United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-99-005
November 1999

Reregistration Eligibility Decision (RED)

Pebulate

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Pebulate which includes the active ingredients Pebulate. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the

implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Venus Eagle at (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative Patricia Moe (703) 308-8011.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

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

e. **Certification With Respect to Citation of Data**. Complete and sign EPA form 8570-34 and 8570-35 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

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

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

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

REREGISTRATION ELIGIBILITY DECISION

Pebulate

LIST B

CASE 2500

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PEBULATE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis

Margaret Cogdell	Science Information and Analysis Branch
Virginia Dietrich	Herbicide and Insecticide Branch
Timothy Kiely	Economic Analysis Branch

Environmental Fate and Effects Assessment

Brian Montague	Environmental Risk Branch I
Richard Mahler	Environmental Risk Branch I

Health Effects Risk Assessment

Yung Yang	Toxicology Branch I
William Hazel	Reregistration Branch I
Susan Hanley	Reregistration Branch I

Registration Support

Juanita Gilchrist	Herbicide Branch

Risk Management

Patricia Moe	Reregistration Branch III

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
BUN	Blood Urea Nitrogen
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
DCI	Data Call In
DEEM™	Dietary Exposure Evaluation Model
DWLOC	Drinking Water Level of Concern
EC	Emulsifiable Concentrate
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
HDT	Highest Dose Tested
HIARC	Hazard Identification Assessment Review Committee
K_{oc}	Organic Partitioning Coefficient
K_{ow}	Octanol/Water Partition Coefficient
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
LOAEC	Lowest Observed Adverse Effect Concentration
µg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PAD	Population Adjusted Dose
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
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
USDA	United States Department of Agriculture
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA) has completed its reregistration eligibility decision (RED) for the pesticide pebulate (S-propyl butyl(ethyl)thiocarbamate) and determined that all uses, when labeled and used as specified in this document, are eligible for reregistration. This decision includes a comprehensive reassessment of the database of studies required to support the use of currently registered products. The Agency made the decisions presented in this RED by considering the requirements of the "Food Quality Protection Act of 1996" (FQPA), which amended the Federal Food Drug and Cosmetic Act (FFDCA) and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), the two Federal statutes that provide the framework for pesticide regulation in the United States.

In establishing or reassessing tolerances, FFDCA, as amended, requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information. In addition, the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity must be considered. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

Pebulate is a thiocarbamate herbicide used for preemergence control of germinating seeds of broadleaf and grassy weeds in sugar beets, tobacco, and tomatoes. There are no registered uses of pebulate in residential settings. There are currently two active registrations: one for the technical grade product and one for an end-use product. Pebulate is typically applied preplant once per season using ground or irrigation equipment and is soil-incorporated immediately after application to prevent loss via volatilization.

Pebulate is a reversible cholinesterase inhibitor, although such effects are seen only at high doses. Neurotoxicity is the major toxic effect of pebulate. Pebulate has low acute oral, dermal, and inhalation toxicity. It is a slight to mild irritant to the eye or skin and is not a skin sensitizer. Based on pebulate use patterns, no long-term inhalation exposure is expected to occur.

In addition to the conventional safety factors (10x for interspecies extrapolation and 10x for intraspecies variability), the FQPA safety factor of 10x was applied for pebulate dietary and aggregate risk assessments. The reason for the additional factor was due to (1) the severe neuropathology exhibited in studies with adult animals, (2) the structural similarities to other thiocarbamates for which increased susceptibility of developing fetuses has been demonstrated, and (3) the outstanding requirement for a developmental neurotoxicity study. The 10x FQPA safety factor is not applied to the general population when it is appropriate only to apply the factor to portions of the population. In the case of pebulate, it is appropriate to apply the factor to infants, children, and woman of reproductive age (13-50 years) only.

Dietary risk assessments reflected highly refined exposure assessments; anticipated residues and percent-crop-treated figures were incorporated. A probabilistic/Monte Carlo acute dietary assessment was conducted using an acute population adjusted dose (aPAD) of 0.5 mg/kg/day for adults and 0.05 mg/kg/day for infants, children, and females (13-50 yr). Chronic risks were calculated using a chronic PAD (cPAD) of 0.007 mg/kg/day for adults and 0.0007 mg/kg/day for infants, children, and females (13-50 yr). Acute and chronic dietary risks to all population subgroups were <1% of the aPAD and cPAD, respectively.

Pebulate was rarely detected in either surface or ground water in available water monitoring studies, and when detected, was present at low concentrations. With the exception of the most conservative estimate of chronic environmental concentrations, calculated by assuming that there would be no binding of the chemical to soil whatsoever, estimated water concentrations of pebulate do not exceed any Drinking Water Levels of Comparison (DWLOCs). The available monitoring data, although not targeted to pebulate, support this assumption.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether pebulate, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that pebulate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals. Tolerances are currently 0.1 ppm for pebulate in tomatoes and sugar beet roots and tops (40 CFR 180.238). The Agency recommends reassessment of all tolerances to the limit of quantitation of the analytical method, 0.05 ppm, because all residues were consistently less than the limit of quantitation.

For occupational handler dermal exposures, risks were below the Agency's level of concern, which is a margin of exposure (MOE) greater than 100, for most scenarios involving pebulate mixers and loaders with the use of personal protective equipment (PPE). In addition to the PPE that is currently on the label (long-sleeved shirts, long pants, shoes, socks, protective eyewear, and chemical-resistant gloves), organic vapor respirators are required when preparing solutions for application at the highest use rates in the western states (defined as California, Arizona, and Nevada) and for chemigation. For commercial operators, closed systems are required for mixing and loading of pebulate for dry bulk fertilizer and in combination with fluid fertilizer. The MOEs for the pebulate applicator exposures are acceptable with the use of the PPE specified on the current label, with only one exception. Applying dry bulk fertilizer to tobacco in the western states requires that the applicator use an organic vapor respirator or a truck with an enclosed cab and an organic vapor air filtration system. In the absence of dermal exposure data, the Agency is also requiring that chemical-resistant gloves be worn during transplanting of crop seedlings and is requiring additional data on this practice.

For acute exposure, pebulate is practically nontoxic to birds and is slightly toxic to mammals. The Agency is not overly concerned about chronic exposures to birds and mammals because of the way pebulate is used, i.e., immediate soil incorporation. Pebulate runoff and drift to adjacent habitats

may prove hazardous to certain families of non-target terrestrial and semi-aquatic plants (mainly grass related species). Risk to aquatic plants is not predicted based on estimated aquatic residue levels.

Although the pebulate database is sufficient to render a reregistration eligibility decision, a deficiency exists for developmental neurotoxicity. Other requirements include labeling changes to (1) increase the preharvest interval for tomatoes from 8 days to 30 days and (2) establish a 4-month plantback interval (PBI) for all rotational crops. If a shorter PBI is desired, additional data must be submitted to upgrade rotational crop studies or limited field rotational crop studies (which include seeking metabolites of potential toxicological concern as well as the parent compound) can be conducted. In addition, ecological effects and environmental fate studies are needed to fully assess the impact of pebulate and its primary degradate, pebulate sulfoxide, on the environment.

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

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5, "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data underlying a pesticide registration. The purpose of the Agency's review is (1) to reassess the potential hazards arising from the currently registered uses of the pesticide; (2) to determine the need for additional data on health and environmental effects; and (3) to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the FQPA (Public Law 104-170) was signed into law. The FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the FIFRA, 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately and EPA initiated an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and nonfood use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in Section 4 of FIFRA. In addition, because statutory deadlines are unaffected with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of pebulate including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document, which is in a revised format, consists of six sections. In an effort to simplify and shorten the RED, the information presented herein is at a higher level than that presented in previous documents; more detailed information can be found in the technical support documents. Section I is the introduction, and Section II describes pebulate, its uses, data requirements, and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for pebulate, and Section V discusses the reregistration requirements for pebulate. Finally, Section VI contains the

Appendices that support this Reregistration Eligibility Decision (RED). The supporting technical documentation for this RED is listed in the Reference section at the back of this document. These references are cited in this RED parenthetically and in italics. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Pebulate
- **Chemical Name:** s-Propyl butylethylthiocarbamate
- **Chemical Family:** Thiocarbamate
- **CAS Registry Number:** 1114-71-2
- **OPP Chemical Code:** 041403
- **Empirical Formula:** $C_{10}H_{21}NOS$
- **Trade Name:** Tillam 6-E
- **Basic Manufacturer:** Zeneca Ag Products

B. Use Profile

The following summarizes the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of pebulate is contained in Appendix A.

Type of Pesticide:	Herbicide
Use Sites:	Soil incorporated application to tomatoes, tobacco, and sugar beets
Target Pests:	Grassy and broadleaf weeds
Formulation Types Registered:	Emulsifiable concentrate (EC)

Rates of Application:

- **Sugar beets**: 4-6 lb of active ingredient (ai)/acre
- **Tobacco**: 4 lb ai/acre
- **Tomatoes**: 3-6 lb ai/acre may be applied; western region only, a maximum of 10 lb ai/acre rate may be applied
- **Dry Bulk Fertilizer**: Tobacco only, 4 lb ai/acre
- **Fluid Fertilizer**: Tobacco and tomato crops only; the label gives application instructions based on a field rate of 1 lb ai/acre, but states that the amount of pebulate active ingredient per acre may be increased to correspond to intended field rate.

Methods of Application

Pebulate is incorporated into the soil during or immediately after application. It can be applied below the surface of the soil, by ground sprayer equipment (including chemigation), subsurface sweeper application (tobacco only), or by soil injection. When pebulate is applied via solid set sprinklers, ¼ to ½ inch of water must be applied to ensure 2- to 4-inch soil penetration of the chemical. Pebulate is mixed with fluid fertilizer (tomato and tobacco use) and immediately soil incorporated. For impregnation on dry bulk fertilizer (tobacco only), there are two scenarios: commercial and on-board application. Commercial processing occurs with a closed rotary-drum mixer or a similar type of closed blender equipped with suitable spray equipment. For on-board applications, pebulate is metered onto dry bulk fertilizer as it is applied to the field, similar to a groundboom application. This method also requires immediate soil incorporation.

Summary of Major Uses

Methods: Soil incorporated or soil injected

Equipment: Boom-type sprayers which precede the cultivation wheels;
Subsurface injection equipment

Timing: Typically applied once per season, preplant. Pebulate can have a second, postemergence layby application, which occurs in conjunction with mechanical weeding

Use Limitations:

The product is to be applied prior to mechanical transplanting of tomatoes and tobacco. Hand transplanting is not permitted.

C. Estimated Usage of Pesticide

The Agency estimates that, on average, approximately 536,000 pounds of pebulate are applied to sugar beets, tomatoes, and tobacco per year. More than 90% of pebulate usage is on tomatoes and tobacco. Application of pebulate to tomatoes constitutes the major use (approximately 55% of the total pounds of pebulate applied), followed by tobacco (35%), and sugar beets (about 10%). Total acreage treated annually with pebulate for the crops ranges from an estimated maximum of 65,000 acres for tomatoes to 8,000 acres for sugar beets, with an estimated 127,000 acres treated per year nationally (*reference 1*). More than 80% of the pebulate usage on tomatoes and sugar beets is concentrated in California. Use of pebulate on tobacco is primarily concentrated in southeastern states (NC, KY, SC, GA, and TN) and Indiana (*reference 2*).

Table 1 summarizes the best available estimates for the uses of pebulate. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Table 1. Maximum Permitted Label Use Rate Table - Pebulate Crop Scenarios

Crop	Rate lb ai/A	Method	Major Area of Use
Tomato	10.0	Preplant soil incorporated	CA
Tomato	10.0*	Postplant irrigation spray equipment usually followed by incorporation	CA (Western region only)
Sugar beets	6.0	Preplant soil incorporated	CA
Tobacco	4.0	Preplant soil incorporated or injected	NC, KY, SC, GA, IN, TN

* The only permitted multiple application is for tomatoes in western regions. With a second layby application, which occurs in conjunction with mechanical weeding, the 10 lb ai/A seasonal limit must still be observed.

D. Data Requirements

The Agency required the registrant to submit studies, as specified in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

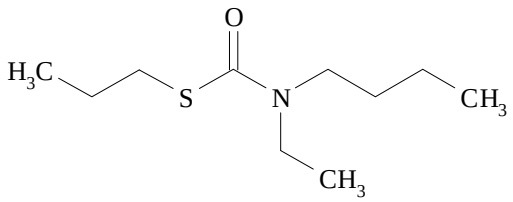
Pebulate was first registered as a pesticide in the United States in 1961. At that time three products were registered that contained the active ingredient pebulate: Tillam Technical, Tillam 6E, and Tillam 10G. In 1987, these products were transferred from Stauffer Basic Chemical Holdings, Inc., to ICI Americas, Inc., which later became Zeneca Ag Products.

In 1996, Tillam 10G was canceled at the request of the registrant following an Agency request for residue data for the 10G formulation. The registrant determined that the product was not marketed in quantities sufficient to justify generating the data. As of 1999, the registrant is supporting continued registration of the technical grade product, EPA Reg. No. 10182-213, and one end-use product, the 6 lb. active ingredient per gallon emulsifiable concentrate (EC), EPA Reg. No. 10182-158.

III. SCIENCE ASSESSMENT

A. Physical/Chemical Properties Characterization

Pebulate [S-propyl butylethylthiocarbamate] is a preplant selective herbicide used for control of grassy and broadleaf weeds in sugar beets, tobacco, and tomatoes.



Empirical Formula:	$C_{10}H_{21}NOS$
Molecular Weight:	203.36

Pebulate technical is an amber liquid with a boiling point of 142°C at 21 mm Hg, a density of 0.9552 g/mL at 20°C, an octanol/water partition coefficient (K_{ow}) of 9.6×10^3 at 25°C, and a vapor pressure of 8.9×10^{-3} mm Hg at 25°C. Pebulate is slightly soluble in water (60 ppm at 20°C), and is miscible with acetone, benzene, isopropanol, methanol, and xylene. No impurities of toxicological concern have been identified. Because pebulate is volatile, exposure by the inhalation route is expected.

B. Human Health Assessment

1. Hazard Profile

Pebulate is in the class of thiocarbamates, which includes molinate, EPTC, butylate, vernolate, and cycloate, and is a reversible cholinesterase inhibitor (that is, pebulate quickly binds to the cholinesterase active site, but is easily replaced by acetylcholine). In contrast, the carbamates, such as formetanate HCL, oxamyl, and aldicarb, are effective cholinesterase inhibitors (although not as effective as the organophosphates). For the carbamates, however, cholinesterase inhibition is rapidly reversible and therefore the anticholinesterase activity must be measured at the optimal time. Consequently, for this class of chemicals, acetylcholine inhibition is the principal toxicological effect of concern and is often the endpoint used for risk assessments.

The thiocarbamates, such as pebulate, are not particularly effective cholinesterase inhibitors; rather, they appear to be direct acting neurotoxic agents. Because the principal toxic effects observed by exposure to thiocarbamates are neurotoxicity (clinical signs, behavioral effects, and/or changes in motor activity) and neuropathology, these neurotoxic effects are often used for endpoint selection in risk assessments rather than cholinesterase inhibition. For this class of compounds, acetyl cholinesterase inhibition is not the primary toxicity concern. Other toxic effects, which are described below, were also observed in laboratory animal toxicology studies. No significant differences were observed in the toxicology studies with regard to gender.

The acute toxicity data showed that pebulate had low acute oral, dermal, and inhalation toxicity. It was a slight to mild irritant to the eye or skin and was not a skin sensitizer. Toxicity categories, which are classified as 1 (most toxic) through 4 (least toxic), were either 3 or 4 for pebulate. There was no evidence of increased tumor incidence in the carcinogenicity studies in rats and mice, and the mutagenic test battery also indicated that pebulate was not mutagenic. Therefore, pebulate was classified as “not likely” to be a human carcinogen.

In the rat, pebulate was readily absorbed, distributed, metabolized and eliminated, primarily in urine, feces, and CO_2. Less than 3% was detected in total tissues. Major metabolites were identified in the urine as pebulate mercapturate, hydroxylated pebulate, butylamine and ethylbutylamine, hydroxyethylbutylamine, and hydroxylated pebulate mercapturate.

Although pebulate sulfoxide and pebulate sulfone are not found as significant metabolites in plants and livestock, they are major soil/water degradates. There is concern that these pebulate degradates may be taken up by rotated crops. These degradates are assumed to be of equal toxicity to parent pebulate in the absence of data showing otherwise. This assumption is consistent with metabolite studies conducted with other thiocarbamates.

The studies the Agency used in making decisions related to pebulate toxicity are shown in Table 2. The dose and endpoints selected for various exposure scenarios are shown in Table 3.

These studies, which the Agency used in quantifying risk (*reference 3*), are summarized after the table, as well as a discussion of the FQPA safety factors.

Table 2. Toxicity Studies for Pebulate Technical

Guideline	MRID#	Type of Study	Results	Core Grade
Acute Toxicity				
§81-1 870.1100	41591701	Acute Oral-Rat	LD_{50}= 1750(♂)/1550(♀) mg/kg Toxicity category 3	Acceptable
§81-2 870.1200	41591701 41677301	Acute Dermal-Rabbit Acute Dermal- Rat	LD_{50} >2000 mg/kg (Rabbit or Rat) Toxicity category 3	Acceptable
§81-3 870.1300	00143575	Acute Inhalation-Rat	LC_{50}= 3.7(♂)/3.5(♀)mg/L Toxicity category 4	Acceptable
§81-4 870.2400	41591703	Eye Irritation-Rabbit	Mild eye irritant Toxicity category 3	Acceptable
§81-5 870.2500	41591702	Skin Irritation-Rabbit	Slight dermal irritant Toxicity category 4	Acceptable
§81-6 870.2600	41614808	Dermal Sensitization- Guinea pig	Not a skin sensitizer	Acceptable
Subchronic Toxicity				
§82-1(a) 870.3100	N/A	90-day feeding-Rat	N/A	Waived*
§82-1(a) 870.3100	N/A	90-day feeding-Mouse	N/A	Waived*
§82-1(b) 870.3150	N/A	90-day feeding-Dog	N/A	Waived*
§82-2 870.3200	41920701	28-day dermal-Rat	NOAEL = 100 mg/kg/day (highest dose tested)	Acceptable
§82-3 870.3465	00143576	90-day Subchronic Inhalation-Rat	NOAEL = 0.0034 mg/L LOAEL = 0.016 mg/L	Acceptable
Chronic Toxicity				
§83-1(b) 870.4100	40969701	1-year Chronic oral-Dog	NOAEL = <5(♂)/5(♀)mg/kg/day LOAEL = 5(♂)/25(♀)mg/kg/day	Acceptable
§83-2(b) 870.4200	41920705	Carcinogenicity-Mouse (18 months)	NOAEL = 34(♂)/47(♀) mg/kg/day LOAEL = 116(♂)/161(♀) mg/kg/day No evidence of Carcinogenicity	Acceptable

Guideline	MRID#	Type of Study	Results	Core Grade
§83-5 870.4300	41213001	Combined Chronic/Oncogenicity -Rat (2 years)	NOAEL = 0.74(♂)/0.85(♀) mg/kg/day LOAEL = 7.12(♂)/9.40(♀) mg/kg/day No evidence of Carcinogenicity	Acceptable
Developmental / Reproductive Toxicity				
§83-3(a) 870.3700	40033301	Developmental-Rat	Maternal NOAEL= 30 mg/kg/day LOAEL= 200 mg/kg/day Developmental NOAEL= 30 mg/kg/day LOAEL= 200 mg/kg/day	Acceptable
§83-3(b) 870.3700	40033201	Developmental-Rabbit	Maternal NOAEL= 30 mg/kg/day LOAEL= 150 mg/kg/day Developmental NOAEL= 150 mg/kg/day (HDT)	Acceptable
§83-4 870.3800	40970001	Two-generation Reproduction-Rat	Parental NOAEL= 0.8 mg/kg/day LOAEL= 6 mg/kg/day Offspring NOAEL= 6 mg/kg/day LOAEL= 50 mg/kg/day Reproductive NOAEL= 50 mg/kg/day (HDT)	Unacceptable**
Neurotoxicity				
§81-7 870.6100	00067869 92138016	Acute delayed Neurotox- Hen	Negative	Acceptable
§81-8ss 870.6200	43217401	Acute neurotoxicity-Rat	NOAEL= 50 mg/kg LOAEL= 150 mg/kg	Acceptable
§82-7 870.6200	43231001	Subchronic neurotoxicity- Rat	Neurotoxicity NOAEL= 3.9(♂)/4.5(♀) mg/kg/day LOAEL= 19.4(♂)/21.5(♀)mg/kg/day Cholinesterase inhibition:Brain, plasma, RBC NOAEL= 3.9(♂)/4.5(♀) mg/kg/day LOAEL= 19.4(♂)/21.5(♀)mg/kg/day	Acceptable
Mutagenicity				
§84-2 870.5100	41556803	Ames Assay (S. typhimurium)	Not mutagenic	Acceptable

Guideline	MRID#	Type of Study	Results	Core Grade
§84-2 870.5375	41556802	In vitro mammalian cytogenetics -human lymphocytes	No induction of chromosomal aberrations	Acceptable
§84-2 870.5550	41614809	Unscheduled DNA synthesis in rat hepatocyte treated in vivo	No conclusion can be reached	Unacceptable
Metabolism				
§85-1 870.7485	42215201 42482501 42482502 42482503	Metabolism	Pebulate was readily absorbed, distributed, metabolized and excreted, primarily in urine (59-76%), feces and CO_2 (4-14% and 13-16%, respectively.) Very little (0.4-1.0%) was detected in tissues. Major metabolites were identified in the urine as pebulate mercapturate, hydroxylated pebulate, butylamine and ethylbutylamine, hydroxyethylbutylamine, hydroxylated pebulate mercapturate. The data suggested that metabolism of pebulate does not appear to be sex- or dose-related and does not bioaccumulate.	Acceptable

NOAEL, No observed adverse effect level; LOAEL, lowest observed adverse effect level; HDT, highest dose tested;
*Subchronic oral toxicity studies were required in the original data call in (DCI) but were never submitted; however, the Agency waived these requirements because information from chronic toxicity studies in rats and dogs can be used in lieu of these data.
**Although this study was unacceptable (*reference 3*), the Agency has determined that little additional information would be obtained about the reproductive and developmental effects of pebulate by repeating this study.

Table 3. Doses and Toxicological Endpoints Selected for Various Exposure Scenarios*

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	NOAEL = 50	Decreased motor activity at 150 mg/kg/day	Acute Neurotoxicity-Rat
	(UF = 100) [FQPA SF=10]	Acute RfD = 0.5 mg/kg/day (1) aPAD for infants, children, and females (13-50 yr) = 0.05 mg/kg/day (2) aPAD for adults other than females (13-50 yr) = 0.5 mg/kg/day	
Chronic Dietary	NOAEL = 0.74	Decreased body weights and increased incidence of cataracts in both sexes at a dose of 7.12 mg/kg/day	Chronic Toxicity - Rat (2 year)
	(UF = 100) [FQPA SF = 10]	Chronic RfD = 0.007 mg/kg/day (1) cPAD for infants, children, and females (13-50 yr) = 0.0007 mg/kg/day (2) cPAD for adults other than females (13-50 yr) = 0.007 mg/kg/day	
Carcinogenicity (Dietary)	Not Applicable	Pebulate is not mutagenic and does not result in increased tumor incidence in rats or mice. pebulate is classified as not likely to be a human carcinogen.	Not Applicable
Short-Term (Dermal)	NOAEL=100 (MOE of concern = 100)	The highest dose tested (100 mg/kg/day)-No effects observed	28-Day Dermal Toxicity- Rats
Intermediate-Term (Dermal)			
Long-Term (Dermal)	Not Applicable	Based on the use pattern, no long-term dermal exposure is expected to occur. Risk assessment is not required.	Not Applicable
Short-term (Inhalation)	NOAEL = 0.003 mg/L (0.89 mg/kg/day)** (MOE of concern = 100)	Prolonged coagulation time, degenerative effects in kidneys of both sexes at dose of 0.016 mg/L.	Subchronic Inhalation- (90 days) Rats
Intermediate-term (Inhalation)			
Long-term (Inhalation)	Not Applicable	Based on the use pattern, no long-term inhalation exposure is expected to occur. Risk assessment is not required.	Not Applicable

NOAEL, No observable adverse effects level; UF, uncertainty factor; RfD, reference dose; FQPA SF, Food Quality Protection Act Safety Factor; MOE, margin of exposure.

*Table is from references *1* and *4*, as modified by the 5/26/99 HIARC decision regarding the NOAEL for dermal scenarios (report in preparation).

**Inhalation dose calculation is detailed in reference *5;* the equation included the Sprague-Dawley rat mean respiratory volume of 10.26 L/hr (at rest) and mean body weight of 0.236 kg.

Acute Dietary

In an acute neurotoxicity study in rats (MRID 43217401), pebulate (purity: 96.1%) was administered in a single gavage dose to groups of 10 male and 10 female Wistar derived rats (Alpk:APfSD strain) at dose levels of 0, 50, 150 or 500 mg of pebulate (in corn oil) per kilogram of body weight.

The following treatment-related findings were observed in the 500 mg/kg male and/or female groups: (1) clinical findings (decreased activity, hunched posture, splayed gait, decreased visual placement response, piloerection, irregular breathing, ptosis, chromodacryorrhea, rigidity during handling, signs of salivation, and urinary incontinence); (2) decreases in group mean body weight and food consumption during the first week after dosing; (3) increases in the landing foot splay and time to tail flick; (4) decreases in the hindlimb grip strength (males) and motor activity; and (5) increased incidence of neuronal cell necrosis in the pyriform and dentate gyrus cortices. Clinical signs were observed at 5-6 hours after dosing and disappeared within 1-2 days.

Treatment-related effects, observed in the 150 mg/kg group, were (1) decreased activity, increased breathing rate, and decreased motor activity in females; and (2) increased incidence of neuronal cell necrosis in the brain of males and females.

Treatment-related findings were not observed in the 50 mg/kg group. Pebulate had no effect on cholinesterase (brain, plasma and erythrocyte) and neurotoxicesterase activities, brain measurements (weight, length and width), and macroscopic pathology.

The lowest observed adverse effect level (LOAEL) for neurotoxicity is 150 mg/kg based on decreased motor activity and the no observed adverse effect level (NOAEL) is 50 mg/kg. This study is classified acceptable and satisfies the guideline (§81-8; OPPTS 870.6200) requirement for an acute neurotoxicity study in rats.

Chronic Dietary

In a two-year chronic toxicity/carcinogenicity study in rats (MRID 41213001), pebulate technical (97.3% a.i.) was administered in the diet to Charles River rats (60 or 70/sex/group) at dose levels of 0, 15, 150, or 1500 ppm (equivalent to 0, 0.74, 7.12, or 75.6 mg/kg/day for males and 0, 0.85, 9.4, or 99.44 mg/kg/day for females, respectively) for two years.

Increased mortality was observed in the high-dose males only during the first 7 months of the study. Clinical signs (pale eyes and extremities, red oral and nasal discharges, and general poor condition) were observed in the high-dose males which died or were sacrificed moribund during the first year of the study. Ophthalmological findings (zonal disjunction, retinal degeneration, and cataracts) were observed mostly in the high-dose males and females, and less frequently in the mid-dose males and females. Complete cataract was observed in 10.7% males

and 14.7% females of high-dose group compared to that in 3.3% males and 0% females of the control group.

Decreased body weights in the high-dose males (↓7-21.4%) and females (↓6.4-39.9%), were observed throughout the study (weeks 2-105), and in the mid-dose males (↓3.4-8.2%) during weeks 3-69 and the mid-dose females (↓4.2-16.6%) during weeks 3-97. Significant body weight gain deficits were observed in the high-dose group (↓39% in males and ↓56.2% in females) when compared to the control. Increased food consumption was observed in the high-dose males and females; and occasionally for the mid-dose males and females.

Hematology parameters showed increased thromboplastin times in the high-dose males and females and increased Factor VII values in the high-dose males at the 12 and 24 months sampling intervals. Clinical chemistry showed increased blood cholesterol and blood urea nitrogen (BUN) levels and decreased triglyceride and glucose values in the high-dose males and females at most sampling times. Necropsy did not reveal treatment-related abnormalities when compared with controls. No significant difference in organ weights was observed in the low- and mid-dose males and females compared to the controls. In the high-dose group, most organ weights and organ/body weight ratios were statistically different from those of the control group. However, because these differences from control were secondary to the observed decreases in body weight gain, they were not indicative of primary organ toxicity. There was an increased incidence and severity of necrotic lesions in the livers of the high-dose male rats dying prematurely. Other microscopic findings in the high-dose male rats dying prematurely included hemorrhages in the epididymides, liver, testes, thoracic spinal cord and thymus; inflammation of epididymides and skin; islet hyperplasia (pancreas) and extramedullary hematopoiesis (liver). Although pebulate causes Wallerian-type degeneration in brain, spinal cord, and peripheral nerves in dogs, this was not observed in this study.

There was no evidence of carcinogenic potential for pebulate in this study. The doses were considered adequate for testing the carcinogenic potential for pebulate in both sexes. The NOAEL for systemic toxicity was 15 ppm (equivalent to 0.74 mg/kg/day for males and 0.85 mg/kg/day for females) and the LOAEL was 150 ppm (equivalent 7.12 mg/kg/day for males and 9.4 mg/kg/day for females) based on decreased body weights of both sexes and increased incidence of cataracts in both sexes. This study is classified acceptable and satisfies the guideline (§83-5; OPPTS 870.4300) requirement for a combined chronic toxicity/carcinogenicity study in rats.

Short and Intermediate Term (Dermal)

In a 28-day dermal toxicity study in rats (MRID 41920701), SPF Wistar-derived albino rats (5/sex/group) received a 6-hour dermal application of pebulate (97.1%) at dose levels of 1, 10, or 100 mg/kg/day for 21 days (5 applications per week) over a period of 30 days. No treatment related mortality was observed. Treatment-related clinical observations included the

following: (1) Slight or moderate erythema and edema in the mid- and high-dose males and females; (2) desquamation, skin sensitive to touch and thickening of the skin in the high-dose males and females; and (3) upward curvature of the spine mostly in the high-dose females. Significant body weight gain deficits (↓28.7%) and reduction of food utilization (↓29%) were observed in the high-dose females only. Hematology showed a 48% reduction in neutrophils count in the high-dose females compared to the control. There were dose-related increases in absolute and relative adrenal weights of males and females, but statistical significance was reached only in the high-dose females. For dermal irritation, the NOAEL was established at 1 mg/kg/day (both sexes) and the LOAEL was 10 mg/kg/day based on erythema and edema. For systemic toxicity, the NOAEL was established at 100 mg/kg/day (the highest dose tested) for both sexes, and the LOAEL was not established. This study is selected because its duration and route of exposure are appropriate for short and intermediate term dermal exposure. Slight to moderate dermal irritations were observed at mid- and high-dose groups. Systemic effects were similar to those observed in other studies. Although there were some body weight gain decrements and decreased food utilization in females at 100 mg/kg/day, they were judged to be confounding because of the following data: (1) there were no difference in absolute body weight; (2) the decreased body weight gain was equivocal at all doses in the females; (3) the decreases were significant only on sporadic days and did not exhibit any consistency over time; and (4) decreased body weight gain can be attributed to the dermal irritation, which was severe in the high dose groups. Based on these factors, the Hazard Identification Assessment Review Committee concluded that the 100 mg/kg/day dose is the NOAEL (not the LOAEL), and this value should be used for the risk assessment.

Inhalation

In a subchronic inhalation study in rats (MRID 00143576), Sprague-Dawley rats (24/sex/group) were exposed (whole body exposure) to pebulate technical (97.7%) aerosol at an analytical concentration of 0, 0.0034, 0.016, or 0.079 mg/L (MMAD 3-7.7 μm) for 6 hours per day, 5 days per week for 14 weeks. No treatment-related mortality was observed. An earlier onset and an increased incidence of salivation were observed in a dose-related fashion. Body weight gain was depressed (↓12% and ↓9% in males and females, respectively) at 0.079 mg/L at the end of the study whereas food consumption remained unaffected by treatment. No treatment-related changes were noted in hematology and clinical chemistry at 3, 9, or 14 weeks. Brain, plasma, and red blood cell cholinesterase activities were measured at weeks 3, 9, and 14 of the study. Significant inhibitions of red blood cell cholinesterase (↓42% in males and ↓39% in females) and brain cholinesterase (↓26% in males only) were observed at the highest dose tested in week 14 of the study.

Blood coagulation time (test for clotting factors) was prolonged in males and females at 0.016 and 0.079 mg/L; bleeding times (test for platelet function) were not significantly increased by treatments. Relative liver weights in both sexes, relative adrenal weights in females, and relative testes weight in males were significantly increased at the highest dose tested. However,

none of these changes were correlated with histopathologic lesions in these organs. In contrast, the relative kidney weights, which were significantly increased in both sexes of the high-dose at 14 weeks, are associated with histopathological changes in the kidney. In males, regenerative tubular hyperplasia was observed to increase with doses at incidences of 4/12, 6/12, 8/11, and 9/11 in control, 0.0034, 0.016, and 0.079 mg/L, respectively. Degeneration and vacuole formation in kidney epithelium of female rats increased from 0/12 in control to 4/12 and 6/12 at the two highest dose levels.

Furthermore, an increase in the incidence of mucigenic epithelial hyperplasia of the nasal turbinate was observed in both sexes (becoming dose-related in females), suggesting possible irritative effects of pebulate to the nasal passage at all doses over the 14-week course of exposure. Under conditions of this study, the NOAEL was 0.0034 mg/L and the LOAEL was 0.016 mg/L based on prolonged coagulation time, degenerative effects in kidney and increased incidences of mucigenic epithelial hyperplasia of the nasal turbinate. This study is classified acceptable and satisfies the guideline (§82-3; OPPTS 870.3465) requirement for a subchronic inhalation study.

2. Food Quality Protection Act Considerations

The Agency is retaining the Food Quality Protection Act (FQPA) safety factor of 10x for protection of infants and children (*references 6 and 7*). The rationale for retention of the FQPA safety factor is as follows:

- Severe neuropathology is exhibited in studies with adult animals (subchronic neurotoxicity study in rats and one-year dog study indicate exposure to pebulate produced neuropathologic changes);

- There is a structural similarity between pebulate and molinate (a thiocarbamate), which is known to produce neurotoxicity/neuropathology;

- Molinate, a chemical analog of pebulate, is a reproductive toxicant in mice, rats, and dogs; and

- There is uncertainty regarding the effect of pebulate on developmental neurotoxicity, as there are no data. A developmental neurotoxicity study will provide additional information about functional parameter development, potential increased susceptibility, and the effects of pebulate on the development of the fetal nervous system.

In the current analysis, the 10x FQPA safety factor is applied to various subpopulations including infants and children as well as females of childbearing age (13-50 years of age). The Agency is concerned about potential developmental (*in utero* exposure) effects of pebulate. The 10x FQPA safety factor is not applied to the general population when it is appropriate only to

apply the factor to portions of the population. In the case of pebulate, it is not appropriate to apply the factor to males or to the general population due to the *in utero* nature of the effect.

3. Dose Response Assessment

All the currently required guideline studies on pebulate were available and provided reasonable confidence when the toxicity endpoints and doses for risk assessment were selected. However, the Agency will require a developmental neurotoxicity study to determine whether or not pebulate has neurologic effects in developing animals.

All of the toxicity endpoints and doses for risk assessment were selected based on the most sensitive toxic effect and were derived from studies that used similar routes of exposure as those expected in possible human exposure scenarios. The doses and toxicological endpoints used in this study are summarized in Table 3.

The Agency calculated the occupational risks associated with dermal and inhalation exposure separately rather than combined. The rationale for separating these exposures is as follows: (1) toxicity studies are available that used administration via the dermal and inhalation routes; and (2) different toxic effects resulted from dermal and inhalation exposure.

4. Risk Assessment

a. Dietary Exposure and Risk

Potential exposure to pebulate residues in the diet occurs through food and water. Residues are possible in treated tomato and sugar beet crops. Data supporting food exposure are adequate for this assessment (*reference 2*). Exposure to pebulate residues in ground and surface water was estimated using conservative modeling techniques; available monitoring data were assessed but were not considered adequate for quantitative risk assessment purposes (*reference 8*).

b. Food Exposure and Risk

Pebulate has an early season soil-incorporated application with extensive soil degradation, soil dissipation, and plant metabolism. No parent compound is identified in plant metabolism studies. Major metabolites found in plants are a series of three different butylamine compounds resulting from hydrolysis of the thiocarbamate moiety; these metabolites are not of toxicological concern at the concentrations expected from registered uses of pebulate (9). Pebulate residues were below the limit of quantitation in all field trials and processing studies.

Pebulate was identified at low levels in milk and fat in livestock metabolism studies using greatly exaggerated doses (up to 223x). However, livestock dietary exposure is expected to be negligible even when using conservative assumptions for livestock diets.

Tobacco was not included in the dietary risk assessment because it is not ingested. It is the Agency's position that any exposure to pesticide residues through the use of tobacco products is negligible when compared to other, well documented, human health risks associated with tobacco use. Therefore, any risk from pebulate through the use of tobacco and tobacco products is not addressed in this RED.

The Agency's dietary risk assessments use the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in the U.S. Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For acute dietary risk assessments, the entire distribution of single day food consumption events is combined with either a single residue level (deterministic analysis) or a distribution of residues (probabilistic analysis, referred to as "Monte Carlo") to obtain a distribution of exposure in milligrams per kilogram of bodyweight per day. For chronic dietary risk assessments, the three-day average of consumption for each subpopulation is combined with residues in commodities to determine average exposure in milligrams per kilogram of body weight per day. For deterministic (Tier 1) analyses, the Agency regulates at the 95^{th} percentile of exposure; for probabilistic analyses, the Agency regulates at the 99.9^{th} percentile of exposure.

The NOAEL and uncertainty factors (UF) are used to establish the "allowable" exposures to a pesticide, which is referred to as the reference dose (RfD). When the FQPA safety factor is also applied, the RfD is divided by the FQPA safety factor, which results in a potentially different figure, the Population Adjusted Dose (PAD). This dose is intended to protect the most sensitive population, and it is for this subpopulation that the Agency considers when making regulatory decisions. Therefore, when the FQPA safety factor is retained, as in the case of pebulate, the PAD is the value used for regulatory decisions rather than the RfD. The dose and endpoints selected for various exposure scenarios are shown in Table 2. The Agency is not concerned when a risk estimate is less than 100% of the acute Population Adjusted Dose (aPAD, which is the dose that an individual could be exposed to on any given day and no adverse health effects would be expected (RfD) divided by the FQPA safety factor).

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods. A risk estimate that is less than 100% of the chronic PAD (cPAD, which is the dose an individual could be exposed to over a lifetime and not expect an adverse health effect, divided by the FQPA safety factor) does not exceed the Agency's risk concern.

Acute and chronic dietary exposure to pebulate result in risk estimates that are significantly below the Agency's level of concern (the aPAD and cPAD, respectively) at all tiers of analysis (i.e., using existing tolerances, reassessed tolerances, and incorporating residue refinements). Residue refinements included anticipated residues from field trials, adjustments for percent crop treated, and a probabilistic/Monte Carlo acute analysis. No monitoring data have been generated for pebulate by the USDA Pesticide Data Program or the U.S. Food and Drug

Administration (FDA). Even though dietary risk was below the Agency's level of concern based on existing tolerances, the maximum level of refinement was used in the event that a cumulative risk assessment is required for pebulate and other chemicals having a common mechanism of toxicity. Applying all of these refinements, acute and chronic dietary risk estimates are calculated as <1% of the acute and chronic population adjusted doses (aPAD and cPAD, respectively) for adults, infants, and children (Table 4) (*10*).

Table 4. Acute and Chronic Dietary Exposure and Risk Estimates for Pebulate.

Population Subgroup	Acute Exposure/Risk Using Anticipated Residues/Monte Carlo		Chronic Exposure/Risk Using Anticipated Residues	
	Exposure (mg/kg/day) 99.9th %-ile	%aPAD	Exposure (mg/kg/day)	%cPAD
General US Population	0.000134	0.03	0.000003	0
Females 13-50	0.000099	0.20	0.000002	0.3
All Infants <1yr	0.000107	0.21	0.000001	0.2
Children (1-6 years)	0.000197	0.39	0.000005	0.7
Children (7-12 years)	0.000200	0.40	0.000004	0.6

The aPAD is 0.5 mg/kg/day for adults, and 0.05 mg/kg/day for infants, children and females 13-50. The chronic population adjusted dose (cPAD) is 0.007 mg/kg/day for adults and 0.0007 mg/kg/day for infants, children, and females 13-50.

c. Water Exposure

The water assessment included residues of parent pebulate and its major soil/water degradate, pebulate sulfoxide. Pebulate sulfoxide is not regulated in plant or livestock commodities because it is not a significant residue in these matrices. However, because pebulate sulfoxide is a major soil/water degradate, the Agency decided that modeling was required for both pebulate and this metabolite. Although there are currently no toxicity data involving testing of pebulate sulfoxide, analogous metabolites are considered to be of toxicological concern for other thiocarbamates. In addition, there is no basis to determine that pebulate sulfoxide would not have similar toxicity to pebulate.

Based on aerobic soil metabolism data and modeling, pebulate initially comprises the majority of the total pebulate and pebulate sulfoxide residues in water, as expected, but the relative concentration of the sulfoxide appears to increase with time. Because drinking water monitoring data were not available for pebulate, the surface and ground water assessments were

based on modeling predictions and, qualitatively, on available water monitoring data. Uncertainty in modeling predictions of ground and surface water residues is due primarily to a lack of environmental fate data for the degradate and the inability to accurately estimate the influence of volatilization of the parent on dissipation. Because conservative input parameters for pebulate sulfoxide were used, modeling of ground and surface water residues is considered to be conservative. For a full discussion of the uncertainties associated with the environmental fate modeling used for this assessment, refer to *reference 8*.

The modeling procedures were conducted for the tobacco use pattern because this use is expected to contribute most to pebulate loading into surface waters due to the large geographical area in which tobacco is grown. Ground water is not of concern for this use pattern, because pebulate is not expected to leach to ground water based on its chemical properties.

Surface Water

Tier II PRZM-EXAMS modeling provides upper-bound predictions of pebulate concentrations in surface water. The assessment assumes 4 lb ai/A of pebulate and 0.732 lb ai/A of pebulate sulfoxide are applied to a sandy loam soil in North Carolina, a major tobacco-growing state. Concentrations of pebulate and pebulate sulfoxide in surface water are not likely to exceed 40 ppb pebulate equivalents for peak (acute) exposure and 2.6 ppb pebulate equivalents for mean (chronic) exposure.

Ground Water

As previously state, pebulate is not expected to leach to ground water based on its chemical properties. However, because of the lack of fate data associated with pebulate sulfoxide, the SCI-GROW model was used to estimate ground water concentrations using the same application rate input data as was used for PRZM/EXAMS. Concentrations of pebulate and pebulate sulfoxide vary considerably with the assumptions made regarding the mobility of pebulate sulfoxide. If the mobility is assumed to be equivalent to that of molinate sulfoxide, then ground water modeling predicts peak and annual concentrations of 1.8 ppb. Although it is not certain as to whether pebulate sulfoxide would behave like molinate sulfoxide in the environment, the low soil:water partitioning for molinate sulfoxide used in the modeling is expected to yield conservative water concentrations. Given the uncertainty associated with using surrogate data, the Agency also considered a "worst case scenario," i.e., if pebulate sulfoxide is assumed to have negligible binding affinity for soil ($K_{oc} = 0$). In this case, the model predicts peak and annual concentrations of 44 ppb, which would exceed the Agency's level of concern. The Agency is requiring environmental fate data to permit refinement of the ground water exposure estimates.

Drinking Water Levels of Comparison

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. The Agency considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution of water allowed in the diet, the Agency first looks at how much of the overall allowable risk is contributed by food and then determines a drinking water level of comparison (DWLOC) to ascertain whether modeled values exceed this level. The Agency compared the DWLOCs and the estimated concentrations of pebulate and pebulate sulfoxide in surface water and ground water generated by modeling with PRZM/EXAMS and SCI-GROW, respectively (Tables 5 and 6).

Table 5. Summary of Acute DWLOC Calculations

Population Subgroup	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Available Water Exposure (mg/kg/day)	Ground Water (SCI-GROW (μg/L)*	Surface Water (PRZM/ EXAMS) (ppb)	Acute DWLOC (μg/L)
U.S. Population	0.5	0.000134	0.5	44/1.8	40	17500
Females 13-50 yr	0.05	0.000099	0.05	44/1.8	40	1,500
All infants	0.05	0.000126	0.05	44/1.8	40	500
Children 1-6 yr	0.05	0.000197	0.05	44/1.8	40	500
Children 7-12 yr	0.05	0.000200	0.05	44/1.8	40	500

*The figure 44 μg/L was calculated with K_{oc} = 0; the 1.8 μg/L was calculated with K_{oc} = molinate sulfoxide (i.e., assumes that the mobilities of pebulate sulfoxide and molinate sulfoxide are the same).

Table 6. Summary of Chronic DWLOC Calculations

Population Subgroup	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Available Water Exposure (mg/kg/day)	Ground Water (SCI-GROW (μg/L)*	Surface Water (PRZM/ EXAMS) (ppb)	Chronic DWLOC (μg/L)
U.S. Population	0.007	0.000003	0.007	44/1.8	2.6	245
Females 13-50 yr	0.0007	0.000002	0.0007	44/1.8	2.6	21
All infants	0.0007	0.000001	0.0007	44/1.8	2.6	7
Children 1-6 yr	0.0007	0.000005	0.0007	44/1.8	2.6	7
Children 7-12 yr	0.0007	0.000004	0.0007	44/1.8	2.6	7

*The figure 44 μg/L was calculated with K_{oc} = 0; the 1.8 μg/L was calculated with K_{oc} = molinate sulfoxide (i.e., assumes that the mobilities of pebulate sulfoxide and molinate sulfoxide are the same).

Acute DWLOCs

Acute DWLOCs greatly exceed even the most conservative estimated environmental concentrations in both surface water and ground water (Table 5). This result indicates that there is no acute dietary concern for pebulate residues in drinking water.

Chronic DWLOCs

Comparing the chronic DWLOCs with the environmental concentrations of pebulate and pebulate sulfoxide (which were estimated using conservative modeling), surface water concentrations are less than the DWLOCs (Table 6). If mobility is assumed to be equivalent to molinate sulfoxide, ground water concentrations are also estimated to be less than the chronic DWLOCs. However, if the mobility is assumed to be much greater [a soil binding affinity of zero (K_{oc} = 0)], then the estimated concentration of pebulate and pebulate sulfoxide in ground water exceeds the chronic DWLOC for infants, children, and females (13-50 years). Thus, there appears to be the slight potential for pebulate residues in ground water to occur at levels of concern, i.e., >DWLOC of 7 or 21 ppb (Table 6). Although the affinity of pebulate sulfoxide to soil could be less than that of molinate sulfoxide, it is unlikely that it will not bind to soil whatsoever. Because of the uncertainties about the environmental fate properties of pebulate sulfoxide (such as K_{oc}), the Agency is requiring data that will permit refinement of these modeling estimates.

d. Other Dietary Concerns

The current pebulate label requires an 8-day preharvest interval (PHI) for tomatoes. This interval is inconsistent with the typical agronomic practices associated with the use of this chemical (i.e., pebulate is primarily a preplant, preemergent pesticide) and the available residue data. Therefore, the Agency is requiring a PHI of 30 days. If the registrant wishes to retain the 8-day PHI, supporting residue data must be submitted.

In addition, based on confined crop rotational studies, residues of likely toxicological concern remain in raw agricultural commodities (RACs) planted up to 4 months after soil treatment and the actual rate of pebulate decline in the environment is unknown. Although residues of the parent compound are not found in significant amounts in plants, there is expected to be much greater exposure to the sulfoxide metabolite than to the parent in rotational crops. The reason is the degradates are expected to be more persistent than the parent compound due to their more polar nature and lower volatility. The degradates are therefore more likely to be the major soil, water, and plant residues (*references 9 and 10*). Therefore, the pebulate label must be amended to require that all crops, including sugar beets and tomatoes, not be rotated earlier than 4 months after treatment with pebulate. Alternatively, a shorter plantback interval may be supported by (1) providing additional data to upgrade existing confined rotational crop

studies or (2) performing limited field crop rotational studies wherein metabolites of potential toxicological concern are sought.

e. Occupational/Residential Risk

The Agency believes that people involved in the application of pebulate can be exposed while working with the pesticide. These people are referred to as handlers and represent those who plant the crop and those who prepare solutions and fertilizer mixtures for use (referred to as mixer/loaders) and those who make the applications by driving the groundboom tractor or other application equipment (referred to as applicators). According to the label, workers can re-enter a pebulate-treated field 12 hours after application. Any worker entering the field before that time must wear personal protective equipment if coming in contact with treated soil (i.e., hoeing tomatoes).

Due to the rapid volatilization of pebulate, there is concern over the use of pebulate in an enclosed area. There are currently no known uses of pebulate in greenhouses, but the label does not prohibit such a use. The pebulate label should be amended to prohibit greenhouse use.

There are no residential uses of pebulate or products available for sale to homeowners. Applications are made using ground-based agricultural equipment, and aerial application is not allowed. If pebulate is applied using common groundboom equipment, it must be incorporated into the soil during or immediately after application to prevent volatilization. It can be also be applied below the surface of the soil to prevent volatility using subsurface sweeper application (tobacco only) or using soil-injection methods. Applications of pebulate in irrigation water, referred to as chemigation, are also allowable. If pebulate is applied during irrigation, it must be watered in with approximately ½ inch of water (as specified on the label) to ensure that it penetrates the surface of the soil to depths between 2 to 4 inches. Pebulate can also be mixed and applied along with fluid fertilizer to tomatoes and tobacco or it can be impregnated on dry bulk fertilizer for application to tobacco. Soil incorporation is also required after the application of pebulate in either liquid or dry fertilizers. There are two methods for the addition of pebulate to dry bulk fertilizer: on-board and in-plant impregnation. With the on-board application (which is not widely used), pebulate is metered onto the dry fertilizer as it is being applied to the field; the equipment used is similar to a groundboom. The in-plant impregnation method is a commercial operation conducted by a dealer or distributor. The pebulate is mechanically mixed with the dry bulk fertilizer using a closed system.

A summary of the use patterns for the occupational exposure and risk assessments is shown in Table 7. All assessments used a single registered end-use product, the 6 lb ai/ gal emulsifiable concentrate (EC). Additional considerations are as follows: (1) as a preemergent herbicide, it must be soil-incorporated for efficacy; and (2) as a postemergent or after transplant application (allowed on tomatoes only), applications must be covered.

Table 7. Summary of Use Patterns

Equipment used for mixing/loading and application	Use Site	Application rate range	Frequency of application
Chemigation equipment	Tomatoes	4 - 6 lb ai/A	1 x / season
Groundboom sprayer	Tomatoes Tobacco Sugar Beets	3 - 10 lb ai/A (10 lb ai/A is tomato only)	1-2 x / season
Drop-type tractor- drawn spreader, specialized truck, soil injection equipment	Tobacco	4 lb ai/A (dry bulk fertilizer application)	1 x / season

The results of the risk assessment (*reference 5*) indicate that risks to mixers and loaders can be mitigated with the use of personal protective equipment (PPE), i.e, long sleeved shirt, long pants, coveralls, and chemical-resistant gloves. In addition, unless a closed system is being used, an organic vapor respirator (Table 8) is required for mixer/loaders. The risk assessments are identical for short-term (one week or less) and intermediate-term (one week to several months) exposure durations.

Table 8. Summary of Short-Term and Intermediate-Term Risks: MOEs for Dermal and Inhalation Scenarios

No.	Exposure Scenario	Crop Type/Use	Acres Treated or Amount Handled per Day	Application Rate		Baseline PPE* MOE		Additional PPE* MOE		Engineering Controls* MOE	
						Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
	Mixer Loader Exposures										
1	Mixing/Loading Emulsifiable Concentrate for Chemigation	Tomatoes	350 acres	6 lb ai/A		1	25	**200**	**250**	NA	NA
				4 lb ai/A		2	37	**290**	**370**	NA	NA
2	Mixing/Loading Emulsifiable Concentrate for Soil Injection and Groundboom Application	Tomatoes (Western Region)	80 acres	10 lb ai/A		3	65	**510**	**640**	NA	NA
		Sugar Beets, Tomatoes, Tobacco		6 lb ai/A		5	**110**	**860**	NA	NA	NA
				4 lb ai/A		8	**160**	**1300**	NA	NA	NA
		Tobacco		3 lb ai/A		10	**220**	**1700**	NA	NA	NA
3	In-Plant Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System)	Tobacco (assuming 40 ten ton trucks loaded per day)	3,200 lb ai/day	4 lb ai/A	1,000 lb fertilizer/A	NA	NA	NA	NA	**250**	**230**
			1,600 lb ai/day	4 lb ai/A	2,000 lb fertilizer/A	NA	NA	NA	NA	**510**	**470**
4	Mixing/Loading Fluid Formulation for Combination with Liquid Fertilizer*	Tomatoes	No Data	10 lb ai/A	10 gallons fertilizer/A	No Data	No Data	No Data	No Data	No Data	No Data
			No Data	10 lb ai/A	20 gallons fertilizer/A	No Data	No Data	No Data	No Data	No Data	No Data
			No Data	10 lb ai/A	40 gallons fertilizer/A	No Data	No Data	No Data	No Data	No Data	No Data

No.	Exposure Scenario	Crop Type/Use	Acres Treated or Amount Handled per Day	Application Rate	Baseline PPE* MOE		Additional PPE* MOE		Engineering Controls* MOE	
					Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
	Applicator Exposures									
5	Applying with a Groundboom Sprayer	Tomatoes (Western Region)	80 acres	10 lb ai/A	**630**	**110**	NA	NA	NA	NA
		Sugar Beets, Tomatoes		6 lb ai/A	**1000**	**180**	NA	NA	NA	NA
		Sugar Beets, Tomatoes, Tobacco		4 lb ai/A	**1600**	**260**	NA	NA	NA	NA
		Tobacco		3 lb ai/A	**2100**	**350**	NA	NA	NA	NA
6	Applying Dry Bulk Fertilizer with a Drop- Type, Tractor-Drawn Spreader	Tobacco	80 acres	4 lb ai/A	**2200**	**160**	NA	NA	NA	NA
7	Applying Dry Bulk Fertilizer with a Specialized Truck	Tobacco	500 acres/day	4 lb ai/A	**350**	26	NA	**260**	**NA**	NA
8	Applying Fluid Fertilizer**	Tomatoes	No Data	10 lb ai/A	No Data	No Data	No Data	No Data	No Data	No Data
9	Soil Injection**	Tobacco	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data

For occupational risk, margins of exposure (MOEs) greater than 100 are considered above the Agency's level of concern. Baseline PPE is defined by PHED as long-sleeved shirts, long pants, shoes, and socks. Additional PPE includes coveralls and chemical-resistant gloves (for dermal) and an organic vapor respirator (inhalation). Engineering Controls are closed systems.

* No data exists in PHED for mixer/loader combining pebulate with a liquid fertilizer. Therefore, no MOEs could be calculated. However, based on information provided by the registrant, the Agency made assumptions and evaluated the risks associated with these scenarios (discussed in the text, above).

** No data exists in PHED for applicators using specialized equipment for the application of a combination of pebulate and fluid fertilizer and for application by soil injection. Therefore, no MOEs could be calculated. However, based on information provided by the registrant, the Agency made assumptions and evaluated the risks associated with these scenarios (discussed in the text, above).

Risk to applicators only exceed the Agency's level of concern for the dry bulk fertilizer to tobacco scenario (No. 7, Table 8). This is due to the large area treated (500 acres/day), which is accomplished using a specialized truck. The risk assessment indicates that there is an inhalation risk which will require the applicator to use an organic vapor respirator. However, this inhalation risk can also be mitigated with the use of engineering controls, i.e., an enclosed cab with an air filtration system equal to that of an organic vapor respirator.

One mixer/loader scenario (No. 4, Table 8) and two applicator scenarios (No. 8 and No. 9, Table 8) are not represented by corresponding surrogate exposure unit values in the Agency's library of actual exposure monitoring data known as Pesticide Handlers Exposure Database (PHED) or any pebulate-specific study data. However, based on information supplied by the registrant characterizing these scenarios (MRID 44875900), the Agency has made the following determinations as to the associated risks.

As described by the registrant, the risk assessment for mixing/loading and applying pebulate with fluid fertilizer (Nos. 4 and 8, respectively, Table 8) would be equal to the scenarios for groundboom (Nos. 2 and 5, respectively, Table 8). Therefore, the same mitigation measures would apply.

For the soil injection applicator (No. 9, Table 8), the risk would be less than for that of the groundboom scenario (No. 2, Table 8). With soil injection, the chemical is sprayed directly into the soil at a depth from 4-6 inches below the soil surface, which would result in even less exposure than for that of a groundboom applicator. Therefore, the mitigation measures would be the same for soil injection and groundboom applicators.

In addition, the registrant identified a noncommercial method for impregnation of drybulk fertilizer, referred to as on-board impregnation. Only the commercial, or in-plant scenario, is shown in Table 8 (No. 3). The Agency concurs that the mixing/loader exposure scenario for on-board impregnation procedure would result in risks similar to that of the groundboom mixer/loader (No. 2, Table 8) and is therefore requiring the same risk mitigation measures. The applicator for this scenario would be equal to that of applying with a groundboom sprayer (No. 5, Table 8); therefore, and the same mitigation measures are required.

Occupational Handler Characterization

Information used in this risk assessment was obtained from the pebulate product label, PHED, and other Agency offices. Maximum application rates stated on the label were used along with more typical use rates to help characterize the range of worker exposures. The PHED values are characterized as central tendency, and do not represent the worst or best case of worker exposure. Further, the PHED unit exposure values for many of the scenarios were AB grade, i.e., the unit exposure values were generated using high quality analytical techniques. Most of the scenarios used from PHED also had many replicates, which increases the confidence

in the data and better represents the worker exposure. Although one mixer/loader and two applicator scenarios did not have corresponding exposure unit values in PHED or any study data, the Agency was able to characterize these scenarios based on additional information provided by the registrant.

Post-Application Risk

The Agency generally completes risk assessments for those individuals who can be exposed from entering previously treated areas to work (i.e., referred to as postapplication exposures). The most common examples of these kinds of exposures are farmworker activities such as picking grapes or citrus. When these kinds of assessments are completed by the Agency, the cultural practices associated with raising the crop and the reason for using the chemical are considered. Pebulate is primarily a preplant or pre-emergent herbicide that is applied only to sugar beets, tobacco, and tomatoes. The Agency does not believe that there are any postapplication exposure concerns associated with the use of pebulate on sugar beet because there are no activities that would involve exposure (such as hand transplanting). Likewise, the Agency did not complete a risk assessment on tomatoes and tobacco because there are no major activities that contribute to postapplication exposure. According to the label, workers can re-enter a pebulate treated field 12 hours after application. Any worker entering the field before that time must wear personal protective equipment if coming in contact with treated soil (i.e., hoeing tomatoes or plug planting into treated soil).

In addition, the current pebulate label addresses a potential risk to personnel who transplant seedlings of tomatoes and tobacco with the following language:

> "... mechanical transplanting only. DO NOT apply Tillam 6-E prior to hand transplanting."

However, current practices may not adequately reduce exposure to such personnel. As described by the registrant (MRID 448759), mechanical transplanting via totally automated systems would only occur in some very large operations. The usual practice is what has been referred to as "mechanically assisted" hand transplanting. For this method, an individual places a starter plant on a wheel that rotates downward, releasing the plant into a mechanically cut furrow. The furrow is then mechanically closed. This semi-mechanized scenario may involve human contact with treated soil. The Agency is therefore requiring that chemical-resistant gloves be worn by the handlers, which would include the transplanters, and is requiring additional confirmatory data to assess the actual exposure and risks involved with this method.

The Agency is aware of a growing interest in the use of pebulate as a partial alternative to methyl bromide, an ozone-depleting pesticide that is being phased out of production. The registrant, as well as USDA researchers, believe that the use of methyl bromide on tomatoes could be replaced by a pebulate and Telone combination. To use a combination that includes a

fumigant such as Telone, however, requires tomato growers to use plastic mulch. Such a cultural practice would in turn necessitate the use of hand transplanting, which is currently prohibited on the pebulate label. If the registrant agrees to conduct the post-application dermal exposure study mentioned above, the Agency would consider whether to lift or relax the current hand transplanting prohibition.

f. Residential Exposure

There are no products containing pebulate that may be used in a residential setting. Therefore, no exposure and risk assessment is necessary for residential scenarios. The Agency recognizes there are many issues related to the use of agricultural chemicals and exposures in the general population. For example, the issues of spray drift and exposures to farmworker children are often raised. However, application methods for pebulate do not include aerial or airblast; as a result, drift is expected to be minimal. The Agency is in the process of developing guidance and procedures for characterizing these kinds of exposures. They are not specifically assessed in this document. This guidance will be included in the revised Standard Operating Procedures for Residential Exposure Assessment, scheduled for publication in 1999.

5. Aggregate Risk Assessments and Risk Characterization

Aggregate risk combines exposure through food, drinking water, and residential uses of a pesticide. Generally, the combined risks from those exposures must be less than 100% of the aPAD and cPAD.

a. Acute Aggregate Risk

Acute aggregate risk estimates do not exceed the Agency's level of concern (0.05 mg/kg/day). This is based on an assessment of the most sensitive subpopulation (children 1-6 years of age). The aggregate acute dietary risk estimates include exposure to pebulate residues in food and water. The Agency used anticipated residues derived from field trial data, percent-crop-treated data, and a probabilistic assessment to refine acute dietary risk (food only). Acute dietary food risk to all population subgroups is <1% of the aPAD. Although the most conservative assumptions (tolerance level residues and 100% crop treated) resulted in risk due to food alone that was below the Agency’s level of concern, refinements were made to permit a more realistic calculation of DWLOCs and in anticipation of a cumulative risk assessment. Estimated peak concentrations of pebulate residues in both surface water and ground water were well below the calculated DWLOCs for all population subgroups. Thus, pebulate is not expected to pose an acute risk of concern to any population.

b. Chronic (Noncancer) Aggregate Risk

The Agency has determined that there is not a chronic aggregate risk of concern for pebulate when considering the cPAD (0.0007 mg/kg/day) for the most sensitive subpopulation, children (1-6 years of age). While aspects of the Agency's chronic aggregate risk assessment show a potential concern, the Agency finds that there is insufficient information at this time to conclude that such a risk is valid. The exposure contribution by the consumption of residues in food is small (i.e., <1% of the cPAD for all population subgroups using anticipated residue and percent-crop-treated data) and there is no residential exposure component. However, the modeled drinking water component of the aggregate risk calculation is equivocal.

The Agency finds a potential concern from drinking water only when considering certain extreme assumptions about the properties of pebulate degradates. When using less extreme assumptions on the environmental fate of pebulate degradates, the Agency finds that modeled water concentration levels do not result in drinking water concerns, and thus, do not result in an aggregate risk of concern. Although sufficiently representative monitoring data are not available to permit quantitative inclusion of drinking water residues in the aggregate risk, the available monitoring data also do not support the modeled estimates.

Even though the Agency believes these modeled estimates may overestimate the aggregate risk, the Agency is requiring additional confirmatory environmental fate data on the degradate, pebulate sulfoxide. These data will allow for the refinement of these assessments and serve to confirm the position that aggregate risk is not a concern.

6. Endocrine Disruptor Effects

EPA is developing a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans and wildlife that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. When this program is implemented, the Agency may require further testing of pebulate for endocrine effects. At this time, there is no evidence of endocrine disruption caused by pebulate.

7. Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, 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 Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but

also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information that may be used for determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

The Agency is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share acetylcholinesterase inhibition as a common mechanism of toxicity. In contrast to the methyl and N-methyl carbamates, the Agency has a less fully developed understanding of whether the thiocarbamates share acetylcholinesterase inhibition as a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. While current data are limited, the thiocarbamates appear to be comparatively weak cholinesterase inhibitors and are generally regulated based on other toxic endpoints. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides) [see the August 31, 1999, EPA Memorandum entitled *September 1999 Meeting of the FIFRA Science Advisory Panel: Working Documents for the Session: "Proposed Guidance for Conducing Cumulative Hazard Assessments for Pesticides that Have a Common Mechanism of Toxicity*" and "*The Carbamate Pesticides and the Grouping of Carbamate with the Organophosphorous Pesticides*"]. Also see 40 CFR section 180.3(e)(5), which presents the Agency's initial grouping of chemicals that would be considered together for the purpose of tolerance reassessment. This grouping includes some carbamate pesticides but not thiocarbamate pesticides as members of the class of acetylcholinesterase-inhibiting compounds.

In September 1999, the Agency presented a paper (cited above) on the common mechanism of toxicity of the carbamate pesticides to the SAP. In that presentation, the Agency noted that although various classes of compounds may inhibit acetylcholinesterase, the potency, reversibility, and related factors may influence whether or not related pesticides should be included in a cumulative risk assessment. The Agency is currently awaiting a report from the SAP.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether pebulate, a thiocarbamate, shares a common

mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that pebulate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

C. Environmental Assessment

In this section, the fate of pebulate in the environment and the ecological effects are described. An assessment was performed to determine the ecological risks associated with the use of pebulate. These data are reviewed by the Agency for making the decisions regarding the reregistration of pebulate.

1. Environmental Fate Assessment

Volatilization appears to be an important route of pebulate dissipation in the environment. Laboratory data show that pebulate volatilizes rapidly (40% of the total amount of pebulate that was applied volatilized from soil in 25 hours). However, pebulate and its degradates did not degrade readily in the other laboratory studies. It did not hydrolyze significantly (>90% of the parent remained after 30 days), and it photodegraded very slowly (half-lives were observed of >30 days) in water and on soil. In aerobic sandy loam soil, pebulate degraded with a half-life of 36 to 60 days; in anaerobic soil, the half-life was >60 days. In an anaerobic aquatic metabolism study, no significant degradation occurred (although volatilization was observed). Pebulate has high to medium mobility in soil (Freundlich K_ds 1.24, 3.25, 4.46, and 7.44 mL/g and with corresponding K_{oc}s = 422, 291, 446, and 576 mL/g) and can run off to surface water. Other data suggest that pebulate is not persistent under field conditions (with half-lives of 4 to 20 days). Significant volatilization of pebulate may occur under field conditions, even with soil incorporation.

A major uncertainty in the environmental fate of pebulate is associated with pebulate sulfoxide, a significant degradation product. A half-life of 103 days for pebulate sulfoxide was calculated from the residue data in the aerobic soil metabolism study submitted for pebulate parent. The organic partitioning coefficient (K_{oc}) for pebulate sulfoxide was estimated as 93 mL/g. This value was calculated using batch equilibrium data on molinate sulfoxide, a chemical analog of pebulate sulfoxide. As with molinate sulfoxide, pebulate sulfoxide is considered very mobile in soil and has the potential to leach in the soil profile and to move with water in surface runoff. Environmental fate data are needed for pebulate sulfoxide to clarify the fate of pebulate residues in the environment.

The moderate value of the calculated Henry's Constant (2.41×10^{-5} atm-m^3/mol) for pebulate, combined with the compound's volatility, suggest that if pebulate reaches the atmosphere, it could be transported in fog, mist, rainwater, and on air currents.

2. Water Resources Assessment

Pebulate is not included among regulated or unregulated chemicals required as analytes in testing of public drinking water supplies. Therefore, drinking water monitoring results are not readily available. Simulation modeling of pebulate along with monitoring data (*reference 8)* indicates the following:

(1) The maximum total pebulate residues (pebulate and pebulate sulfoxide) concentrations in surface water are 40 μg/L for acute exposure and 2.6 μg/L for chronic exposure. These values are based on the PRZM-EXAMS models.

(2) U.S. Geological Survey (USGS) monitoring data report a maximum pebulate concentration of 0.8 μg/L in surface water. However, these data were not targeted to a pebulate use event (that is, water monitoring did not occur in conjunction with a pebulate application in a particular area). This is significantly less than model predicted residues, although it is possible that targeted monitoring for pebulate could result in higher residues.

(3) SCI-GROW modeling indicates that total pebulate residue concentrations in ground water are not likely to exceed 1.8 μg/L for both peak (acute) and annual average (chronic) concentration. The most conservative modeling scenario [where the pebulate sulfoxide organic partitioning coefficient is equal to zero ($K_{oc} = 0$)] predicts total residues of 44 μg of pebulate equivalents per liter.

(4) Nontargeted USGS groundwater monitoring data report maximum pebulate concentrations of 0.005 μg/L, although it is possible that targeted monitoring could show higher residues.

3. Hazard Profile

Birds: Acute and Subacute Dietary Toxicity

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) was required to establish the toxicity of pebulate to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Two subacute dietary studies are required to establish the toxicity of a pesticide to birds; the preferred test species are mallard duck and bobwhite quail. For acute oral and subacute dietary toxicity, pebulate is classified as practically nontoxic to avian species (Table 9).

Table 9. Avian Acute Oral and Subacute Dietary Toxicity

Acute Oral Toxicity (Guideline 71-1)						
Species	**% ai**	**LD_{50} (mg/kg)**	**NOAEL**	**Toxicity Category**	**MRID**	**Guideline Status**
Mallard duck	96%	>2000 mg/kg	N.R.	Practically nontoxic	41920702	Fulfilled
Subacute Dietary Toxicity (Guideline 71-2)						
Species	**% ai**	**LC_{50}**	**NOAEL**	**Toxicity Category**	**MRID**	**Guideline Status**
Bobwhite quail	95%	>5200 ppm	N.R.	Practically nontoxic	41614803 42294201	Fulfilled
Mallard duck	96%	>5606 ppm	650 ppm	Practically nontoxic	41614804 42294201	Fulfilled

N. R., Not reported

Birds: Chronic Effects

Avian reproduction studies are usually required for pesticides when the following conditions are met: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, and (2) information derived from mammalian reproduction studies indicates reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the product. Due to the use pattern associated with pebulate (a single application with immediate soil incorporation), repeated exposure to residues is not expected and chronic toxicity data for avian species is waived.

Mammals: Acute and Chronic Toxicity

The Agency requires wild mammal acute toxicity testing on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern, and pertinent environmental fate characteristics. For pebulate, as in most cases, rat or mouse acute toxicity values (Table 2) are substituted for wild mammal testing. Based on laboratory rat acute toxicity data, pebulate is slightly toxic to mammals (Table 10). Chronic exposure is not expected to occur based on the use pattern and chemical characteristics of pebulate (*reference 8*).

Table 10. Mammalian Acute Oral Toxicity

Species	LD_{50} mg/kg	NOAEL	Toxicity Category
Rat (male)	1,750 mg/kg	N.R.	3
Rat (female)	1,550 mg/kg	N.R.	3

N.R., Not reported

Terrestrial Insects

Honey bee acute contact and dietary exposure studies are not required because bee exposure on blooming plants is unlikely because of the predominant use pattern for pebulate (preplant application). A layby application, which is an application of pesticide concurrent with mechanical weeding, occurs after planting. It is intended to be applied to clean, cultivated soils and is also immediately soil-incorporated. A honey bee foliar residue contact toxicity study is therefore waived because there is no significant potential for honey bee exposure to vegetative surfaces after application.

Terrestrial Wildlife or Insect Incidents

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide product registrants to submit adverse effects information about their products to the Agency. At the time of publication of this RED, the Agency has not received any reports of adverse effects to nontarget terrestrial wildlife or insects from the use of pebulate.

Fish: **Acute Toxicity**

Two acute toxicity studies are required to establish the toxicity of a pesticide to freshwater fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Acute toxicity testing with estuarine/marine fish species is desirable when the end-use product active ingredient is expected to reach an estuarine environment.

Based on the data reviewed for pebulate, the pesticide is classified as slightly toxic to the freshwater and marine/estuarine fish species tested species (Table 11). Use on tobacco crops is expected to occur adjacent to estuarine areas, and therefore acute testing of an estuarine species is needed to provide a complete risk assessment for this crop use. The studies reviewed to date are not acceptable due to the use of shorter than the recommended exposure times (Table 12). However, because no significant level of toxicity has been observed in other studies, at this time the Agency is reserving the requirement for this test.

Table 11. Freshwater Fish Acute Toxicity of Pebulate (Guideline 72-1)

Species Tested	%ai	LC_{50} and CLs* (ppb)	MRID	Guideline Status
Bluegill sunfish	95.9	6,300 (5,200 - 8,300)	41614805	Fulfilled
Bluegill sunfish	77.3	7,900 (6,000 -10,400)	4761615	Fulfilled
Rainbow trout	95.9	7,400 (6,000 - 9,300)	41614806	Fulfilled
Mosquitofish	77.5	10,000 (N.R.)	00084743	Fulfilled

*All studies were 96-hours of exposure; Cls, 95% confidence limits

Table 12. Marine/Estuarine Fish Acute Toxicity of Pebulate (Guideline 72-3)

Species Tested	%ai	LC_{50} (CLs) in PPB	MRID	Guideline status
Longnose killifish	78	48 hr = 7,400 (N.R.)	40228401	Not fulfilled
Striped mullet	78	48 hr = 6,300 (N.R.)	40228401	Not fulfilled

Fish: Chronic Toxicity

A freshwater fish early life-stage test, estuarine fish early life stage test or full life-cycle test is required for pesticides when end-use products are expected to produce residues that may be transported to water from the various intended use sites. Chronic testing guideline conditions may be required if (1) the presence of the chemical in water is likely to be recurrent, (2) aquatic acute median lethal dose is <1 mg/L, (3) the estimated environmental concentration (EEC) in water is 1/100th of any acute median lethal dose, or (4) studies of other organisms indicate the reproductive physiology of fish may be affected. Because low acute toxicity is displayed in freshwater fish exposed to pebulate, and the chronic toxicity values are not expected to be as low as predicted EEC levels, the chronic testing guidelines for pebulate are waived.

Aquatic Invertebrates: **Acute Toxicity**

Pebulate is classified as only slightly to moderately toxic to freshwater aquatic invertebrates on an acute basis (Table 13a). An acute toxicity test with estuarine/marine molluscs is required because the end-use pebulate product is expected to reach this environment due to its use on tobacco. The shrimp study reviewed to date was not conducted for 96 hours and does not fulfill the guideline requirements (Table 13b). However, because no significant level of toxicity has been observed in other studies, at this time the Agency is reserving the requirement for this test in shrimp.

Table 13a. Freshwater Invertebrate Acute Toxicity (Guideline 72-2)

Species Tested	%ai	48 hr EC_{50} or 96 hr LC_{50} (ppb)	MRID	Guideline Status
Water flea, *Daphnia magna*	96%	48 hr = 6,630 (5,400-8,600)	41614807	Fulfilled
Scud, *Gammarus fasciatus*	96%	96 hr = 10,000 (7,000-13,400)	40098001	Fulfilled

Table 13b. Marine/Estuarine Invertebrate Acute Toxicity of Pebulate (Guideline 72-3)

Species Tested	%ai	LC_{50} (CLs)	MRID	Guideline Status
White shrimp, *Penaeus setiferous*	68%	48 hr = 10,000 ppb (N.R.)	40228401	Supplemental

N.R., Not reported

Freshwater and Marine Invertebrates: Chronic Toxicity

Pebulate displays low acute toxicity to freshwater invertebrates. Predicted EEC levels are at least 50 times below acute toxicity levels; therefore, the chronic testing guidelines for pebulate are not required.

Freshwater, Estuarine and Marine Aquatic Incidents

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide product registrants to submit adverse effects information about their products to the Agency. At the time of publication of this RED, no aquatic organism kills that directly implicate pebulate usage have been submitted.

Toxicity to Plants

Terrestrial plant testing (seedling emergence and vegetative vigor) is required if an herbicide meets the following criteria: (1) it has a terrestrial nonresidential outdoor use pattern and may move off the application site through volatilization (vapor pressure is $>1.0 \times 10^{-5}$ mm Hg at 25ºC) or drift (aerial or irrigation); or (2) there may be endangered or threatened plant species associated with the application site. Therefore, these tests were called in for pebulate.

For seedling emergence and vegetative vigor testing, the response of various plant species relative to a control, are measured at various levels relative to the use rate of the chemical. Some of these data are shown in Table 14; the entire list of species tested can be found in reference *8*. The results showed that pebulate runoff and drift to adjacent habitats may prove hazardous to certain families of nontarget terrestrial and semiaquatic plants (mainly grass related species). No risk to aquatic plants is predicted based on estimated aquatic residue levels (Tables 15).

Table 14. Terrestrial Plant Toxicity (Guideline 122-1: Fulfilled)*

Species Tested	Seed Emergence (MRID 42285301)		Vegetative Vigor (MRID 44735901)		Most sensitive affected parameter
	EC_{25}	NOAEL	EC_{25}	NOAEL	
Tomato	N/A	N/A	>3.6 lb ai/A	1.5 lb ai/A	Vegetative vigor; phytotoxicity
Cabbage	N/A	N/A	> 4.3 lb ai/A	1.5 lb ai/A	Vegetative vigor; phytotoxicity
Onion	N/A	N/A	> 6.0 lb ai/A	6.0 lb ai/A	Vegetative vigor; no affects
Soybean	5.78 lb ai/A	3.0 lb ai/A	2.4 lb ai/A	1.5 lb ai/A	Vegetative vigor; phytotoxicity
Ryegrass	N/A	N/A	0.65 lb ai/A	0.38 lb ai/A	Vegetative vigor; dryweight
Purple nutsedge	0.52 lb ai/A	N/A	N/A	N/A	Seed emergence; dryweight

*The entire list of species tested can be found in reference *8*.

Table 15. Aquatic Plant Toxicity (Guideline 123-2: Fulfilled)

Species Tested	% ai	EC_{50} (CLs)	MRID	Guideline Status
Anabaena flos aquae	95.5%	8,200 ppb (7,200 - 9,300 ppb)	42265105	Fulfilled
Skeletonema costatum	95.5%	260 ppb (240 - 280 ppb)	42265102	Fulfilled
Navicula pelliculosa	95.5%	2,850 ppb (2,100 - 4,000 ppb)	42265101	Fulfilled
Selenastrum capricornutum	95.5%	230 ppb (150 - 350 ppb)	42265103	Fulfilled
Lemna gibba	95.5	1,800 ppb (1,500 - 2,200 ppb)	42265102	Fulfilled

CL= 95% Confidence limits

4. Risk Assessment

Risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the risk quotient (RQ) method. Risk quotients are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

Risk quotients are then compared to the Agency's levels of concern (LOCs). These LOCs are used to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria are used to indicate when a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) acute high - potential for acute risk is high and regulatory action may be warranted in addition to restricted use classification; (2) acute restricted use - the potential for acute risk is high, but may be mitigated through restricted use classification; (3) acute endangered species - endangered species may be adversely affected; and (4) chronic risk - the potential for chronic risk is high regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

Exposure and Risk to Nontarget Terrestrial Wildlife

The acute risk quotients (RQs) for broadcast applications of nongranular products are tabulated below. They are based on estimated environmental residue levels calculated in the terrestrial exposure portion of this document divided by the median lethal concentration or chronic no observable adverse effects concentration (NOAEC) of the most sensitive species tested. The exposure estimates used for the terrestrial risk assessment are based on Hoerger and Kenega (1972) as modified by Fletcher *et al*. (1972) (*reference 8*).

Birds

Pebulate is not expected to exceed half of the median lethal concentration for bobwhite quail or mallard duck at the maximum permitted application rate of 10 lbs ai/acre, and therefore hazard from a single application of pebulate is unlikely (Table 16). Due to the use practice of immediate soil incorporation of pebulate, there is no continuous exposure to birds; therefore there is no expected chronic risk to birds. The study results show that the residues of pebulate on the bare ground and in incorporated soil residues are much below the dietary levels of concern (RQ <0.1). The RQs for insects and seeds would apply to liquid applications before incorporation only and therefore exposure is brief or unlikely.

Table 16. Avian Acute Dietary Maximum Risk Quotient Ranges on Day of Application

Crop	Maximum Application Rate of Pebulate	EEC of Pebulate in Soil* (ppm)	Maximum EEC Range of Pebulate on Insects (ppm)	Maximum EEC Range of Pebulate on Seeds (ppm)	Soil RQ	Insects RQ	Seeds RQ
Tomato	10 lb ai/A	220-3.6	1,350	70	< 0.08	<0.5	<0.012
Tomato	6.0 lb ai/A	132-2.2	810	42	< 0.05	<0.3	<0.007
Sugar beets	6.0 lb ai/A	132-2.2	810	42	< 0.05	<0.3	<0.007
Tobacco	4.0 lb ai/A	88-1.4	540	28	< 0.03	<0.2	<0.004

LC_{50} of > 5,200 ppm for bobwhite quail used in calculation of risk quotient
*Soil Surfaces = 22 ppm for each 1.0 pound of active ingredient applied; 6" incorporation = 0.36 ppm every pound of active ingredient applied (*reference 8*).

Mammals

Risk quotients are usually calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). Because pebulate is soil incorporated, exposure to residues are expected only from insects and seeds (Tables 17a and 17b); foliar residues are not expected. Large mammals (1000 g) are less likely to feed on insects, seeds, or soil invertebrates; therefore they were not included in this analysis.

Table 17a. Risk Quotients for Dietary Consumption of Insects by Small Mammals

Crop	Rate (lbs ai/A)	Single Application EEC for Insects (ppm)	Acute RQ for a 15g Mammal	Acute RQ for a 35 g Mammal
Tomato	10	1,350	0.8	0.5
Sugar Beet	6.0	810	0.5	0.3
Tobacco	4.0	540	0.3	0.2

Table 17b. Risk Quotients for Dietary Consumption of Seeds by Small Mammals

Crop	Rate (lbs ai/A)	Single Application EEC for Seeds (ppm)	Acute RQ for a 15 g Mammal	Acute RQ for a 35 g Mammal
Tomato	10	70	0.02	0.014
Sugar Beet	6.0	42	0.03	0.018
Tobacco	4.0	24	0.014	0.01

Risk quotients were calculated using the following parameters: LD_{50} = 1,550 mg/kg for female rat; 15 g mammal consumes 95% of food matter as small insects or fruit per day; 35 g mammal consumes 66% of food matter as small insects or fruit per day; all applications were EC formulations applied by ground equipment.

Exposure and Risk To Aquatic Organisms

Pebulate estimated concentrations in surface water do not exceed concern levels for acute effects to fish or invertebrates (*reference 8*). No conclusions regarding potential chronic risk are possible due to lack of chronic data. Modeling indicates that pebulate will not degrade rapidly in aquatic habitats and prolonged exposure is possible. The Agency is requiring estuarine invertebrate testing for molluscs, because the use of pebulate on tobacco could result in estuarine exposure. The studies for fish and shrimp or mysid are reserved at this time.

Exposure and Risk to Nontarget Plants

Calculated runoff and drift from a 10 lb ai/A application to tomatoes suggest that levels of concern for growth and toxicity are exceeded for nontarget terrestrial and semiaquatic plants from runoff (Tables 18a and 18b). Risk to aquatic plants (nonendangered and endangered) is possible for runoff and/or drift at maximum application rates (Table 19).

Table 18a. Terrestrial Plant Risk Quotient Table (Seed Emergence)

Most Sensitive Species	EC_{25}	Amount of Pebulate	EEC with 2" soil incorporation	EEC for a Semiaquatic 10 Acre Watershed to 1 Acre Shoreline	Terrestrial Plant RQ	Semi-Aquatic Plant RQ	Endangered plants
Purple nutsedge	0.52 lb ai/A	10 lbs ai/A	0.04 lb ai/A	0.4 lb ai/A	0.08	0.8	0.11
Velvet leaf	3.05 lb ai/A	10 lbs ai/A	0.04 lb ai/A	0.4 lb ai/A	0.01	0.13	N/A

Table 18b. Terrestrial Plant Risk Quotient Table (Vegetative Vigor)

Most Sensitive Species	EC_{25}	Amount of Pebulate	EEC with 5% drift EEC	EEC for a Semiaquatic 10 Acre Watershed to 1 Acre Shoreline	Terrestrial Plant RQ	Semi-Aquatic Plant RQ	Endangered plants
Ryegrass	0.65 lb ai/A	10 lb ai/A	0.5 lb ai/A	N/A	0.76	N/A	1.3

Seed Emergence EC_{25}, ground incorporated uses; Vegetative Vigor EC_{25}, solid set sprinkler system with 5% drift.

Table 19. Aquatic Plant Risk Quotient*

Species	EC_{50}	Rate	EEC	RQ Pond	RQ Drift 5% to Surface	Endangered Species RQ
Selenastrum capricornutum	260 ppb	10 lb ai/A	141 ppb (GENEEC)	0.54	1.41	1.85
		6.0 lb ai/A	85 ppb (GENEEC)	0.33	0.84	1.12
		4.0	35 ppb (PRZM/EXAMS)	0.13	0.56	0.46

* Based on NOAEC for *Lemna gibba* of 76 ppb. There are no endangered algal plants, only macrophytes.

Endangered Species

Endangered species LOCs are exceeded for pebulate for acute hazard to endangered plants (grasses and sedges) for several uses. Use on tomatoes, sugar beets and tobacco are expected to be located in counties where endangered plants are known to exist. Nearly 100 endangered or threatened species are in counties with tomato crops, 35 listed species are in counties with tobacco production, and 55 species are in counties with sugar beet production. Sensitivity of these species may be variable, as was observed in terrestrial plant test results. Locations of listed habitats for these species may also be localized within individual counties.

The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of pebulate may be required to protect endangered and threatened plant species, but these limitations have not yet been defined. The Agency anticipates that a consultation with the U.S. Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

5. Risk Characterization

Based on low acute toxicity to birds and mammals, probable low exposure potential due to soil incorporation, and high volatility, pebulate is not likely to pose an acute risk to birds or most mammals. Some acute and chronic risk to strictly insectivorous mammals may exist before incorporation, although exposure may be mitigated by volatility and incorporation of pebulate into soils. No chronic data are available to characterize long-term effects to birds from pebulate.

Pebulate does not appear to pose a significant risk to aquatic organisms. Risk quotients for freshwater fish, invertebrates, and aquatic plants were below the Agency's levels of concern for acute effects. Chronic toxicity endpoints are not expected to be substantially lower than predicted EEC levels, although no direct conclusions are possible due to the lack of actual chronic toxicity data. Chronic aquatic data may be requested if pebulate uses are increased. Although pebulate use on tobacco could result in estuarine exposure, the potential risk to estuarine species is difficult to predict because there are no acceptable estuarine toxicity data.

Little hazard to nontarget terrestrial plants is expected from incorporated applications of pebulate. However, risk quotients based on default spray drift assumptions from irrigation systems and possible runoff exposure suggest potential adverse effects on growth in nontarget terrestrial plants exposed to pebulate. There is uncertainty for this conclusion because (1) there are no data from which to directly estimate drift exposure and (2) pebulate is volatile, which is likely to reduce exposure. There is also some uncertainty associated with the potential for exposure from volatilized residues depositing on nontarget plants.

The risk to honeybees or other nontarget beneficial insects from direct pebulate contact or contact with foliar pebulate residues cannot be assessed due to lack of insect toxicity data. However, risk to honeybees or other beneficial insects is expected to be minimal because pebulate is soil-incorporated.

6. Data Requirements

Environmental Fate

Because of the lack of key data, a complete quantitative environmental fate assessment cannot be completed at this time. However, volatilization may be the principal route of dissipation in the environment. Field data measuring volatility is required to substantiate this qualitative assessment and to quantify the extent to which volatilization occurs under actual use conditions. The Agency is requiring two new field dissipation studies be conducted in tobacco (Southeast) and tomato (California) crops to account for agricultural and geographical variability.

Although pebulate volatilizes substantially, the absorption spectrum of pebulate and lack of photodegradation on soil and in water indicate that pebulate probably will not undergo degradation in air. Furthermore, because there is insufficient guidance available for the data requirement and the study is difficult to carry out, a photodegradation in air study is not required at the present time. However, once the methodologies for photodegradation of pesticides in air are resolved, the need for such a study will be reassessed.

At this time, the only environmental fate parameter for pebulate sulfoxide is an aerobic soil metabolism half-life ($t_{1/2}$= 103 days, estimated from the degradate's decline in the aerobic soil metabolism study). Environmental fate data are needed for pebulate sulfoxide to perform a quantitative assessment of the environmental fate of pebulate residues.

Ecological Effect Data Requirements

The Agency is requiring a study for acute toxicity of pebulate to estuarine molluscs. It is reserving the studies on estuarine fish and shrimp at this time.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission

of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing pebulate 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 pebulate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of pebulate.

These data were sufficient to allow the Agency to determine that pebulate can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing pebulate as the active ingredient are eligible for reregistration. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency made its reregistration eligibility determination based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that all uses of pebulate are eligible for reregistration; however, the Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the reregistration of pebulate. The Agency may also require the submission of additional data (1) to support the registration of products containing pebulate, (2) if the data requirements for registration change, or (3) the guidelines for generating such data change.

B. Determination of Eligibility Decision

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

C. Regulatory Position

To lessen the risks posed by pebulate, the Agency is requiring the following mitigation measures for products containing pebulate. The specific language for the label is specified in Section V.

<u>To reduce the amount of residue in food crops.</u>

- Require a PHI of 30 days for tomatoes
- Establish a 4 month plantback interval (PBI) for all food crops

To protect workers

- Require the use of PPE (including coveralls, chemical-resistant gloves, and organic vapor respirators) for all chemigation mixers/loaders
- Require the use of PPE (including coveralls, chemical-resistant gloves, and organic vapor respirators) for all mixer/loaders when preparing solutions for an application in the western states at the highest use rate (>6 lb ai/Acre)
- Require the use of PPE (including chemical-resistant gloves and coveralls) for all mixer/loaders when preparing solutions for an application in all states other than the western states (i.e., at rates of ≤6 lb ai/Acre)
- Require closed mixing/loading systems for commercial operations that impregnate dry bulk fertilizer with pebulate
- Require closed mixing/loading systems for commercial operations that combine pebulate (fluid formulation) with liquid fertilizer.
- Require the use of organic vapor respirators or an enclosed cab with a filtration system equal to that of an organic vapor respirator for commercial applicators when applying dry bulk fertilizer impregnated with pebulate to tobacco
- Prohibit greenhouse uses
- Require the use of chemical-resistant gloves for workers involved with mechanical transplanting or mechanically assisted transplanting of tomatoes and tobacco and require the submission of data on these exposure scenarios. As specified on the current label, hand transplanting is not permitted.

To protect nontarget plant species

- Require labeling to implement best management practices to protect nontarget terrestrial and semiaquatic plants (mainly grass related species) from runoff and drift.

D. Food Quality Protection Act Findings

1. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for pebulate, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices and scenarios, and the environmental behavior of pebulate.

There are no pebulate products registered for home use; therefore there is no residential exposure factored into the aggregate risk assessment. The Agency has concluded that for the acute and chronic dietary risk assessments, risks to all population subgroups were <1% of the aPAD and cPAD, respectively, and therefore are not at levels of concern to the Agency.

For the water assessment, using surrogate data, the acute and chronic drinking water levels of concern are not exceeded. However, taking another approach and using a worst case assumption (where the binding affinity to soil is assumed to be 0), the Agency finds a concern for chronic dietary exposure to residue-containing groundwater. However, residues at the modeled level are not supported by available monitoring data (NAWQA database: 4 detections in 3023 samples; STORET database: 0 detections in 3197 samples). Although these monitoring data are not ideal for assessing pebulate (i.e., they were not targeted for pebulate), they do provide some real world data on the amount of pebulate in the environment. For these reasons, the worst case data are considered too conservative and probably not realistic. The Agency is therefore not taking action to restrict pebulate at this time but is requiring environmental fate data to verify these conclusions. Using the surrogate data for the water assessment, the Agency has no concern for aggregate acute or chronic dietary risks.

The Agency is concerned with not only the effects of the parent compound, but also the chemical degradates (such as pebulate sulfoxide). There are currently no environmental fate data available for pebulate sulfoxide, so surrogate data on molinate sulfoxide was used. Molinate sulfoxide is a degradate of molinate, which is also a thiocarbamate and a chemical analog of pebulate. Pebulate degradates are assumed to have the same toxicity as the parent and are expected to be more persistent than the parent compound in the environment due to their more polar nature and lower volatility. They are therefore more likely to be the major soil, water, and plant residues. The Agency has concerns regarding the environmental fate of these compounds and their impact on rotational crops and therefore is requiring a 4-month plantback interval for all food crops, including tomatoes or sugar beets. A shorter rotational interval can be established if data are submitted that demonstrate a shorter plantback interval is sufficient.

Pebulate is a thiocarbamate, which is a class of chemicals known to have neurotoxic effects. Pebulate has been shown to cause brain weight decrements in a subchronic neurotoxicity study in rats. Neurohistopathologic findings (such as degeneration in the sciatic nerve fibers) have also been observed in rat and dog studies. The Agency is requiring a developmental neurotoxicity study as a condition of reregistration.

2. Determination of Safety for Infants and Children

The Agency has determined that the established tolerances for pebulate, 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, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors 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 pebulate residues in this population subgroup.

All doses for risk assessment purposes were assessed using the conventional safety factors of 10x for interspecies extrapolation and 10x for intraspecies variability. In addition, the FQPA safety factor of 10x was retained for pebulate because of (1) the severe neuropathology exhibited in studies with adult animals, (2) the structural similarities to other thiocarbamates for which increased susceptibility of developing fetuses has been demonstrated, and (3) the outstanding requirement for a developmental neurotoxicity study. In the current analysis, the 10x FQPA safety factor was applied to the various populations of infants and children as well as to females (13-50 years, i.e., females of childbearing age), because the Agency is concerned about potential developmental (*in utero* exposure) effects of pebulate. The 10x FQPA safety factor is not applied to males or to the general population. As discussed above, acute and chronic dietary risk estimates for pebulate were calculated to be <1% of the acute and chronic population adjusted doses (aPAD and cPAD, respectively) for adults, infants, and children (*reference 6*).

3. Endocrine Disruptor Effects

The FQPA requires the Agency to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disruptor Screening Program was published in the Federal Register of December 28, 1998 (63 RE 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of pebulate and end-use products for endocrine effects may be required.

E. Tolerance Reassessment

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, 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 Agency is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share acetylcholinesterase inhibition as a common mechanism of toxicity. Although current data are limited, the thiocarbamates appear to be comparatively weak cholinesterase inhibitors and are generally regulated based on other toxic endpoints. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides). This issue is currently under review by the SAP, as discussed previously (Chapter III, Cumulative Effects).

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether pebulate, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that pebulate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

Tolerances are established for residues of pebulate in tomatoes and sugar beet roots and tops at 0.1 ppm (40 CFR 180.238). Based on field trial data, the Agency recommends reassessment of all tolerances to the limit of quantitation of the analytical method, 0.05 ppm, because all residues were consistently less than the limit of quantitation (Table 20).

Table 20. Tolerance Reassessment Summary for Pebulate.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Reason	Comment
Sugar beets (roots and tops)	0.1	0.05	Reduce tolerance to the limit of quantitation (LOQ), because detected residues were consistently less than the LOQ	Separate tolerance should be listed as follows: *Beet, sugar, root* *Beet, sugar, tops (leaves)*
Tomatoes	0.1	0.05	Reduce tolerance to the LOQ, because detected residues were consistently less than the LOQ	*Tomato*

1. Codex Harmonization

No maximum residue limits for pebulate have been established by CODEX for any agricultural commodities. Therefore there are no issues regarding compatibility with respect to U.S. tolerances.

F. Human Health Risk Mitigation

Dietary

The current pebulate label requires an 8-day preharvest interval (PHI) for tomatoes. This interval is inconsistent with typical agronomic practice (i.e., pebulate is a preemergent pesticide) and the available residue data. Therefore, the Agency is requiring a PHI of 30 days. If the registrant wishes to retain the 8-day PHI, supporting residue data must be submitted.

The Agency is also requiring a 4 month plantback (crop rotation) interval for all crops, including sugar beets and tomatoes. The reason is that based on confined crop rotational studies, residues of likely toxicological concern (such as pebulate sulfoxide) are likely to be found in raw agricultural commodities (RACs) planted up to 4 months after soil treatment for the primary crop. The actual rate of pebulate decline and that of its degradates in the environment is unknown. However, there is expected to be much greater exposure to the degradates in rotational crops because the degradates are more persistent than the parent compound due to their more polar nature and lower volatility. To support a PBI shorter than 4 months, the existing confined crop studies must be upgraded or limited field rotational crop studies (to include seeking metabolites of potential toxicological concern as well as the parent compound) must be conducted.

Occupational

The Agency believes there is risk to workers from exposure to pebulate. To ensure worker safety, the Agency is requiring mitigation measures in the form of PPE and engineering controls. The Agency is also requiring confirmatory data in some instances; these data will be used to reevaluate the risks, which could result in revision of the mitigation measures. For most applicators and handlers, the PPE that is specified on the current label (long sleeve shirt, long pants, closed shoes, protective eyewear, and chemical resistant gloves) is unchanged. Most mixers/loaders are also required to use a double layer of clothes (coveralls); organic vapor respirators are additionally required for people who prepare emulsifiable concentrate solutions for chemigation. The PPE on the current label and organic vapor respirators are also required for mixers and loaders who are preparing solutions for soil injection and groundboom applications at the concentrations in the western states, because of the amount of exposure at the highest use rate ($\geq$6 lbs ai/acre). The use of respirators in these instances result in acceptable MOEs for these handlers. Commercial applicators who prepare large quantities of dry bulk fertilizer impregnated with pebulate must use a closed mixing and loading system. In addition, applying dry bulk fertilizer requires the use of an enclosed cab truck with a air filtration system equal to that of an organic vapor respirator. With the use of engineering controls, PPE can be reduced [according to the Worker Protection Standard (WPS)].

On October 18, 1995, a data call-in (DCI) notice was issued under section 3(c)(2)(B) of FIFRA, 7 U.S.C. Section 136a (c)(2)(B). This Notice required submission of data necessary to evaluate exposure to persons entering fields and/or areas treated with pesticides.

The DCI required the following three studies: (1) Guideline 132-1(a), Foliar Residue Dissipation; (2) Guideline 133-3, Dermal Exposure Upon Reentry; and (3) Guideline 133-4, Inhalation Exposure Upon Reentry. Guideline 132-1(a) requires data to estimate postapplication residue exposure resulting from a pesticide used at the use site. This information is compound and product specific and the use of generic or surrogate data is not possible. Guidelines 133-3 and 133-4 will be used in estimating postapplication exposure. These data are used to develop

transfer coefficients which relate the amount of pesticide residue available on the treated surface area with how much pesticide residue is deposited onto or inhaled by an individual performing activities in a treated area. These data will enable the Agency to determine appropriate reentry intervals for re-entering fields after pesticide treatments. These data requirements may require registrants to generate data, to supply missing data, and to replace unacceptable data to support product registration and reregistration.

The registrant requested a data waiver based on the following reasons: (1) there are no foliar uses registered, (2) layby applications are applied as a directed spray to the soil at the base of the plant or banded and immediately soil incorporated, and (3) chemigation applications are confined to preplant and preemergent crop situations only. The Agency agreed that exposure to foliar residues should be minimal. However, the potential for worker dermal exposure exists during transplanting activities (e.g., hand exposure). If the transplanting were done mechanically, then exposure should be minimal and dermal exposure data would not be necessary. The Agency agreed to waive the dermal study if there was no contact with the soil. Consequently, the registrant added the following restriction to the label: "TILLAM 6-E may be applied prior to mechanical transplanting only. DO NOT apply TILLAM 6-E prior to hand transplanting." The rationale was that with this restriction in place, there would be no dermal exposure, negating the need for the studies.

However, as explained by the registrant (MRID 44875900), mechanical transplanting via totally automated systems only occurs in some very large operations. The normal cultural practice is for a person to place a plant into a wheel, root upward. The wheel rotates downward, releasing the plant into a mechanically cut furrow. The furrow is then closed mechanically while the wheel continues to move around for reloading. This scenario involves possible human exposure, which was not the expectation when the Agency agreed to the mechanical transplant restriction and waived the studies. In addition, a handler walks behind this machine to straighten misaligned plants. The Agency is therefore requiring that chemical resistant gloves be worn by all such handlers and is calling in the data for the dermal and inhalation studies (guidelines 133-3 and 133-4, respectively).

Zeneca, the registrant for pebulate, is part of an industry-wide Agricultural Reentry Task Force, which was formed by several registrants to develop reentry exposure data required by the October 18, 1995 DCI. This Task Force will generically address the inhalation (133-4) guideline requirement and will submit these data to the Agency by October 29, 2001. As stated previously, the dermal study is chemical specific and must be conducted specifically for pebulate and the degradants of concern, such as pebulate sulfoxide. The PPE required for all exposure scenarios of pebulate are shown in Table 21.

Table 21. Summary of Worker Personal Protective Equipment*

No.	Exposure Scenario	Additional Required PPE	Engineering Controls
1	Mixing/Loading EC for Chemigation	Organic vapor respirator; Coveralls	None
2	Mixing/Loading EC for soil injection and ground boom application in regions other than the western states	Coveralls	None
3	Mixing/Loading EC for soil injection and ground boom application in the western states only**	Organic vapor respirator; Coveralls	None
4	Mixing/Loading EC for impregnation on dry bulk fertilizer (In-Plant Commercial Operation)	N/A	Closed System Required
5	Mixing/Loading EC for impregnation on dry bulk fertilizer (On-board Operation)	Organic vapor respirator; Coveralls	None
6	Mixing/Loading Fluid Formulation for Combination with Liquid Fertilizer (Commercial Operation)	N/A	Closed System Required
7	Mixing/Loading Fluid Formulation for Combination with Liquid Fertilizer (Noncommercial Operation)	Organic vapor respirator; Coveralls	None
8	Applying with a Groundboom Sprayer	No	None
9	Applying Dry Bulk Fertilizer with a Drop Type Tractor Drawn Sprayer	No	None
10	Applying Dry Bulk Fertilizer with Specialized Truck Equipment**	Organic vapor respirator	None
		No	Enclosed cab with organic vapor filtration system
11	Soil Injection Application	No	No

*The PPE specified on the pebulate label at the time of publication of this RED is long sleeve shirt, long pants, closed shoes, protective eyewear, and chemical resistant gloves.
**Either an organic vapor respirator or an enclosed cab may be used.

G. Ecological Risk Mitigation

The use of herbicides such as pebulate poses concern for nontarget plants in the vicinity of the application sites. There is low potential for risk to aquatic plants from the use of pebulate on estimated aquatic residue levels from runoff. Present labeling language does advise the user that pebulate should not be applied directly to water, surface water, or intertidal areas. This advisory language must continue to appear on all product labels.

Based on its use on tobacco, pebulate is expected to reach estuarine environments in the Southeast. In addition, modeling indicates that pebulate will not degrade appreciably in aquatic habitats and prolonged exposure is possible for aquatic organisms. At this time, information is not available on the effects of pebulate in the estuarine environment, particularly on molluscs. The Agency is therefore calling in data to determine the effects of pebulate on this environment.

Pebulate does not exceed risk concerns for acute effects to birds or most mammals. Estimated concentrations of pebulate do not exceed concern for acute effects to fish or invertebrates. Chronic risks to these groups is not expected due to the soil incorporation of pebulate and subsequent reduced exposure potential. Volatility may also reduce the likelihood of continuous exposure. In addition, the Agency has not received any reports of adverse effects to nontarget terrestrial wildlife, insects, or aquatic organisms from uses of pebulate.

H. Occupational (WPS) Labeling Rationale

During the reregistration process, EPA considers all relevant generic and product-specific information to decide what protections and risk mitigation measures are needed for all products. Products may have more than one occupational use; thus, these uses may or may not be covered by the WPS.

The 1992 Worker Protection Standard for Agricultural Pesticides established certain worker-protection requirements [such as PPE and restricted-entry intervals (REIs)] to be specified on the label of all products that contain uses covered by the WPS. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. Uses covered by the WPS include all commercial and research uses on farms, forests, nurseries, and in greenhouses to produce agricultural plants (including food, feed and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). The WPS covers not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. The WPS labeling requirements pertaining to PPE, REI, and notification are interim measures.

At this time, all products containing pebulate are intended solely for occupational use (i.e. mixed, loaded, and applied by commercial applicators) and is not available to homeowners. Therefore, all of these uses are covered by the WPS.

Personal Protective Equipment for Handlers (Mixers, Loaders, and Applicators)

For the end-use product, PPE requirements for pesticide handlers is long sleeve shirt, long pants, closed shoes, protective eyewear, and chemical-resistant gloves. In addition, for pebulate, the use of an organic-vapor respirators is required in some instances to mitigate the risks of inhalation exposure (Table 21). For occupational-use products, PPE is established using the process described in PR Notice 93-7 or more recent EPA guidelines.

Post Application Restrictions

Under the WPS, interim REIs for all uses covered by the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category 1, the

interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category 1, but one or more of the three is classified as category 2, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category 1 or 2, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

For pebulate, EPA has determined that no additional regulatory action is needed on the basis of acute or other adverse effects of the active ingredient; the REI of 12 hours is maintained. During the reregistration process, the early-entry PPE requirements will be established on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient. The acute toxicity endpoints used in this RED may not meet current acceptability criteria. The acceptability status of these data may be reassessed during product reregistration.

I. Other Labeling Requirements

1. Endangered Species Statement

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

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling as specified in section V. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method: "Do not allow this product to drift."

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of pebulate for the eligible uses has been reviewed and determined to be substantially complete. The following studies are required:

New Guideline	Old Guideline No.	Description
830.6313	63-13	Stability to Metals
850.1025	72-3 b	Oyster Acute Toxicity (Shell Deposition)
850.1055	72-3 b	Bivalve Acute Toxicity (Embryo Larvae)
870.6300	83-6	Developmental Neurotoxicity in Rats
875.2400	133-3	Dermal Exposure
875.2500	133-4	Inhalation Exposure*
835.1220	163-1	Leaching/Adsorption/Desorption
835.8100	163-3	Field Volatility from Soil**
835.6100	164-1	Terrestrial Field Dissipation***
860.1900	165-2	Field Accumulation in Rotational Crops†

Note: To ensure that the studies will cover all of the areas of concern to the Agency, the registrant should submit a protocol to the Agency for these studies prior to conducting the trials.

*This data requirement will be submitted by the Agricultural Reentry Task Force.

**The volatilization measurements required for this study can be conducted in conjunction with the terrestrial field dissipation studies.

***The Agency is requiring two new field dissipation studies, which will account for cultural practices and geographical variability: one for tobacco (Southeast region) and one for tomato (California) crops. These data will enable confirmation of pebulate dissipation pathways.

†This data is required to support a preharvest interval of less than 30 days for tomatoes. Additionally, if a plantback harvest interval of less than 4 months is desired, existing confined crop rotational studies must be upgraded or limited field studies (to include seeking metabolites of potential toxicological concern and the parent) must be submitted for all crops (including tomatoes and sugar beets).

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must contain the labeling language presented in Table 22.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Label changes are necessary to implement mitigation measures outlined in Section IV above. Specific language to implement these changes is specified in the following table.

3. Required Labeling Changes Summary Table

The changes to the pebulate label as a result of this RED are summarized in Table 22.

Table 22: Summary of RED Labeling Requirements for Pebulate		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
Required on all MUPs	"Only for formulation into herbicide products for the following use(s):" [*fill blank only with those uses that are being supported by MP registrant*].	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for 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(s)."	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Drift or runoff may adversely affect non-target plants. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA.	
General Application Restrictions for products applied as liquid sprays (regardless of type of application equipment)	"Do not allow this product to drift"	
End Use Products Intended for Occupational Use (WPS)		
PPE Requirements Established by the RED Based on the Active Ingredient.	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. 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." Commercial handlers engaged in impregnating this product onto dry bulk fertilizer or in mixing this product with liquid fertilizer must wear (in addition to using the enclosed system described below): -- long-sleeved shirt & long pants, -- shoes plus socks, and -- chemical-resistant gloves, such as (registrant inserts correct glove types).	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 22: Summary of RED Labeling Requirements for Pebulate		
Description	**Required Labeling**	**Placement on Label**
PPE Requirements Established by the RED Based on the Active Ingredient.	[Personal Protective Equipment (PPE), continued] Mixers and loaders must wear: -- long-sleeved shirt & long pants, -- shoes plus socks, -- chemical-resistant gloves, such as (registrant, insert correct glove types) and -- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or -- a canister approved for pesticides (MSHA/NIOSH approval prefix TC-14G), or -- an organic vapor (OV) cartridge or canister with any N*, R, P, or HE prefilter." EXCEPTIONS: A RESPIRATOR IS NOT REQUIRED FOR MIXERS AND LOADERS SUPPORTING SOIL INJECTION AND GROUNDBOOM AT RATES ≤1 GALLON (4 QTS) Applicators, persons assisting in mechanical transplanting after Tillam 6-E has been applied, and other handlers exposed to the dilute product must wear: -- Long-sleeved shirt & long pants, -- Shoes plus socks, -- Chemical-resistant gloves, such as (registrant inserts correct glove types) In addition, applicators applying dry-bulk fertilizers with specialized equipment designed to cover more than 80 acres per day must use and enclosed cab with a filtration system equal to that of the respirator (described below) or wear a NIOSH-approved respirator with -- an organic-vapor removing cartridge with a prefilter approved for pesticides MSHA/NIOSH approval number prefix TC-23C), or -- a canister approved for pesticides (MSHA/NIOSH approval prefix TC-14G), or -- an organic vapor (OV) cartridge or canister with any N*, R, P, or HE prefilter [* If Tillam 6-E contains oil or has instructions that would allow concurrent application with an oil-containing material, registrant must remove the "N" in the respirator statement.]	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)
User Safety Requirements (Required on Products Which Require Coveralls in the PPE)	*In addition to the above statements* "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)

Table 22: Summary of RED Labeling Requirements for Pebulate		
Description	**Required Labeling**	**Placement on Label**
Engineering Controls	Engineering Controls Commercial (for-hire) handlers engaged in impregnating this product onto dry bulk fertilizer or in mixing this product with liquid fertilizer must: -- use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4), and -- in addition to wearing the required PPE, have immediately available for use in case of an accident: chemical-resistant footwear, and a NIOSH-approved respirator with (1) an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or (2) a canister approved for pesticides (MSHA/NIOSH approval prefix TC-14G), or (3) an organic vapor (OV) cartridge or canister with any N*, R, P, or HE prefilter." "When other handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4, 5), the handler PPE requirements may be reduced or modified as specified in the WPS." [* If Tillam 6-E contains oil or has instructions that would allow concurrent application with an oil-containing material, registrant must remove the "N" in the respirator statement.]	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 saturates the clothing layers and reaches the skin. User should 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: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.)
Environmental Hazards	"Environmental Hazards" "Drift or runoff may adversely affect nontarget plants. Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Note: persons assisting in mechanical transplanting in fields after Tillam 6-E has been applied are classified as handlers and must wear the personal protective equipment listed for handlers in the Precautionary Statements during and after expiration of the REI."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	"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 plants, soil, or water, is: -- coveralls, -- chemical-resistant gloves, and -- shoes plus socks"	

Table 22: Summary of RED Labeling Requirements for Pebulate		
Description	**Required Labeling**	**Placement on Label**
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Mechanical transplanting only. Do not apply Tillam 6-E prior to hand transplanting." "For use outdoors only. Do not use in a greenhouse."	For WPS Products place in the Directions for Use directly above the Agricultural Use Box. For non-WPS Products, Place in Directions for Use in General Precautions and Restrictions
Site Specific Application Restrictions	The label must specify a preharvest interval (PHI) of 30 days. The label must specify a 4-month plantback interval (PBI) for all crops. The label must specify the following industry best management practices to protect nontarget terrestrial and semiaquatic plants.	Directions for Use under General Precautions and Restrictions and or Application Instructions

C. Existing Stocks

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

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

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9. Olinger, Christine L., *Molinate, Pebulate, and Cycloate Plant Metabolism; Issues to be Presented to the Metabolism Committee on May 18, 1992*, EPA Memorandum, May 14, 1999.

10. Hazel, William, J., PhD, *Pebulate. Reassessment of Confined Crop Rotational Studies*, EPA Memorandum, May 12, 1999.

VI. APPENDICES

Appendix A: PEBULATE (CASE 2500): USE PATTERNS ELIGIBLE FOR REREGISTRATION

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps.	Min. Retreatment Interval	Restrictions/Comments
Tomatoes					
Preplant, at-plant, post-plant soil incorporated Broadcast or banded* Groundboom Soil injection Chemigation	6 lb/gal EC [10182-158]	6	1**	N/A	Use on direct seeded or transplanted (mechanical only) tomatoes; do not use prior to hand transplanting Direct seeded, western region (defined as California, Arizona, and Nevada) use maximum rate on heavy textured soils, 4 lb ai/A on light textured soils (<10% organic matter)
Preplant, at-plant, post-plant soil incorporated Broadcast or banded* Groundboom Soil injection Chemigation***	6 lb/gal EC [10182-158]	10	1**	N/A	Use on plug-planted tomatoes, western region (defined as California, Arizona, and Nevada) only Do not use prior to hand transplanting
Postemergence soil incorporated Broadcast or banded* Ground equipment	6 lb/gal EC [10182-158]	3	1**	N/A	Use in SC only

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps.	Min. Retreatment Interval	Restrictions/Comments
Pre- or post-plant Broadcast Sprinkler	6 lb/gal EC [10182-158]	6	1**	N/A	Western region (defined as California, Arizona, and Nevada), use maximum rate on heavy textured soils, 4 lb ai/A on light textured soils (<10% organic matter)

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps.	Min. Retreatment Interval	Restrictions/Comments
Tomatoes (continued)					
Layby (directed), soil incorporated Banded Ground equipment	6 lb/gal EC [10182-158]	6	1**	N/A	Use maximum rate on heavy textured soils, 4 lb ai/A on light textured soils (<10% organic matter)
Sugar beets					
Preplant soil incorporated Broadcast or banded Ground equipment	6 lb/gal EC [10182-158]	6	1	N/A	Use maximum rate on heavy textured soils, 4 lb ai/A on light texture soils (<10% organic matter)
Tobacco					
Preplant soil incorporated Broadcast or banded** Ground equipment Impregnation on dry bulk fertilizer	6 lb/gal EC [10182-158]	4	1	N/A	Do not use prior to hand transplanting

EC, emulsifiable concentrate

* For banded application, reduce the amount per acre proportionately, depending on band width, and row spacing.

**Split applications are permitted as long as the seasonal total does not exceed the single maximum use rate.

***Solid set sprinkler type

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 605-6000.

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pebulate

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	**All**	41556805
61-2A	**Start. Mat. & Mfg. Process**	**All**	41614802
61-2B	**Formation of Impurities**	**All**	41614802
62-1	**Preliminary Analysis**	**All**	41614801
62-2	**Certification of limits**	**All**	41614801
62-3	**Analytical Method**	**All**	41614801
63-2	**Color**	**All**	41556805
63-3	**Physical State**	**All**	41556805
63-4	**Odor**	**All**	41556805
63-5	**Melting Point**	**All**	41556805
63-6	**Boiling Point**	**All**	41556805
63-7	**Density**	**All**	41556805
63-8	**Solubility**	**All**	41556805
63-9	**Vapor Pressure**	**All**	41556805
63-11	**Octanol/Water Partition**	**All**	41556805
63-12	**pH**	**All**	41556805
63-13	**Stability**	**All**	Required
63-14	**Oxidizing/Reducing Action**	**All**	41556805

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pebulate

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	**All**	41556805
63-16	**Explodability**	**All**	41556805
63-17	**Storage stability**	**All**	41556805
63-18	**Viscosity**	**All**	41556805
63-19	**Miscibility**	**All**	41556805
63-20	**Corrosion characteristics**	**All**	41556805
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**		41920702
71-2A	**Avian Dietary - Quail**		41614804, 42294201
71-2B	**Avian Dietary - Duck**		41614803, 42294201
72-1A	**Fish Toxicity Bluegill**		41614805, 41614806
72-1C	**Fish Toxicity Rainbow Trout**		41614806
72-2A	**Invertebrate Toxicity**		41614807
72-3B	**Estuarine/Marine Toxicity - Mollusk**		Required
123-1A	**Seed Germination/Seedling Emergence**		42285301
123-1B	**Vegetative Vigor**		44735901
123-2	**Aquatic Plant Growth**		42265101, 42265102, 42265103, 42265104, 42265105
TOXICOLOGY			

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pebulate

REQUIREMENT		USE PATTERN	CITATION(S)
81-1	**Acute Oral Toxicity - Rat**		415191701
81-2	**Acute Dermal Toxicity - Rabbit/Rat**		41591701, 41677301
81-3	**Acute Inhalation Toxicity - Rat**		00143575
81-4	**Primary Eye Irritation - Rabbit**		41591703
81-5	**Primary Dermal Irritation - Rabbit**		41591702
81-6	**Dermal Sensitization - Guinea Pig**		41614808
81-7	**Acute Delayed Neurotoxicity - Hen**		00067869, 92138016
82-1A	**90-Day Feeding - Rodent**		Waived
82-1B	**90-Day Feeding - Non-rodent**		Waived
82-2	**21-Day Dermal - Rabbit/Rat**		41920701 (28-day study)
82-4	**90-Day Inhalation - Rat**		00143576
82-5B	**90-Day Neurotoxicity - Mammal**		Waived
83-1A	**Chronic Feeding Toxicity - Rodent**		41213001
83-1B	**Chronic Feeding Toxicity - Non-Rodent**		40969701
83-2A	**Oncogenicity - Rat**		41213001
83-2B	**Oncogenicity - Mouse**		41920705
83-3A	**Developmental Toxicity - Rat**		40033301
83-3B	**Developmental Toxicity - Rabbit**		40033201

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pebulate

REQUIREMENT		USE PATTERN	CITATION(S)
83-4	**2-Generation Reproduction - Rat**		40970001
83-6	**Developmental Neurotoxicity**		Required
84-2A	**Gene Mutation (Ames Test)**		41556803
84-2B	**Structural Chromosomal Aberration**		41556802
84-4	**Other Genotoxic Effects**		4164809
85-1	**General Metabolism**		42215201, 42482501, 42482502, 42482503
	OCCUPATIONAL/RESIDENTIAL EXPOSURE		
132-1A	**Foliar Residue Dissipation**		Waived
132-1B	**Soil Residue Dissipation**		Waived
133-3	**Dermal Passive Dosimetry Exposure**		Required
133-4	**Inhalation Passive Dosimetry Exposure**		Required
	ENVIRONMENTAL FATE		
160-5	**Chemical Identity**		41556805
161-1	**Hydrolysis**		151943
161-2	**Photodegradation - Water**		41920703
161-3	**Photodegradation - Soil**		D154348, D154351, review dated 6/28/93
162-1	**Aerobic Soil Metabolism**		42810901, 44875900, 4063710102
162-2	**Anaerobic Soil Metabolism**		42791001

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pebulate

REQUIREMENT		USE PATTERN	CITATION(S)
162-3	**Anaerobic Aquatic Metabolism**		42791001
163-1	**Leaching/Adsorption/Desorption**		41556801, 43040901, Required
163-2	**Volatility - Lab**		41920704
163-3	**Volatility - Field**		Required
164-1	**Terrestrial Field Dissipation**		Required
165-2	**Field Rotational Crop**		Required*
165-3	**Accumulation - Irrigated Crop**		43040901, 43042201
165-4	**Bioaccumulation in Fish**		41614810, 43042201
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**		42519901, 42519902
171-4B	**Nature of Residue - Livestock**		43327802, 43327801
171-4C	**Residue Analytical Method - Plants**		43030701, 43016303, 43016304, letter dated 29 April from B. Hazel
171-4E	**Storage Stability**		44080801, 44080802
171-4K	**Crop Field Trials**		43503801

*These data are required to support a preharvest interval of less than 30 days for tomatoes. To support a plantback harvest interval of less than 4 months, upgraded confined rotational studies or limited field studies (to include seeking metabolites of potential toxicological concern and the parent) must be submitted for all crops, including tomatoes and sugar beets.

GUIDE TO APPENDIX C

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

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

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

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

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state the following:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

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

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

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

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are as follows:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form (Insert A)
Attachment 3	-	Requirements Status And Registrant's Response Form (Insert B)
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

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

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

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

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in
Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert A). If you choose this option, this is the only form that you are required to complete.

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

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

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

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

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

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

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

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

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form (Insert B) and option 6b and 7 on the Data Call-In Response Form(Insert A). If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be

initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2, Agreement to Share in Cost to Develop Data --

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

parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

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

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

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may

only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets

the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

Option 5, Upgrading a Study --

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

submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies --

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

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

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to

consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

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

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

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

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form (Insert B). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no

longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration

concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,

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

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection

of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

PEBULATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Patricia Moe at (703) 308-8011.

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

Patricia Moe, Chemical Review Manager
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Pebulate

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

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

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request.

You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

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

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

This page has been inserted as a place marker and is replaced by an electronically generated generic DCI sample Part A form page number 1 in the actual Printed version of the Red document

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled

PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

***See: guideline comment**

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In

Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

This page has been inserted as a place marker and is replaced by an electronically generated generic DCI sample Part B form page number 1 in the actual Printed version of the Red document

This page has been inserted as a place marker and is replaced by an electronically generated generic DCI sample Part B form page number 2 in the actual Printed version of the Red document

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

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

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

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

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

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

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a

Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). If you choose this option, this is the only form that you are required to complete.

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the

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

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the

data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You

must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

To meet the requirements of the DCI Notice for submitting an existing study, **all of the following three criteria must be clearly met**:

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

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

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study

may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

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

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be

the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

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

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5.

All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

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

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

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

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

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE ADVERSE EFFECTS

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

SECTION VI.INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

PEBULATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Venus Eagle at (703) 308-8045.

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

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

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

Item 1-4. Already completed by EPA.

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

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

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

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

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

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

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify

that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

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

There is no batching for pebulate, as there are is only one end-use product.

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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@epamail.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 (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in 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

Biopesticides and Pollution Prevention Division (BPPD) Contacts

Antimicrobials Division Organizational Structure/Contact List

c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

e. 40 CFR Part 158, Data Requirements for Registration (PDF format)

f. 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' Web Site

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) the following address:

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

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

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 1-800-858-7378 or through their Web site: 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 the submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
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 CAS number if one has been assigned.

Documents Associated with this RED

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

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