Year"; A Cursory Evaluation for Phenmedipham (DP #302062),* February 28, 2005

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments incorporate food, drinking water, and any residential (if applicable) exposures to determine exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children.

1. Toxicity of Phenmedipham

The Agency has reviewed all human health toxicity studies submitted for phenmedipham and has determined that the available toxicity studies are satisfactory to support a RED for all currently registered phenmedipham uses. Further details on the toxicity of phenmedipham can be found in the *Phenmedipham: Human Health Risk Assessment*. The Agency has reviewed the potential toxicity of MHPC, the primary degradate, and believes that MHPC is not likely to be as toxic as the parent compound. For the purposes of this upper-bound human health risk

assessment for the RED, phenmedipham *per se* and its degradate MHPC are assumed to be of equal toxicity.

Toxicity Profile

There are no studies that identify an acute hazard based on toxic effects from phenmedipham exposure that would likely result from a single oral exposure. Therefore, an acute dietary endpoint was not selected. Even though an acute assessment was not conducted, submitted studies support that the assessments are protective of all populations, including children and females 13-49 years of age. The toxicology database is adequate to characterize the toxicity of phenmedipham. The acute toxicity profile for phenmedipham is listed in Table 2.

Table 2. Acute Toxicity Profile for Phenmedipham

Study	MRID	Results	Toxicity Category
81-1 Acute Oral - Rat 870.1000	00067579, 00076497	LD50 > 8 gm/kg	IV
81-2 Acute Dermal - Rabbit 870.1200	00155585	LD50 > 4 gm/kg	III
81-3 Acute Inhalation - Rat 870.1300	N/A	Study waived 1/15/1988	---
81-4 Eye Irritation - Rabbit 870.2400	00155587	Non-irritant	IV
81-5 Skin Irritation - Rabbit 870.2500	00155586	Non-irritant	IV
81-6 Dermal Sensitization 870.2600	40502706	Not a sensitizer	---

Oral exposure in subchronic and chronic studies with phenmedipham shows that the red blood cell is the primary target, resulting in hemolytic anemia. The severity of the hematology effects observed in the subchronic studies did not progress with time when examined in the chronic feeding studies. Also, the Agency has classified phenmedipham as "not likely to be carcinogenic to humans," based on the absence of treatment-related tumors in rats or mice at dose levels that were considered adequate to assess carcinogenicity.

FQPA Safety Factor Determination

The Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor (SF), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. FQPA authorizes the Agency to modify the tenfold FQPA SF only if reliable data demonstrate that the level of exposure is safe for infants and children.

The toxicology database for phenmedipham is adequate for FQPA SF considerations. There are clear No Observed Adverse Effects Levels (NOAELs) and clear dose-responses in the developmental rat and rabbit and two-generation reproduction (rat) study. A developmental neurotoxicity study is not required since there is no evidence of neurotoxicity or neuropathy from the available studies.

Based on a review of both hazard and exposure data, the Agency has reduced the special FQPA SF to 1X because there are low concerns, and no residual uncertainties with regard to pre- and/or postnatal toxicity. Also, the dietary food exposure assessment uses proposed tolerance level residues and 100% crop treatment information for all commodities (by using these screening-level assessments chronic exposure will not be underestimated), and the dietary drinking water assessment (Tier 1) uses values designed to provide health protective, high-end estimates of water concentrations.

Toxicological Endpoints for Risk Assessment

The No Observed Adverse Effects Level (NOAEL) of 24 mg/kg/day was used to determine dietary risk. A 100X uncertainty factor (UF) is used to account for interspecies extrapolation and intraspecies variability (10X and 10X, respectively). The toxicological endpoints used in the human health risk assessment for phenmedipham are listed in Table 3.

Table 3. Summary of Toxicological Dose and Endpoints for Phenmedipham (Dietary)

Exposure Scenario	Dose for Use in Risk Assessment	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all population subgroups)	None	NA	No appropriate endpoint from oral toxicity studies
Chronic dietary (all populations)	NOAEL = 24 mg/kg/day UF = 100 Chronic RfD = 0.24 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD / FQPA SF = 0.24 mg/kg/day	Combined chronic toxicity/cancer study-rats LOAEL=118 and 171 mg/kg/day in males and females, respectively, based on hemolytic anemia in both sexes, decreased body weight/body weight gain & food efficiency in females, increased renal pelvic epithelial hyperplasia and mineralization in males
Incidental oral (all durations)	Not Applicable. No residential uses are registered for phenmedipham. (NOAEL of 24 mg/kg/day, if needed in future)		
Cancer	N/A	Classification not likely to be a human carcinogen	

NOAEL = No Observed Adverse Effects Level
LOAEL = Lowest Observed Adverse Effects Level
cPAD = chronic Population Adjusted Dose
RfD = Reference Dose

2. Dietary Exposure and Risk from Food

Dietary (food) exposure assessments were conducted for phenmedipham using Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3). The residue on treated food commodities are based on established tolerances for each commodity, as well as the proposed increase of the spinach tolerance to 4.0 ppm. Each crop is assessed as if 100% of the crop is treated. The dietary exposure and risk estimates resulting from intake of food with residues of phenmedipham were determined for the general U.S. population and all sub-population groups. No cancer dietary exposure assessment was conducted because studies support that there is no carcinogenic concern from phenmedipham exposure.

An acute endpoint was not selected because the available data did not show an effect that would likely result from a single dose; therefore, the Agency did not conduct an acute risk assessment. For the chronic (non-cancer) dietary risk assessment, the three-day average food consumption for each sub-population member was combined with upper-end residues to determine chronic dietary exposure.

A population adjusted dose, or PAD, is the reference dose (RfD) adjusted for the FQPA SF. A chronic dietary risk estimate that is less 100% of the chronic PAD (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed EPA's level of concern. In the case of phenmedipham, the FQPA SF has been reduced to 1X, so the cRfD is identical to the cPAD. Risks less than 100% of the PAD are not of concern to the Agency.

Acute. The acute dietary risk is not assessed because of the low toxicological profile of phenmedipham, and is not of concern.

Chronic. The chronic dietary risk from food alone is below the Agency's level of concern. Chronic dietary exposure from food comprises less than 1% of the cPAD for the U.S. population and all subgroups.

3. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers chronic (lifetime) drinking water risks and uses modeling to estimate those exposures, or monitoring data, if available. For phenmedipham, screening-level computer models (FIRST and SCIGROW) were used to estimate concentrations of phenmedipham *per se* and its main degradate MHPC in drinking water sources. Risk from exposure to phenmedipham in drinking water is further discussed in the section titled "Aggregate Exposure and Risk."

Monitoring Data. The USGS National Water Quality Assessment (NAWQA) database did not contain any reports of detection for phenmedipham or MHPC in the U.S. Also, the EPA monitoring database, STORET, and the California Department of Pesticide Regulation database were searched and no detections were reported.

Model Results

Surface water and groundwater estimated drinking water concentrations (EDWCs) were modeled (FIRST and SCIGROW, respectively) based on sugar beet usage to provide upper-end results being that: 1) this crop represents the major use of phenmedipham; 2) this crop has the highest seasonal rate of application at 1.012 lb ai/A; and 3) a single aerial application is assumed to assess the possible direct deposition of spray drift in water bodies. In the surface water (FIRST) modeling, the default percent cropped area (PCA) of 0.87 is used for sugar beets. Table 4 lists the screening-level EDWCs for phenmedipham *per se* and MHPC in drinking water.

Table 4. Modeled (Tier 1) Estimated Drinking Water Concentrations for Phenmedipham			
Chemical	**Acute (peak) Surface Water Concentration (ppb)**	**Chronic (average) Surface Water Concentration (ppb)**	**Ground Water Concentration (ppb)**
Phenmedipham	29.1	10.8	0.06
MHPC	5.3	1.7	0.07

4. Residential and Non-Occupational Exposure

Phenmedipham is not registered for any residential (home/garden) use, nor is it used in or around public areas, schools, or recreational areas where children might be exposed. Because, there is no expected residential exposure, a residential risk assessment was not conducted.

5. Aggregate Exposure and Risk

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from the following major sources or pathways: food, drinking water, and, if applicable, residential exposure. In the case of phenmedipham, the aggregate risk estimates only consider combined food and drinking water exposures because there are no registered residential uses of phenmedipham.

Chronic Aggregate Risk

The chronic aggregate risk assessment incorporates phenmedipham-treated food commodities and phenmedipham-contaminated drinking water concentrations, which are then combined using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.02). All chronic aggregate risk estimates for all population subgroups are less than 1% of the cPAD. The chronic aggregate risk assessment is considered an upper-bound (Tier 1) assessment, which is conservative and protective of subpopulations, including infants and children. Table 5 below lists the chronic aggregate exposure estimates for phenmedipham.

Table 5. Chronic Aggregate Exposure and Risk Estimates (Food and Drinking Water)		
	cPAD (0.24 mg/kg/day)	
	Exposure (mg/kg/day)	**% cPAD**
U.S. General Population	0.000439	<1
All infants (<1 year)	0.001491	<1
Children 1-2 years	0.000740	<1
Females 13-49 years	0.000415	<1

6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk for all of these exposure scenarios is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a NOAEL or LOAEL. The target MOE for phenmedipham is 100, which is based on the standard uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. MOEs greater than 100 do not exceed the Agency's level of concern. Phenmedipham MOE estimates were determined by a comparison of the scenario-specific

exposure estimates to the dose level (NOAEL) of 24 mg/kg/day for both short- and intermediate-term assessment. The use of Personal Protective Equipment (PPE) reduces the amount of exposure to workers when used properly. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely reenter.

Phenmedipham exposure occurs in a variety of patterns. Occupational exposures to phenmedipham can occur for a single day, or up to weeks at a time for custom (commercial) applicators that are completing a number of applications for several different clients. This is an upper-bound assessment, which presents handler risk estimates for both short- (1 to 30 days) and intermediate-term (1 month to 6 months) exposure durations. No long-term exposure (>6 months) is expected from applications of phenmedipham.

Occupational Toxicity

Since a 21/28-day dermal toxicity study is not available for phenmedipham, a dermal absorption factor of 10% was used based on a rat dermal absorption study for desmedipham. There are no inhalation toxicity studies available, so an absorption factor of 100% is assumed for inhalation exposure. Table 6 below lists the dermal and inhalation toxicological endpoints used in the occupational risk assessment.

Table 6. Summary of Toxicological Dose and Endpoints for Phenmedipham

Short-term dermal (1-30 days) Intermediate-term dermal (1-6 months)	Oral NOAEL = 24 mg/kg/day (Dermal absorption rate = 10%)	Occupational LOC* for MOE = 100	Combined chronic toxicity/cancer study-rats LOAEL=118 and 171 mg/kg/day in males and females, respectively, based on hemolytic anemia in both sexes, decreased body weight/body weight gain & food efficiency in females, increased renal pelvic epithelial hyperplasia and mineralization in males
Short-term inhalation (1-30 days) Intermediate-term dermal (1-6 months)	Oral NOAEL = 24 mg/kg/day (Inhalation absorption rate = 100%)		

*LOC = Level of Concern

Occupational Handler Risk

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. There are three main exposure scenarios based on use sites, formulations, and various equipment that may be used for phenmedipham applications.

- Mixer/Loaders: liquid formulations for aerial and groundboom applications
- Applicators: aerial and groundboom spray applications
- Flaggers for aerial spray applications

All handler MOE estimates consider combined dermal and inhalation exposures. Baseline PPE consists of long pants, long-sleeved shirt, shoes, and socks. Current phenmedipham labels state that applicators and other handlers must wear baseline PPE with chemical-resistant gloves. With the use of baseline PPE and chemical-resistant gloves for

mixer/loaders, all handler exposure scenarios result in MOEs greater than 100, which are not of concern to the Agency. See Table 7 below for a summary of exposure risk estimates.

Table 7. Summary of Occupational Handler Exposure Risk Estimates

Exposure Scenario	Crop	Application Rate (lbs a.i./A)	Area Treated (Acres)	Combined MOEs (Dermal and Inhalation)		
				Baseline[1]	Baseline & Gloves	Engineering Control (Closed cockpit)
MIXER/LOADER						
Aerial	Spinach (processing, seed, fresh market), garden beets	1	350	16	1,400	---
	Sugar beets	0.63	350	26	2,400	---
Groundboom	Spinach (processing, seed, fresh market), garden beets	1	80	72	6,000	---
	Sugar beets	0.63	80	110	---	---
APPLICATOR						
Aerial	Spinach (processing, seed, fresh market), garden beets	1	350	No data	No data	8,600
	Sugar beets	0.63	350	No data	No data	14,000
Groundboom	Spinach (processing, seed, fresh market), garden beets	1	80	9,800	---	---
	Sugar beets	0.63	80	16,000	---	---
	Swiss chard (seed)	0.25	80	39,000	---	---
FLAGGER						
Flagging	Spinach (processing, seed, fresh market), garden beets	1	350	3,300	---	---
	Sugar beets	0.63	350	5,300	---	---

[1] Baseline protection includes: long-sleeve shirt, long pants, shoes and socks.

Occupational Post-Application Risk

The Agency considers all post-application activities that could result in dermal exposures to phenmedipham residues. Inhalation exposure is negligible in post-application scenarios, and is not assessed. To reduce potential post-application exposure, a restricted entry interval (REI) is established to determine the time period that must elapse before workers can safely reenter into a treated area. The Agency assessed the following post-application exposure scenarios: irrigation, scouting, hand-weeding, and thinning. No chemical-specific dislodgable foliar residue (DFR) data are available; therefore, the Agency used DFR estimates based on standard assumptions. For phenmedipham, post-application MOEs greater than 100 are not of concern to the Agency. For all occupational post-application scenarios, there are no risks of concern to the Agency at

day zero (REI of 12 hours after application). See Table 8 below for a summary of exposure risk estimates.

Table 8. Summary of Occupational Post-applicator Exposure Risk Estimates at Day 0 (after 12 hours)

Crop	Application Rate (lbs ai/A)	Activity	Transfer Coefficient (cm^2/hour)	MOEs
Garden beets	1.0	Irrigating, scouting, hand weeding, thinning	300	3,400
Spinach (processing, seed, fresh market)	1.0	Hand weeding, thinning	1,500	680
			500	2,000
Sugar beets	0.63	Irrigating, scouting	1,500	1,100
		Hand weeding, thinning	100	16,000
Swiss chard (seed)	0.25	Irrigating, scouting	1,500	2,700
		Hand weeding, thinning	500	8,100

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Pesticide Illness Surveillance Program, National Pesticide Information Center, and NIOSH SENSOR. According to the Poison Control Center database, one case was reported in 1993 involving a 46-year old adult who reported various symptoms after exposure to phenmedipham. However, all of the symptoms were categorized as "unknown if related to this exposure." Thus, no conclusion should be drawn from this isolated case. From the California Pesticide database, there were five cases that reported illness after potential exposure to phenmedipham. However, in none of the cases was phenmedipham determined to be the primary cause of illness.

The review of the databases shows that phenmedipham has not caused a significant number of reactions or illness to workers or in others. However, the very limited data available show that there may be a risk of dermatitis from exposure to phenmedipham.

B. Environmental Risk Assessment

Aquatic and terrestrial organisms may be exposed to phenmedipham residues from areas adjacent to treated fields. The Tier 1 aquatic model GENEEC was used to estimate surface water concentrations of phenmedipham *per se* and MHPC to assess risks to aquatic organisms. Terrestrial organisms may be exposed to phenmedipham from consuming plants, seeds, and insects with phenmedipham residues. The ELL-FATE modeling was used to measure potential exposure to terrestrial organisms.

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs); the higher the RQ, the

greater the potential risk. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. Further details on the toxicity of phenmedipham can be found in the *EFED RED Chapter for Phenmedipham*. A summary of the Agency's environmental risk assessment for phenmedipham is presented below.

1. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure associated with phenmedipham use. No additional data is needed from the registrant at this time.

The environmental fate of phenmedipham varies based on the site-specific properties of the soil to which it is applied. Phenmedipham is relatively immobile in the soil, but some studies indicate that its major degradate, MHPC, show greater potential for mobility. Both phenmedipham *per se* and MHPC appears to show low to moderate persistence under most environmental scenarios. However, under acidic conditions, the degradation rates are considerably slower, and phenmedipham may persist longer. Additional information on the environmental fate of phenmedipham can be found in the supporting documents referenced in Appendix C.

2. Toxicity and Risk Characterization

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target aquatic and terrestrial organisms. The EECs are used to calculate RQs. An RQ is the estimated ratio of exposure concentration to the toxicity endpoint. The calculated RQs use the EECs that are based on the maximum single application rate of phenmedipham, which would yield the maximum phenmedipham and MHPC exposure estimates. The RQ is then compared to the LOC to determine if exposure to phenmedipham and its degradates would pose a risk to non-target organisms. Table 9 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 9. Agency's LOCs and Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.	0.5	0.5	1
Acute Restricted Use - there is potential for acute risk, but may be mitigated through restricted use classification.	0.2	0.1	N/A
Acute Endangered Species - endangered species may be adversely affected; regulatory action may be warranted.	0.1	0.05	1
Chronic Risk - there is potential for chronic risk; regulatory action may be warranted.	1	1	N/A

3. Fish and Aquatic Invertebrates Exposure and Risk

For exposure to fish and aquatic invertebrates, EPA considers surface water and sediment. The Tier 1 aquatic model GENEEC was used to estimate surface water concentrations of phenmedipham *per se* and the degradate MHPC. Exposure to aquatic invertebrates in sediment is not assessed due to phenmedipham's low persistence in sediment. This model was also used to derive EECs to measure potential exposures to freshwater aquatic organisms in surface water. The maximum single application rate of 0.975 lb a.i./A to spinach and red beet crops is the highest application rate that would yield the maximum EECs. Table 10 lists the EECs for phenmedipham *per se* and MHPC in surface water.

Table 10. EECs of Phenmedipham in Surface Water Based on 0.975 lbs a.i./A Rate

	Surface Water Concentration (ppb)				
	24-hour	**4-day**	**21-day**	**60-day**	**90-day**
Phenmedipham	16.95	16.83	16.07	14.53	13.51
MHPC	4.18	n/a	4.10	3.94	n/a

The available acute toxicity data on phenmedipham, outlined in table 11 below, indicate that RQs for freshwater fish and invertebrates are below the Agency's LOC on an acute basis. Acute toxicity to marine/estuarine fish was not assessed, based on the low level of phenmedipham use along coastal regions in the U.S. Chronic effects on freshwater organisms from exposure to phenmedipham were also not assessed, based on phenmedipham's lack of stability in water. Also, the acute and chronic risks for estuarine/ marine fish and invertebrates were not assessed due to the low level of phenmedipham use along U.S. coastal regions.

Table 11. Fish and Invertebrates Exposure and Risk Estimates

Test	**Test Species**	**EEC (ppm)**	**LC_{50}/EC_{50}**	**Toxicity Classification**	**Agency LOC**	**RQ**
PHENMEDIPHAM						
Acute	Freshwater Fish *(Rainbow trout)*	0.01695	1.7 ppm[1]	Moderately toxic	0.5	<0.01
	Freshwater Invertebrate *(Waterflea)*	0.01695	1.88 ppm[1]	Moderately toxic	0.5	<0.01
MHPC						
Acute	Freshwater Invertebrate *(Waterflea)*	0.00418	14 ppm	Slightly toxic	0.5	<0.01

[1] Based on desmedipham data.

LC_{50}/EC_{50} = Median lethal concentration where 50% death in test animals is expected

4. Terrestrial Organism Exposure and Risk

The Agency assessed potential risk to birds and mammals based on residues on different types of foliage that may be sources of exposure. Residue values for phenmedipham were derived from the maximum single application rate of 0.975 lb ai/A of phenmedipham *per se*, and 0.076 lb/A of MHPC that may be present in the field.

a. Birds

The Agency expects birds to be exposed to residues of phenmedipham *per se* and MHPC on food items, because treated fields provide a habitat rich in food sources attractive to various avian species. Because there were no acute effects from the highest test dosage on birds, acute risks for birds were not assessed and there are no acute bird risks of concern to the Agency. Chronic dietary toxicity studies indicate that chronic RQs for birds are below the Agency's LOC.

The maximum labeled uses of phenmedipham on all crops result in RQs for birds which are below the Agency's LOC. See Table 12 for expected environmental residues of phenmedipham and MHPC and risk estimates.

Table 12. Avian Species (Maximum) Exposure and Risk Estimates

Test	Test Species	EEC (ppm)	Endpoint/ LC_{50}/ EC_{50}	Agency LOC	RQ
PHENMEDIPHAM					
Chronic	Reproduction *(Bobwhite Quail)*	234	NOAEC >1200 ppm	1	0.195
MHPC					
Chronic	Reproduction *(Bobwhite Quail)*	18.24	NOAEC >1200 ppm	1	0.02

b. Mammals

The Agency expects mammals to be exposed to residues of phenmedipham *per se* and MHPC on food items, because treated fields provide a habitat rich in food sources attractive to various mammalian species. Because there were no acute effects from the highest test dosage on mammals, acute risks for mammals were not assessed and there are no acute mammal risks of concern to the Agency. Table 13 lists the EECs and the estimated chronic RQs for mammals. The labeled uses of phenmedipham on all crops result in chronic RQs for mammals that are below the Agency's LOC.

Table 13. Mammalian Exposure and Risk Estimates

Test	Test Species	EECs (ppm)	Endpoint/ LC_{50}/ EC_{50}	Agency LOC	RQ
PHENMEDIPHAM					
Chronic	2-generation Reproduction/ *(Rat)*	234	NOAEL = 500 mg/kg	1	0.47
MHPC					
Chronic	2-generation Reproduction/ *(Rat)*	18.24	NOAEL = 500 mg/kg	1	<0.01

5. Non-Target Plant Exposure and Risk

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff, spray drift, or volatilization. Like terrestrial plants, non-target aquatic plants may

be exposed to pesticide from the same routes. EECs were calculated using the highest estimated surface water concentrations.

Currently, the Agency is not assessing chronic effects on aquatic plants. The Tier I risk assessment indicate that RQs for non-endangered and endangered terrestrial and aquatic plants are all below the Agency's LOC. Tables 14 and 15 below list the risk estimates for terrestrial and aquatic plants, respectively.

Table 14. Terrestrial Plant Exposure and Risk Estimates for Phenmedipham *per se* and MHPC

Crop	Application Rate (lbs a.i./A)	EECs (maximum)	Non-endangered/ Endangered	Agency LOC	RQ Seedling Emergence	RQ Vegetative Vigor
Spinach and garden beets	0.975	0.1073	Non-endangered	1	0.57	0.29
			Endangered	1	0.86	0.39
Sugar beet	0.633	0.0696	Non-endangered	1	0.37	0.19
			Endangered	1	0.56	0.25
Swiss chard	0.244	0.0268	Non-endangered	1	0.14	0.07
			Endangered	1	0.21	0.10

Table 15. Aquatic Plant Exposure and Risk Estimates for Phenmedipham *per se* and MHPC

Test Species	Non-endangered/ Endangered	EEC (ppm)	Endpoint[1]/ LC_{50}/ EC_{50}	Agency LOC	RQ
PHENMEDIPHAM					
Green Algae	Non-endangered	0.01695	0.19	1	0.089
	Endangered	0.01695	NOEC <0.03	1	<0.565
Duckweed	Non-endangered	0.01695	>0.32	1	0.053
	Endangered	0.01695	NOEC <0.32	1	<0.053
MHPC					
Green Algae	Non-endangered	0.00418	0.19	1	0.02
	Endangered	0.00418	NOEC <0.03	1	<0.13
Duckweed	Non-endangered	0.00418	>0.32	1	0.01
	Endangered	0.00418	NOEC <0.32	1	<0.01

[1] Based on desmedipham data.
NOEC = No observed effects concentration

6. Ecological Incidents

To date, there have been two reported incidents related to phenmedipham exposure with terrestrial plants. Both incidents occurred on June 20, 2002 in Richland County, MT, following ground broadcast applications of liquid formulation containing phenmedipham, desmedipham and ethofumesate. The incidents reported stunting damage to a combined total of 1,100 acres of sugar beet crops. It was determined that all three pesticides in the formulation were factors in the incidents. To date, there are no reports of phenmedipham-related incidents involving any other terrestrial organisms or any aquatic organisms.

7. Endangered Species Concerns

The Agency has reviewed data and other information for phenmedipham and its degradates and concludes that this herbicide does not warrant action under the Endangered Species Act, because EPA's screening-level assessment shows 'no effect' on listed species or their critical habitat (RQ values were below the level of concern for endangered species). This determination was derived from the evaluation of relevant toxicity tests that were conducted on aquatic and terrestrial organisms, as well as, aquatic and terrestrial plants.

In accordance with the agreement between the U.S. EPA's Office of Pesticide Programs and the U.S. Fish and Wildlife and National Marine Fisheries Services (Letter of Agreement, http://endangered.fws.gov/consultations/pesticides/evaluation.pdf), the Agency has provided in this risk assessment an interpretation of the listed species' LOCs in terms of the chance of an individual effect should organisms be exposed to a media concentration or dose corresponding to 1/10 or 1/20 of the LC_{50}, LD_{50}, or EC_{50} used as the acute toxicity measurement endpoint for a particular taxonomic group. By looking at effects at various concentrations, a dose response curve can be derived, where one can statistically predict the effects likely to occur at various pesticide levels. Based on the maximum labeled application rates for sugar beets, red garden beets, spinach, and Swiss chard, there are no endangered species risk concerns, should exposure actually occur. Therefore, EPA has determined that phenmedipham will not affect listed endangered species.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing phenmedipham 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 phenmedipham.

The Agency has completed its assessment of the dietary, occupational, and ecological risk associated with the use of pesticide products containing the active ingredient phenmedipham. Residential risks were not assessed because there are no registered residential uses of phenmedipham. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of phenmedipham to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that phenmedipham-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Label changes are described in Section V. Appendix A summarizes the uses of phenmedipham that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of phenmedipham, and lists the submitted studies that the Agency found acceptable.

Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of phenmedipham. If all changes outlined in this document are incorporated into the product labels, then all current risks for phenmedipham will be adequately mitigated for the purposes of this determination.

B. Public Comment Period

Because the risks associated with the use of phenmedipham were low and did not warrant mitigation measures, a Phase 3 public comment period on the phenmedipham risk assessments for risk refinement and mitigation were not conducted. However, a 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket number OPP-2004-0384 at http://www.epa.gov/edockets/. The RED document and technical supporting documents for phenmedipham are also available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number OPP-2004-0384. In addition, the phenmedipham RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Food Quality Protection Act Findings

"Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to phenmedipham is within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. Because there are no registered residential uses of phenmedipham, residential exposures were not considered in the aggregate assessment for phenmedipham. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for phenmedipham meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and drinking water.

Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for phenmedipham, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, as amended by FQPA and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of phenmedipham. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of phenmedipham. As discussed in Chapter III, the total acute dietary (food alone) risk was not assessed as no acute oral endpoint was observed. Thus, there are no acute exposure risks of concern. Further, the chronic dietary (food alone) risk from phenmedipham is not of concern. Aggregate chronic risks from food and drinking water exposures are also below the Agency's LOC.

Determination of Safety to Infants and Children

EPA has determined that the established tolerances for phenmedipham, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of phenmedipham residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of phenmedipham, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects

observed, and other information. The FQPA Safety Factor has been reduced to 1X for phenmedipham, because there are no residual uncertainties for pre- and/or post-natal toxicity.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, phenmedipham may be subject to additional screening and/or testing.

3. Cumulative Risks

Risks summarized in this document are those that result only from the use of phenmedipham. The FQPA requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Although the Agency bridged data from desmedipham to complete the risk assessments, and desmedipham has a similar structure and mode of action in plants, the Agency has no information indicating phenmedipham shares a common mechanism of toxicity with desmedipham or any other substances. It should be noted that, although phenmedipham is a carbamate, it is not a cholinesterase inhibitor. In the future, if additional information suggests phenmedipham shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Tolerance Reassessment Summary

Current Tolerances Under 40 CFR §180.278

The existing tolerances for residues of phenmedipham, established under 40 CFR §180.278 are listed in Table 16. The current tolerance expression listed in 40 CFR §180.278 is "methyl-m-hydroxycarbanilate m-methylcarbanilate"; this is to be changed to 3-methoxycarbonylaminophenyl-3-methylcarbanilate. The Agency recommends that the designation "N" be deleted from the 40 CFR §180.278 tolerance entries for garden beets and sugar beets (roots and tops).

The Agency reviewed processed commodity studies submitted under PP#0F0089, for dried sugar beet pulp and sugar beet molasses, as part of the dietary assessment. Phenmedipham residues from the dried pulp and molasses do not pose any risks of concern. Thus, the Agency is proposing to add two additional tolerances to 40 CFR § 180.278: a 0.5 ppm tolerance for dried sugar beet pulp, and a 0.2 ppm tolerance for sugar beet molasses. Submitted studies show that phenmedipham residues concentrated 3X and 1.3X more in dried sugar beet pulp and molasses, respectively, than the current residue tolerance expressions of 0.1 ppm for raw sugar beet roots and tops.

IR-4 had submitted studies (to propose allowing phenmedipham to be used on fresh-market spinach. Residues of treated spinach harvested 20-24 days post-treatment ranged from <0.05 ppm (below the method level of quantification) to 3.6 ppm. The IR-4 petition (PP#4E6853) included a proposal to reduce the pre-harvest interval from 40 days to 21 days. The Agency assessed potential dietary and occupational exposure risks from fresh-market spinach with residue estimates of up to 4.0 ppm. Exposure risks to residues from fresh-market spinach are below the Agency's LOC. Thus, the Agency proposes that the spinach tolerance be increased to 4.0 ppm to accommodate the proposed new use on fresh-market spinach. The registrant will need to submit amended labels with spinach use to include the revised 21-day PHI for fresh market spniach. Table 16 lists the current and proposed tolerances for phenmedipham.

Table 16. Current and Proposed Tolerances for Phenmedipham under 40 CFR § 180.278

Commodity	Current Tolerance (ppm)	Tolerance Reassessment	Comment
Tolerance Currently Listed under 40 CFR § 180.278			
Beet, garden	0.2 (N)	0.2	The Agency recommends removing the "N" designation.
Beet, sugar, roots	0.1 (N)	0.1	The Agency recommends removing the "N" designation.
Beet, sugar, tops	0.1 (N)	0.1	The Agency recommends removing the "N" designation.
Spinach	0.5	4.0	The registrant must submit amended labels with spinach use to include the revised PHI from 40 days to 21 days.
Tolerance to be Proposed under 40 CFR § 180.278			
Beet, Sugar, dried pulp	None	0.5	
Beet, Sugar, molasses	None	0.2	

Codex Harmonization

No CODEX maximum residue levels (MRLs) have been established for phenmedipham.

Residue Analytical Methods - Plants and Livestock (GLN 860.1340)

The reregistration requirements for residue analytical methods are fulfilled. Adequate methods are available for data collection and for the enforcement of tolerances phenmedipham in/on garden beets, sugar beets (roots and tops), and spinach. Since no tolerances exist, or are required for milk, eggs, and edible livestock tissues, enforcement methods for the determination of phenmedipham residues in livestock commodities are not needed.

E. Regulatory Rationale

The Agency has determined that phenmedipham is eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of phenmedipham.

There are no phenmedipham human health dietary (food and drinking water), aggregate, occupational, or residential exposures of risk concern. Moreover, this assessment is protective of the general U.S. population and all population subgroups, including infants and young children. Thus, no mitigation measures to address human health risks are necessary for the reregistration of phenmedipham.

There are no exposure scenarios with phenmedipham that pose ecological risks of concern to the Agency, including for endangered species. Thus, no mitigation measures to address ecological risks are necessary for the reregistration of phenmedipham.

F. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing phenmedipham. In addition, the end-use product labels must be amended to include a 120-plant back interval for cereal grains. Alternatively, if the registrant wishes to support a 30-day plant back interval for cereal grains, data from limited field rotational crop studies are required. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to carry out its responsibilities under FIFRA in compliance with the Endangered Species Act (ESA). The ESA requires Federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat and require Federal agencies to use their authorities to further the purposes of the Act by carrying out programs for the conservation of listed species. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and considers ecological parameters, pesticide use

information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species.

The Agency has reviewed data and other information for phenmedipham and its degradates and concludes that this herbicide does not warrant action under the Endangered Species Act, because EPA's screening-level assessment shows 'no effect' on listed species or their critical habitat (RQ values were below the level of concern for endangered species). This determination was derived from the evaluation of relevant toxicity tests that were conducted on aquatic and terrestrial organisms, as well as, aquatic and terrestrial plants.

In accordance with the agreement between the U.S. EPA's Office of Pesticide Programs and the U.S. Fish and Wildlife and National Marine Fisheries Services (Letter of Agreement, http://endangered.fws.gov/consultations/pesticides/evaluation.pdf), the Agency has provided in this risk assessment an interpretation of the listed species' LOCs in terms of the chance of an individual effect should organisms be exposed to a media concentration or dose corresponding to 1/10 or 1/20 of the LC_{50}, LD_{50}, or EC_{50} used as the acute toxicity measurement endpoint for a particular taxonomic group. By looking at effects at various concentrations, a dose response curve can be derived, where one can statistically predict the effects likely to occur at various pesticide levels. Based on the maximum labeled application rates for sugar beets, red garden beets, spinach, and Swiss chard, there are no endangered species risk concerns, should exposure actually occur. Therefore, EPA has determined that phenmedipham will not affect listed endangered species.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, the EPA will continue to work with all interested parties on this important issue.

Because of the low risks associated with the use of phenmedipham, as summarized in this document, the Agency concludes that spray drift mitigation is not needed as part of the reregistration eligibility determination. Thus, no additional mitigation to address human health and environmental risks from spray drift are warranted.

V. What Registrants Need to Do

The Agency has determined that phenmedipham is eligible for reregistration provided that the required label amendments are made. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Table 17. The Agency intends to issue Data Call-In (DCIs) Notices requiring label amendments and product specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. Below are the label amendments that the Agency intends to require for phenmedipham to be eligible for reregistration. No generic data for phenmedipham are needed at this time.

A. Manufacturing Use Products

Additional Generic Data Requirements

The generic data base supporting the reregistration of phenmedipham for currently registered uses has been reviewed and determined to be substantially complete. No additional data is needed at this time to support the reregistration decision for phenmedipham.

Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 17.

B. End-Use Products

Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant 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 the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Karen Jones at 703-308-8047.

Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 17. Generally, conditions for the distribution and sale of products bearing old

labels/labeling will be established when the label changes are approved. However, specific 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.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 17 describes how language on the labels should be amended.

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language for Manufacturing Use Products**	**Placement on Label**
Manufacturing Use Products		
Required on all MUPs	"Only for formulation into an herbicide for: 1) the following uses: sugar beets, garden beets, spinach, and the Special Local Needs (SLN) registration for use on Swiss chard grown for seed in Washington State;"	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"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)." "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."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Directions for Use
All End Use Products		
Pre-harvest Interval Restrictions	Proposed PHI reduction from 40 days to 21 days for spinach: "Do not apply [insert product name] to spinach later than 21 days prior to harvest."	Use Precautions
End-Use Products Intended for Occupational Use (WPS and non-WPS)		
Handler PPE Requirements for Liquid (EC) Formulation	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks, and -chemical-resistant gloves for mixers and loaders.	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language for Manufacturing Use Products**	**Placement on Label**
	separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	immediately following the PPE requirements
Engineering Controls for Aerial Application	Enclosed Cockpits "Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following PPE and User Safety Requirements
Engineering Controls for Flagging for Aerial Applications	"Human flagging is prohibited. Flagging to support aerial application is limited to the use of Global Positioning System (GPS) or mechanical flaggers."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following PPE and User Safety Requirements
User Safety Recommendations	"**USER SAFETY RECOMMENDATIONS"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE 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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Restricted-entry Interval for WPS products as required by Supplement Three of PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Reentry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice of 93-7	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: For all end-use products: -coveralls, -chemical-resistant gloves made of any waterproof material, -shoes plus socks."	Directions for Use, Agricultural Use Requirements Box
General Application	"Do not apply this product in a way that will contact workers or other persons, either	Place in the Directions for Use directly

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language for Manufacturing Use Products**	**Placement on Label**
Restrictions	directly or through drift. Only protected handlers may be in the area during application."	above the Agricultural Box, if there is one, otherwise place in the Directions for Use under General Precautions and Restrictions.
Application Restrictions	Plant Back Interval "Do not plant or transplant cereal grains in the treated area for at least 120 days following an application of this product."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic organisms. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to fish and aquatic organisms in adjacent aquatic sites. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements: Hazards to Humans and Domestic Animals
Spray Drift Label Language for Products Applied as a Spray	"**SPRAY DRIFT MANAGEMENT**" "Avoiding spray drift at the application site is the responsibility of the applicator and the grower. The interactions 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 boom length must not exceed 70% of the wingspan or 85% of the rotor blade diameter." "Do not make any type of application into temperature inversions." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind."	Directions for Use under General Precautions or Restrictions and/or Application Instructions

VI. Appendices

Appendix A. Use Patterns Subject to Reregistration for Phenmedipham, Case #0277								
Application Timing Application Type Application Equipment	**Formulation EPA Reg. No.**	**Maximum Single Application Rate**	**Maximum No. of Applications per Year**	**Maximum Seasonal Rate**	**Pre-harvest Interval (days)**	**Application Interval (days)**	**Reentry Interval**	**Limitations**
BEETS (garden/ table)								
foliar band treatment/spray aerial/ground sprayer	EC [264-616] [75240-4]	0.975 lb ai/A	1	0.975 lb ai/A	60	4-6	24 h	
postemergence broadcast ground	EC [WA010015]	0.244 lb ai/A	2	0.488 lb ai/A	60	28	24 h	SLN for WA state, for seed only
SWISS CHARD								
postemergence broadcast ground	EC [WA010015]	0.244 lb ai/A	2	0.488 lb ai/A	60	28	24 h	SLN for WA state, for seed only
SPINACH								
foliar band treatment/spray aircraft/ground/sprayer	EC [264-616] [75240-4]	0.975 lb ai/A	1	0.975 lb ai/A	21	4-6	24 h	
SUGAR BEET								
evening, foliar band treatment/broadcast aircraft/ground/sprayer	EC [264-631]	0.383 lb ai/A	NS	1.0 lb ai/A	NS	7	NS	
evening, foliar band treatment/broadcast aircraft/ground	EC [264-633]	0.383 lb ai/A	NS	0.967 lb ai/A	75	7	24 h	
foliar band / broadcast/ spray aircraft/ground/sprayer	EC [264-815]	0.375 lb ai/A	NS	0.660 lb ai/A	75	5	48 h	
foliar band treatment/broadcast aircraft/ground	EC [264-621] [75240-5]	0.609 lb ai/A	NS	0.975 lb ai/A	75	7	24 h	
evening, foliar band treatment/broadcast aircraft/ground/sprayer	EC [264-632] [75240-6]	0.375 lb ai/A	NS	0.653 lb ai/A	75	5-7	48 h	
at emergence, postemergence band/broadcast aircraft/ground	EC [264-816]	0.633 lb ai/A	NS	1.012 lb ai/A	75	7	24 h	

NS = Not Specified

Appendix B
Data Supporting Guideline Requirements for the Reregistration of Phenmedipham

REQUIREMENT			Use Patterns	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**	**Study Description**		DMP = desmedipham
830.1550	61-1	Product Identity and Composition	All	40392701
830.1600	61-2A	Description of materials used to produce the product	All	40392702
830.1620	61-2B	Description of production process	All	40392703
830.1670	61-2B	Formation of Impurities	All	40392703
830.1700	62-1	Preliminary Analysis	All	40392704
830.1750	62-2	Certification of limits	All	40392705
830.1800	62-3	Analytical Method	All	40392706
830.6302	63-2	Color	All	00049829
830.6303	63-3	Physical State	All	00049829
830.6304	63-4	Odor	All	00049829
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	40392711
830.700	63-12	pH	All	40392710
830.7200	63-5	Melting Point	All	40392707
830.7300	63-7	Density	All	40392708
830.7370	63-10	Dissociation constants in water	All	40435101
830.7550	63-11	Partition coefficient, shake flask method	All	40435102
830.7840	63-8	Solubility	All	40435101; 40392709
830.7950	63-9	Vapor Pressure	All	00142752
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	A, B	41607004
850.2200	71-2A	Avian Dietary Toxicity - Quail	A, B	00248231 (DMP)
850.2200	71-2B	Avian Dietary Toxicity - Duck	A, B	00248230 (DMP)
850.2300	71-4A	Avian Reproduction - Quail	A, B	43544902 (DMP)

Appendix B
Data Supporting Guideline Requirements for the Reregistration of Phenmedipham

REQUIREMENT			Use Patterns	CITATION(S)
850.2300	71-4B	Avian Reproduction - Duck	A, B	43544901 (DMP) 44862703 (DMP)
850.1075	72-1A	Fish Toxicity Bluegill	A, B	00237908 (DMP)
850.1075	72-1C	Fish Toxicity Rainbow Trout	A, B	00237908 (DMP)
850.1010	72-2A	Invertebrate Toxicity	A, B	00235009 (DMP) 45414202 (MHPC)
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	A, B	Waived
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B	Waived
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp	A, B	Waived
850.1300	72-4A	Fish Early Life Stage - Daphnid	A, B	Waived
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B	Waived
850.1400	72-4C	Freshwater Fish - Acute Toxicity	A, B	Waived
850.4100	122-1A	Terrestrial Plant Toxicity, Seedling Emergence	A, B	41774101 (DMP)
850.4100	122-1B	Terrestrial Plant Toxicity, Vegetative Vigor	A, B	41816401 (DMP)
850.5400	122-2	Aquatic Plant Growth	A, B	43053502 (DMP) 43053505 (DMP)
850.4225	123-1A	Seedling Germination and Seedling Emergence	A, B	42366302 (DMP) 46168001 (DMP)
850.4250	123-1B	Vegetative Vigor	A, B	42366301 (DMP) 46157701
850.4400	123-2	Aquatic Plant Growth	A, B	43053501 (DMP) 44909602
850.3020	141-1	Honey Bee Acute Contact	A, B	41711402 (DMP)
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A, B	00067579; 00076497
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A, B	00155585
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B	Waived
870.2400	81-4	Primary Eye Irritation-Rabbit	A, B	00155587
870.2500	81-5	Primary Skin Irritation	A, B	00155586

Appendix B
Data Supporting Guideline Requirements for the Reregistration of Phenmedipham

REQUIREMENT			Use Patterns	CITATION(S)
870.2600	81-6	Dermal Sensitization	A, B	40502706
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	A, B	46020201; 40502702
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	A, B	45408601
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A, B	Waived
870.3700	83-1A	Chronic Feeding Toxicity - Rat	A,B	44976601
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	A, B	Waived
870.4200b	83-2b	Carcinogenicity – Mouse	A, B	43941403 40502701 (supplemental)
870.3700	83-3A	Developmental Toxicity - Rat	A, B	40857101; 41731100-1
870.3700	83-3B	Developmental Toxicity - Rabbit	A, B	42602901
870.3800	83-4	2-Generation Reproduction - Rat	A, B	44862702; 45316801
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity: Rats	A, B	46304901
870.4200	83-2B	Carcinogenicity Mice	A, B	43941403; 40502701
870.5100	84-2	Bacterial Reverse Gene Mutation	A, B	40502704
870. 5300	84-2	HGPRT Forward Mutation Assay/V79 Cell Line	A, B	40540202
870.5375	84-2B	Cytogenetics	A, B	43517701
870.5550	54-2	Unscheduled DNA synthesis in mammalian cells in culture	A, B	40502705
870.7485	85-1	General Metabolism	A, B	43153501
870.7600	85-3	Dermal Penetration and Absorption	A, B	46266101
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400	133-3	Dermal Passive Dosimetry Exposure	A, B	None (based on LOAEL from 46304901)
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A, B	none
ENVIRONMENTAL FATE				

Appendix B Data Supporting Guideline Requirements for the Reregistration of Phenmedipham				
REQUIREMENT			**Use Patterns**	**CITATION(S)**
835.2120	161-1	Hydrolysis	A, B	40502708
835.2240	161-2	Photodegradation - Water	A, B	42429901
835.2410	161-3	Photodegradation - Soil	A, B	00142742
835.4100	162-1	Aerobic Soil Metabolism	A, B	00142744
835.4200	162-2	Anaerobic Soil Metabolism	A, B	42099101; 42990301
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	Not required (reserved)
835.4300	162-4	Aerobic Aquatic Metabolism	A, B	46302501
835.1240	163-1	Leaching/Adsorption/Desorption	A, B	40765701-2; 43209301; 00142747; 00142749; 42099102
835.1410	163-2	Laboratory Volatilization	A, B	Waived
835.8100	163-3	Field Volatilization	A, B	Waived
835.6100	164-1	Terrestrial Field Dissipation	A, B	42891601; 46412301-2; 42180501
850.1730	165-4	Bioaccumulation in Fish	A, B	40912801
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A, B	Waived
860.1300	171-4B	Nature of Residue - Livestock	A, B	42991101; 41852301
860.1340	171-4C	Residue Analytical Method - Plants	A, B	40946401; 43774601
860.1380	171-4E	Storage Stability - Plants	A, B	42991105
860.1500	171-4K	Crop Field Trials (Leafy Vegetables)	A, B	Not required
860.1500	171-4K	Crop Field Trials (Alfalfa, forage and hay)	A, B	Not required
860.1500	171-4K	Crop Field Trials (Clover, forage and hay)	A, B	Not required
860.1500	171-4K	Crop Field Trials (Trefoil, forage and hay)	A, B	Not required
860.1850	165-1	Confined Accumulation in1 Rotational Crops	A, B	45490102, 42907501
860.1900	165-2	Field Accumulation in Rotational Crop Study	A, B	Not required (reserved)
OTHER				
840.1100	201-1	Droplet Size Spectrum	A, B	Not required (reserved)
840.1200	202-1	Drift Field Deposition Evaluation	A, B	Reserved

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket contains the risk assessments and related documents as of March 31, 2005. The availability announcement will be published in the Federal Register. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: www.epa.gov/pesticides/reregistration. The following list details all documents related to the Phenmedipham RED.

Health Effects Documents

1. *Phenmedipham: Human Health Risk Assessment,* February 28, 2005
2. *Phenmedipham: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document,* February 28,2005
3. *Phenmedipham: Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision (RED) Document,* February 28, 2005
4. *Phenmedipham: Summary of Analytical Chemistry and Residue Data for Reregistration Eligibility Decision (RED) Document,* February 28, 2005
5. *Phenmedipham: Summary of Product Chemistry Data for Reregistration Eligibility Decision (RED) Document,* February 28, 2005
6. *PHENMEDIPHAM: Report of the Cancer Assessment Review Committee,* January 12, 2005

Ecological Fate and Effects Documents

7. *EFED RED Chapter for Phenmedipham,* March 31, 2005
8. *Tier I Estimated Drinking Water Concentrations of Phenmedipham and its Degradate (MHPC) for use in Human Health Risk Assessment,* August 4, 2004

Biological and Economical Analysis Documents

9. *Characterization of the Span of Time Between Planting and Harvesting as "Season" Versus "Year"; A Cursory Evaluation for Phenmedipham (DP #302062),* February 28, 2005

Additional Reference Documents

10. *Guidance for the Reregistration of Pesticide Products Containing Phenmedipham as the Active Ingredient,* March 30, 1987
11. *Phenmedipham Use Closure Memorandum Case No. 0277 PC Code 098701,* July 8, 2004

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

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

MRID No.	Citation
44726	Kassebeer, H. (1971) Rate of Uptake, Metabolism and Storage of Phenmedipham in Various Plants. (Translation; unpublished study received Apr 14, 1971 under 1F1160; prepared by Christian- Albrechts-Univ., Institute of Phytopathology, Germany, submitted by Nor-Am Agricultural Products, Inc., Naperville, Ill.; CDL: 093480-B)
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Appendix E. Generic Data Call-In (GDCI)

The Agency has determined that the current database is sufficiently complete for the Phenmedipham Reregistration Eligibility Decision. Thus, no additional data is required to support the reregistration of phenmedipham at this time. However, the Agency reserves the right to issue a Data Call-In if any additional data is needed in the future.

Appendix F. Product Data Call-In (PDCI)

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0277 Phenmedipham Chemical # and Name 098701 Phenmedipham	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-098701-NNNN

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0277 Phenmedipham EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-098701-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Product Chemistry Data Requirements (Conventional Chemical)									
830.1550	Product Identity and composition	(1)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1600	Description of materials used to produce the product	(2)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1620	Description of production process	(3)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.1650	Description of formulation process	(4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.1670	Discussion of formation of impurities	(5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1700	Preliminary analysis	(6 ,7 ,8)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.1750	Certified limits	(9 ,10)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1800	Enforcement analytical method	(11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6302	Color	(12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0277 Phenmedipham EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-098701-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
				1	2	3				
830.6303	Physical state	(13)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6304	Odor	(14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions	(15 ,16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.6314	Oxidizing or reducing action	(17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6315	Flammability	(18)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6316	Explodability	(19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6317	Storage stability of product	(20)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6319	Miscibility	(21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6320	Corrosion characteristics	(22)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6321	Dielectric breakdown voltage	(23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	

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Date

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
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INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0277 Phenmedipham EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-098701-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.7000	pH of water solutions or suspensions	(24 ,25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.7050	UV/Visible absorption						A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7100	Viscosity	(26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.7200	Melting point/melting range	(27 ,28)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.7220	Boiling point/boiling range	(29 ,30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.7300	Density/relative density	(31 ,32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.7370	Dissociation constant in water	(33 ,34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method	(35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	(36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7840	Water solubility: Column elution method, shake flask method	(37)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	

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Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0277 Phenmedipham EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-098701-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.7860	Water solubility, generator column method (38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7950	Vapor pressure (39 ,40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
	Toxicology Data Requirements (Conventional Chemical)								
870.1100	Acute Oral Toxicity (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
870.1200	Acute dermal toxicity (42 ,43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
870.1300	Acute inhalation toxicity (44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
870.2400	Acute eye irritation (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
870.2500	Acute dermal irritation (46 ,47)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
870.2600	Skin sensitization (48 ,49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	

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Date

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

1 Data must be provided in accordance with the "Product Composition" Section.(158.155)

2 Data must be provided in accordance with the "Description of Materials used to Produce the Product" Section.(158.160)

3 Data must be provided in accordance with the "Description of Production Process" Section.(158.162)

4 Data must be provided in accordance with the "Description of Formulation Process" Section.(158.165)

5 Data must be provided in accordance with the "Description of Formation of Impurities" Section(158.167)

6 Data must be provided in accordance with the "Preliminary Analysis" Section.(158.170)

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0277 Phenmedipham

DCI Number: PDCI-098701-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

7 Required for TGAIs and products produced by an integrated system.

8 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

9 Data must be provided in accordance with the "Certified Limits" Section(158.175)

10 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

11 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)

12 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0277 Phenmedipham

DCI Number: PDCI-098701-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

13 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

14 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

15 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

16 Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

17 Required if the product contains an oxidizing or reducing agent

18 Required when the product contains combustible liquids.

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Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

19 Required when the product is potentially explosive.

20 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

21 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

22 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

23 Required if the end-use product is a liquid and is to be used around electrical equipment.

24 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

25 Required if the product is dispersible with water.

26 Required if the product is a liquid.

27 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

28 Required when the TGAI is solid at room temperature.

29 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

30 Required if the TGAI is liquid at room temperature.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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DCI Number: PDCI-098701-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

31 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

32 True density or specific density are required for all test substances. Data on bulk density is required for MPs that are solid at room temperature.

33 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

34 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

35 Required if the TGAI or PAI is organic and non-polar.

36 Required if the TGAI or PAI is organic and non-polar.

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0277 Phenmedipham

DCI Number: PDCI-098701-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

37 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

38 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

39 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

40 Not required for salts.

41 Not required if test material is a gas or a highly volatile liquid.

42 Not required if test material is a gas or a highly volatile liquid.

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

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

Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

43 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

44 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

45 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

46 Not required if test material is a gas or a highly volatile liquid.

47 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

48 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

49 Required if repeated dermal exposure is likely to occur under conditions of use.

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK NC	27709
75240	AGVALUE-DP, LLC	MANDAVA ASSOCIATES	1730 M STREET, N.W., SUITE 906	WASHINGTON DC	200364510

Appendix G. EPA's Batching of Phenmedipham Products for Meeting Acute Toxicity Data Requirements for Reregistration

Usually, in an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products, the Agency will batch 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.).

In the case of phenmedipham, the products listed in Table G-1 could not be batched.

Table G-1. Formulations of Phenmedipham

Formulation	Registration No.	Active Ingredient(s)
Technical	264-618	97% phenmedipham
	75240-1	95% phenmedipham
Emulsifiable Concentration	264-616, 75240-4	15.9% phenmedipham
	264-816	15.0% phenmedipham, 15.0% desmedipham, 15.0% ethofumesate
	264-621, 75240-5, WA000013	8.0% phenmedipham, 8.0% desmedipham
	264-815	13.1% phenmedipham, 10.2% desmedipham, 15.9% ethofumesate
	264-632, 75240-6	7.0% phenmedipham, 7.0% desmedipham, 7.0% ethofumesate
	264-631	6.0% phenmedipham, 6.0% desmedipham, 6.0% ethofumesate
	264-633	6.0% phenmedipham, 6.0% desmedipham, 6.0% ethofumesate

Appendix H. List of Registrants Sent this Data Call-In notice

- Bayer CropScience (formerly Aventis CropScience) USA, L.P.
  2 T.W. Alexander Drive, P.O. Box 12014
  Research Triangle Park, NC 27709

- AgValue-DP, LLC
  11324 17th Avenue Ct. NW
  Gig Harbor, WA 98332

Appendix I. List of Available Related Documents and Electronically Available Documents

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The documents listed in Appendix C are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents may also be obtained by contacting the person listed on the respective Chemical Status Sheet.