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Office of
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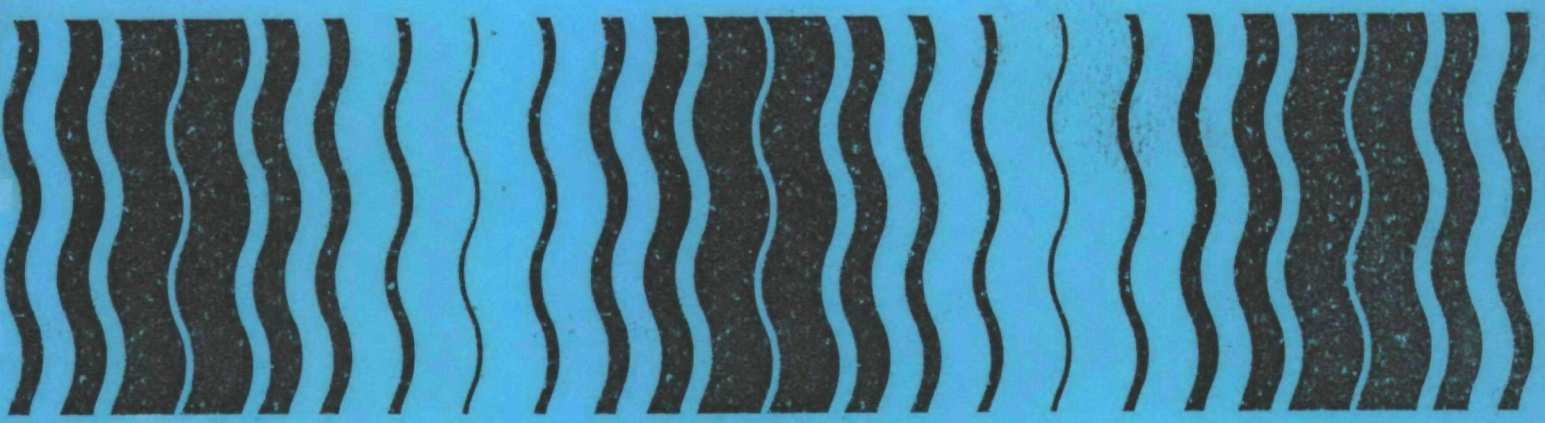
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Propham as the Active Ingredient



30 MAR 1987

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING THE ACTIVE INGREDIENT

PROPHAM
(047601)

CAS Number 122-42-9

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

ai: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline)

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guideline requirements and thus do not support registration of a product.

EEC: Estimated environmental concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

HDT: Highest dose tested

Invalid: Studies which are deficient in some vital parameter or those studies which have been judged not to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations

MP: Manufacturing-use product

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level--the maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: (Provisional Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient

PGI: Pre Grazing Interval, a time period after pesticide application, specified on the products labeling, that livestock are not permitted in the treated field for grazing.

PHI: Pre Harvest Interval, a time period after pesticide application, specified on the products labeling, when harvest of the crop is not permitted.

PLD: Provisional Limiting Dose, a limiting dose level used when the available data are insufficient to establish an ADI or PADI. (the lowest NOEL X a safety factor, where the safety factor is higher than normally used due to lack of confidence in the data base for the ADI or PADI calculations)

Technical: Active ingredient as manufactured

TMRC: (Theoretical Maximum Residue Contribution) An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

TABLE OF CONTENTS

APPENDICES

I. DATA APPENDICES

Guide to Tables

Table A

Table B

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Generic Data Exemption Statement

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide

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[1]The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

Common Name	- Propham
Chemical Name	- Isopropyl carbanilate
Chemical Abstracts Service (CAS) Number	- 122-42-9
EPA Shaughnessy Number	- 047601
Empirical Formula	- $C_{10}H_{13}NO_2$
Trade Name	- Chem-Hoe, Birgin, Triherbide
Physical State	- Solid
Color	- Tan to light grey
Odor	- Faint amine-like odor
Melting Point	- 87 to 88 °C
Octanol/Water Partition Coefficient	- 445 $\pm$ 17 over a propham concentration range of 0.5 to 100 ppm (pure active ingredient)

B. Use Profile

Type of Pesticide	- Herbicide
Pests Controlled	- Grassy weeds and some annual broadleaf weeds
Registered Uses	- Terrestrial food and nonfood crops
Predominant Uses	- Alfalfa, clover, sugar beets, and lettuce
Mode of Activity	- Inhibition of cell division
Formulation Types Registered	- Flowable concentrate (43 and 31 percent active ingredient) and granular (15 percent active ingredient) formulations
Method of Application	- Ground or aerial equipment

III. AGENCY ASSESSMENT

A. Summary. The following summarizes the results of the Agency's assessment of the existing scientific data base for propham. A more thorough discussion of the Agency's assessment follows this section.

1. Propham has low acute oral and dermal toxicity and is classified in toxicity Category III. Available data include a rat subchronic toxicity study deemed supplementary because of numerous deficiencies (no ophthalmologic examinations were performed; analytical data for analysis of blended diet for stability, homogeneity and concentration were not presented; certain recommended tissues were not examined histologically; and several recommended blood electrolyte assays were not performed), and an acceptable rat teratology study in which the no observed effect level (NOEL) for developmental effects (37.6 mg/kg) is lower than the NOEL for maternal toxicity (375.8 mg/kg). A complete toxicological assessment is not possible until the additional toxicology data required in table A of this document are submitted.

2. Data are insufficient to thoroughly assess the environmental fate, including the potential to contaminate ground water. Additional data are being required.

As a result of this review, the Agency has identified missing data which are essential in completing assessment of the environmental and human risks associated with the use of propham. These data must be submitted in order to maintain registrations of products or register new products containing propham. Specific data requirements are listed in Appendix A, Tables A and B.

B. Toxicological Assessment

1. Acute toxicity. Propham has low acute oral and dermal toxicity and is classified in toxicity Category III (see Appendix II for discussion of toxicity categories). In an acute oral toxicity study, female Sprague-Dawley rats were slightly more sensitive than male rats with respective oral LD_{50} values of 2360 $\pm$ 118 mg/kg and 3000 $\pm$ 232 mg/kg.

In an acute dermal toxicity study with rabbits, the acute dermal LD_{50} is greater than 3000 mg/kg.

Studies are required to establish the irritation potential of the technical material to the eye and skin. There are no reliable data available with respect to acute inhalation toxicity; a study in rats is required. A subacute dermal toxicity study is also required.

2. Subchronic Toxicity. Only one subchronic toxicity study in rats is available. In a 90-day feeding study, using dietary levels of propham technical of 0, 250, 1000 and 2000 ppm, 30 rats/sex/group were assigned to each of the treatment groups; 10/sex/group were sacrificed at the midpoint of the study (6 weeks) for interim evaluation. The NOEL was found to be 250 ppm (approximately 12.5 mg/kg/day), based upon transient but significant dose-related plasma cholinesterase inhibition in females in the 1000 ppm and 2000 ppm groups. Because of numerous deficiencies, the subchronic toxicity study must be repeated in rodents. An additional subchronic oral toxicity study, in a nonrodent species, and a 21-day dermal toxicity study are also required.

3. Chronic and Long Term Studies

   a. Chronic Toxicity. Potential effects of chronic exposure to propham have not been established. No studies are available which meet EPA standards. Chronic oral toxicity studies are required in rodent and nonrodent species.

   b. Oncogenicity. Sufficient data are not available to definitively assess the oncogenic potential of propham. The following information is available from studies which do not meet requirements but are considered to provide supplementary information:

      In a screen of 130 chemicals, propham was administered (1) to newborn mice ($B6C3F_1$ and $B6AKF_1$ strains) via gastric intubation at a dose level of 215 mg/kg daily from 7 days to 4 weeks (weaning), and a dietary concentration of 560 ppm until termination at 18 months; and (2) by a single subcutaneous injection to 4 week old weanling mice of both strains, with no further treatment through termination at 18 months. Propham was listed among those compounds which did not cause a significantly ($p \leq 0.01$) increased incidence of tumors in comparison with negative controls in any of the major tumor groups studied (i.e., hepatomas, pulmonary tumors, lymphomas). However, there was reported to be a significant ($p \leq 0.02$) increase in total tumors among orally treated animals. In the absence of a tissue specific increase in tumors, these data do not provide compelling evidence of oncogenic potential.

No significient compound-related toxic effects were found in a 2-year oncogenicity study with $B6C3F_1$ mice. The test consisted of in utero exposure by treatment of the parents with a diet containing 0, 100, 330, or 560 ppm for 16 weeks prior to mating and through gestation and lactation. The weanlings were fed 0, 300, 1000, and 3000 ppm with the high dose doubled at 62 weeks through termination (6000 ppm).

In a study with golden hamsters fed a diet containing 2000 ppm propham for 33 months, no evidence of an increase over control incidence of tumors was found.

Oncogenicity testing in two mammalian species (rats and mice) is required (guideline §158.135, 83-2).

c. Teratogenicity. In a teratology study, pregnant rats (16 to 20 per dose group) were administered propham by gavage on days 5 through 15 of gestation at doses of 0, 37.6, 375.8 and 1878.8 mg/kg. The high level tested exceeded the maximum tolerated dose, resulting in excessive mortality. Body weight gain of surviving high dose dams was significantly reduced. Increased resorptions and dead fetuses, as well as reduced fetal body weights, were associated with treatment at the high dose level. Developmental effects including hydrocephalus, myelomeningocele, and incomplete ossification of the parietal and frontal bones of the skull, were attributable to treatment with propham at the high dose level. Fetuses in the mid-dose group also showed increased incidences of incomplete ossification of the skull. The NOEL's for maternal toxicity and developmental effects were found to be 375.8 and 37.6 mg/kg, respectively. A NOEL for fetotoxicity was not established due to excessive mortality of the dams at the high dose.

Results of a teratology study in mice were inconclusive. In that study, only one dose level of propham (850 mg/kg) was tested and no maternal toxicity was reported; controls were inadequate; and individual data were not reported. These data do not meet minimum Agency standards, and are considered supplementary.

An additional teratology study with propham, using a second mammalian species (other than the rat), is required (§158.135, 83-3).

d. Reproduction. No studies on reproductive effects of propham technical material are available. A study is required (§158.135, 83-4).

e. Mutagenicity. No mutagenicity tests with propham technical are available. These tests are required (§158.135, 84-2, three studies).

f. Metabolism. No metabolism studies are available. These studies are required (§158.135, 85-1).

C. Other Science Findings

1. Ecological Effects. Propham has a very low acute oral toxicity to birds based on poorly designed tests, is slightly toxic to coldwater and warmwater fishes and is moderately toxic to freshwater invertebrates. Additional data are required on avian oral and dietary toxicity. The application of propham on registered use sites is unlikely to result in an environmental hazard to nontarget organisms.

No data are available on plant protection. However, based on propham's use patterns (crops and fallow land where there is no exposure to endangered plants) the phytotoxicity data are not required. According to available information, application of propham on registered use sites is unlikely to result in an environmental hazard to nontarget plants and animals.

2. Environmental Fate. With the exception of an aerobic soil metabolism study, available data are insufficient to fully assess the environmental fate of, and the exposure of humans and nontarget organisms to, propham. Data are required as set forth in Table A of this document.

Based on the acceptable aerobic soil metabolism study, ring-labeled [^{14}C]propham (test substance uncharacterized), at 2 ppm, degraded with a half-life of 7 to 14 days under aerobic conditions in a sandy loam soil incubated in the dark at 25 °C and 60% of water holding capacity. By the day 91 interval, 1% of the applied propham remained unaltered, 68.5% had been evolved as $^{14}CO_2$, and 36% was soil-bound. Two degradates, each < 0.02 ppm, were isolated from the soil but not identified.

D. Tolerance Reassessment. Interim tolerances have been established for residues of propham in the following raw agricultural commodities (40 CFR 180.319):

Commodities	Parts Per Million (ppm)
Hay of alfalfa, clover, and grass	5.0
Alfalfa, clover, and grass	2.0
Flaxseed, lentils, lettuce, peas, safflower seed, spinach, and sugar beets (roots and tops)	0.1
Eggs; milk; and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep	0.05

EPA has evaluated the residue and toxicology data supporting these interim tolerances. The results of this evaluation follow:

Data gaps exist for plant and animal metabolism and for storage stability. When the required data are received, the conclusions summarized below with respect to adequacy of tolerances and sufficiency of residue data are subject to change. Tolerances for residues in animal commodities will not be assessed until the requested animal metabolism studies are completed and reviewed.

The available data are not sufficient to assess the adequacy of interim tolerances for residues of propham in or on sugar beet roots, sugar beet tops, lettuce, spinach, peas (succulent and dry), lentils, grass forage, grass hay, alfalfa forage, alfalfa hay, flaxseed, and safflower seed. Additional data are required.

Processing studies are required for the following commodities: (i) dried pulp, molasses, and refined sugar from sugar beets; (ii) meal and hulls from flaxseed; and (iii) meal and oil from safflower seed. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

Based on the current registered uses and available data, the registrant must: (i) propose appropriate Pregrazing Intervals/ Preharvest Intervals (PGIs/PHIs) for clover, lettuce, spinach, and sugar beets; (ii) designate propham registration for grasses as either pasture or rangeland use, and propose an appropriate PGI and PHI if pasture use is designated; (iii) propose tolerances and provide supporting residue data for pea vines, pea vine hay, lentil forage, lentil hay, and flax straw; and (iv) propose that the interim tolerances under 40 CFR 180.319 be converted to "permanent" tolerances at the same or, if necessary, different concentrations and that these be supported by the requested residue data. As an alternative to item (iii) above, the registrant may propose feeding restrictions for pea vines, pea vine hay, and flax straw. If the registrant(s) does not make the required selections, EPA will presume that residue levels remain at day 0 levels.

The following changes must be made to commodity definitions in the tolerance statement when permanent tolerances are requested, and the data gaps listed in this standard are satisfied: (i) "alfalfa" to "alfalfa forage"; (ii) "clover" to "clover forage"; (iii) "grass" to "grass forage"; and (iv) "peas" to "peas (succulent and dry)", in keeping with current terminology.

The Provisional Limiting Dose (PLD) for propham is 0.0125 mg/kg. This PLD is based on a 3-month rat feeding study, with a NOEL of 12.5 mg/kg/day (approximate conversion from 250 ppm), and applying a safety factor of 1000. This is equivalent to a PLD of 0.75 mg/day for a 60 kg individual. The Theoretical Maximum Residue Concentration (TMRC), based on the total tolerances listed and a daily food intake of 1.5 kg, is 0.043 mg/day, utilizing 5.7 percent of the PLD.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales. Based on review and evaluation of all available data and other relevant information on propham, the Agency has made the following determinations. Where labeling requirements are imposed, specific language is set out in Section D of this Chapter.

1. The Agency is not initiating a Special Review of propham at this time.

   Rationale: Since available data are limited, the Agency is not yet able to make a determination as to whether any of the criteria specified in 40 CFR 154.7 have been met or exceeded.

2. No significant new uses* will be considered until the Agency has received data sufficient to thoroughly evaluate propham.

   Rationale: The toxicology data base on propham is not sufficient to consider establishment of new significant tolerances. In addition, the metabolism of propham in plants and animals is not adequately defined.

3. The Agency is requiring the following residue chemistry data: plant and animal metabolism and storage stability studies; residue studies for sugar beet roots, sugar beet tops, lettuce, spinach, peas (succulent and dry), lentils, grass forage, grass hay, alfalfa forage, alfalfa hay, flaxseed, and safflower seed: and processing studies to determine residues in dried pulp, molasses, and refined sugar from sugar beets; meal and hulls from flaxseed; and meal and oil from safflower seed. Petitions for food/feed additive tolerances will be required if residues concentrate.

   Rationale: Adequate data are not available to assess the adequacy of existing tolerances or to ascertain the need for food/feed additive tolerances in processed commodities.

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* Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the Theoretical Maximum Residue Contribution of greater than 1 percent.

4. The Agency is requiring the registrant to: (i) propose appropriate Pre Grazing Intervals/Pre Harvest Intervals (PGIs/PHIs) for clover, lettuce, spinach, and sugar beets; (ii) designate the propham registration for grasses as either pasture or rangeland use, and propose an appropriate PGI and PHI if pasture use is designated; and (iii) propose tolerances and provide supporting residue data or propose feeding restrictions for pea vines, pea vine hay, lentil forage, lentil hay, and flax straw. These proposals must be submitted with the revised labeling and in accordance with the timeframe required by this document for submittal of revised labeling or the Agency will impose appropriate feeding restrictions. (refer to chapter IV, D of this document, Required Labeling)

   Rationale: Data are unavailable to demonstrate what PGI/PHI is needed for the cited crops in order to assure that tolerance levels are not exceeded. Adequate information is not available regarding the use for grasses and this use must be clarified and fully supported. There is currently no protective mechanism (either tolerances or feeding restrictions) to prevent excessive residues of propham in pea vines, pea vine hay, lentil forage, lentil hay, and flax straw. If the requested information is not submitted, EPA will have no alternative but to assume that day zero residues remain on cropsand appropriate action will be initiated using that assumption.

5. The Agency is requiring the registrant to propose that the interim tolerances under 40 CFR 180.319 be converted to "permanent" tolerances under a separate paragraph of the published tolerance expressions at the same or, if necessary, different concentrations and provide the requested residue data to support these tolerances.

   In addition, the registrant must propose the following changes to commodity definitions in the tolerance statement: (i) "alfalfa" to "alfalfa forage"; (ii) "clover" to "clover forage"; (iii) "grass" to "grass forage"; and (iv) "peas" to "peas (succulent and dry)".

   Rationale: Interim tolerances were established when petitions for tolerances for negligible residues were pending. Since available data do not support the interim tolerances, as established, permanent tolerances can not be set based on currently available data. Therefore, when data are submitted in accordance with this document, the registrant must request conversion to permanent tolerances, and revise the commodity definitions to conform to current terminology or the Agency will propose revocation of the tolerances.

6. The Agency is requiring additional toxicological data, as set forth in Table A of this document to assess the toxicity of propham. Certain acute, subchronic, and chronic testing is required.

   Rationale: These data are normally required under 40 CFR 158 for products with propham's use patterns. Existing data are insufficient to permit the Agency to thoroughly assess the toxicity of propham.

7. The Agency is requiring additional ecological effects data (see Table A).

   Rationale: Available data are insufficient or lacking to fully assess the hazard from propham use to the avian population.

8. The Agency is requiring environmental fate data as set forth in Table A.

   Rationale: Because the requirements have not been fully satisfied available data are insufficient to fully assess the environmental fate of propham. The leaching data that are available indicate a potential for ground water contamination. Hydrolysis, photodegradation, metabolism, leaching, dissipation, and accumulation studies are required.

9. The Agency is not establishing a reentry interval at this time.

   Rationale: Data adequate to assess the need for a reentry interval for field workers are not available. Once data are received and evaluated, the Agency will determine the need for such an interval. An interim interval is not required because of the low acute toxicity demonstrated by the available data.

10. The Agency is requiring environmental precautionary labeling.

    Rationale: The Agency's regulations (40 CFR 162.10) require environmental hazards labeling. Updated labeling consistent with 162.10 is required. Additional required labeling statements to protect wetlands are specified in the registration standard Section D.3.

11. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and /or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.130 Environmental Fate

161-1 Hydrolysis
161-2,3 Photodegradation
163-1 Leaching and Adsorption/Desorption
164-1 Soil Dissipation (Field)
165-1 Rotational Crops (confined)

12. While data gaps are being filled, registered manufacturing-use products (MPs) and end-use products (EPs) containing propham as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). The limited, available data do not indicate any immediate, serious concern.

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Criteria for Registration. To be registered or reregistered under this Standard, products must contain propham as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section as well as comply with the data requirements in the attached 3(c)(2)(b) notice.

C. Acceptable Ranges and Limits

1. Product Composition Standard. To be registered or reregistered under this Standard, MPs must contain propham as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as each impurity found at greater than 0.1 percent.

2. Acute Toxicity Limits. The Agency will consider registration of technical grade and MPs containing propham provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns. To be registered under this Standard, EPs may be labeled only for the commodities listed below. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

   a. Terrestrial, nondomestic, food uses on: sugar beets, lettuce, alfalfa, clovers (lidino,white, red, and crimson), peas (dry or green), lentils, safflower, and spinach.

   b. Terrestrial, nondomestic, nonfood uses on: established grasses grown for seed, flax and established perennial grass and fallow land, drainage ditchbanks, fencerows, roadsides, and lanes.

D. Required Labeling All products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains additional label requirements.

No pesticide product containing propham may be released for shipment by the registrant 4 months after issuance of this Standard unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing propham may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person 18 months after issuance of this Standard unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement. The ingredient statement for MPs must list the active ingredient as: isopropyl carbanilate.

2. Use Pattern Statements. All MPs must state that they are intended for formulation into EPs for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Required Precautionary Statements All Products

   "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional office of EPA."

   "Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

4. Pregrazing and Preharvest Interval Requirements

   The registrant must: propose appropriate PGI's/PHI's for clover, lettuce, spinach, and sugar beets; designate the propham registration for grasses as either pasture or rangeland use; propose an appropriate PGI and PHI if pasture use is designated; propose feeding restrictions for pea vines, pea vine hay, lentil forage, lentil hay, and flax straw. These changes must appear on the label as specified above or EPA will take actions referred to in regulatory position number 4 chapter IV, A of this document.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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3 If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Fxpert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted

in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of 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 or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Prometryn as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Prometryn in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Prometryn as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Prometryn either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor, PM-25
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to 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 out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). 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 MRIL number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED PROPHAM TECHNICAL

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 1/	Timeframe for Submission2/
§158.120 Product Chemistry					
Product Identity and Composition:					
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes		Yes1/	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00145691	Yes3/	6 months
61-3 - Discussion of Formation of Impurities	TGAI	Partially	00145691	Yes4/	6 months
Analysis of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	00145691	Yes5/	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Yes	00145691	No	--
63-3 - Physical State	TGAI	Yes	00145691	No	--
63-4 - Odor	TGAI	Yes	00145691	No	--

TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED PROPHAM TECHNICAL

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 1/	Timeframe for Submission2/
§158.120 Product Chemistry (Cont'd)					
Physical and Chemical Characteristics (Cont'd)					
63-5 - Melting Point	TGAI	Yes	00145691	No	--
63-6 - Boiling Point	TGAI	N/A6/	--	No	--
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	00145691	Yes7/	6 months
63-8 - Solubility	TGAI or PAI	Partially	00145691	Yes8/	6 months
63-9 - Vapor Pressure	PAI	Partially	00145691	Yes9/	6 months
63-10 - Dissociation Constant	PAI	No	--	Yes	6 months
63-11 - Octanol/Water Partition Coefficient	PAI	Yes	00145691	No	--
63-12 - pH	TGAI	No	--	Yes	6 months
63-13 - Stability	TGAI	Partially	00145691	Yes10/	6 months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	--	No	--

TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED PROPHAM TECHNICAL

Footnotes

1/ For all unregistered technical or manufacturing-use products product chemistry data must be submitted in accordance with §158.120.

2/ Timeframes listed start on the issuance date of this document.

3/ Details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures must be submitted for each unregistered technical. Also, the name and address of the manufacturer, producer or supplier of each beginning material used to produce the above products, as well as submission of a copy of all available technical specifications, data sheets and other documents in which the manufacturer, producer or supplier of each beginning material describes its composition and properties must be submitted.

4/ A discussion of each impurity believed to be present at $\geq$ 0.1 percent, based on knowledge of the beginning materials, all possible chemical reactions, and any contamination, is required for each unregistered technical.

5/ Five or more representative samples of each technical must be analyzed for propham, each impurity present at $\geq$ 0.1 percent (w/w), and each additional "toxicologically significant" impurity by analytical methods supported by validation studies of their precision and accuracy.

6/ Not required, since the PAI is solid at room temperature.

7/ Available information is inadequate because determination was performed at 30 °C, instead of 20 or 25 °C.

8/ Most results were not stated quantitatively, and the temperature at which the determinations were made was not stated.

9/ The identity of the tested compound was not stated (must be pure active ingredient).

10/ Information was not supplied concerning the effects of metals, metal ions, normal temperatures, or sunlight.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00038956, 00082681 00115437, 00115443, 00115446, 00115447 00134707	Yes2/	18 months3/
- Livestock	PAIRA & Plant Metabolites	Partially	00082676, 00091226 00091227, 00115396 00115398, 00115439 00115440, 00115441 00115442	Yes4/	18 Months
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	Partially5/	00115448, 00119929	Yes6/	36 months
- Animal residues	TGAI & Metabolites	No	--	Yes6/7/	36 months
- Storage Stability Data	PAI	Partially	00119929	Yes8/	15 months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use[9/]					
- Crop Group #1 - Root and Tuber Vegetables[10/]					
o Crop 1 - Sugar beet roots					
- Crop Field Trials	TEP	Partially	00119929	Yes[11/13/]	18 Months
-- Processed Food/Feed	EP	No	-	Yes[12/13/]	24 Months
- Crop Group #2 - Leaves of Root and Tuber Vegetables[14/]					
o Crop 1 - Sugar beet tops					
-- Crop field trials	TEP	Partially	00119929	Yes[15/]	18 Months
- Crop Group #3 - Leafy Vegetables (except Brassica Vegetables) 16/					
o Crop 1 - Lettuce					
-- Crop field trials	TEP	Partially	00119929	Yes[17/]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use					
o Crop 2 - Spinach					
-- Crop field trials	TEP	Partially	00119929	Yes 18/	18 Months
- Crop Group #4 - Legume Vegetables (Succulent or Dried) 19/					
o Crop 1 - Lentils					
-- Crop field trials	TEP	No	-	Yes 20/	18 Months
o Crop 2 - Peas (succulent and dried)					
-- Crop field trials	TEP	Partially	00119929	Yes 21/	18 Months
- Crop Group #5 - Grass Forage, Fodder, and Hay					
-- Crop field trials	TEP	Partially	00119929	Yes 22/	18 Months
- Crop Group #6 - Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) 23/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use					
o Crop 1 - Alfalfa forage and hay					
-- Crop field trials	TEP	Partially	00119929	Yes 24/	18 Months
o Crop 2 - Clover forage and hay					
-- Crop field trials	TEP	Partially	00119929	No 25/	
- Miscellaneous Commodities					
o Crop 1 - Flax					
-- Crop field trials	TEP	Partially	00119929	Yes 26/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 27/	24 Months
o Crop 2- Safflower					
-- Crop field trials	TEP	No	-	Yes 28/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 29/	24 Months
Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	No	-	Reserved 30/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Footnotes

1/ Timeframes listed start on the issuance date of this document.

2/ The uptake, distribution, and metabolism of [^{14}C] propham in legume forage, a root crop, and a leafy vegetable following soil and foliar application (tested separately) must be included. The identities and quantities of residue in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Data reflecting solvent extraction efficiency of propham residues must also be represented. Representative samples from these tests must also be analyzed by enforcement methods to ascertain that these methods are capable of determining all metabolites of concern. Depending on the results of the requested plant metabolism studies, additional metabolites may also be considered of concern in the future.

3/ Registrants are provided 18 months to submit data commencing with the first planting season after issuance of the Standard, consistent with PR Notice 85-5.

4/ Metabolism studies are required utilizing ruminants, poultry, and swine in which animals must be dosed for a minimum of 3 days with [^{14}C] propham at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 2 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, and muscle and also skin of hen and swine and gizzard of hen. Data reflecting solvent extraction efficiency of propham residues are also required. Representative samples from the above-described tests must also be analyzed by current enforcement methods to ascertain the validity of these methods.

5/ The submitted analytical methods have not been subjected to a method trial.

6/ Residues of propham per se in or on crop samples must be subjected to analysis under the multiresidue protocols. Protocols for methods I, II, III, and IV are available from National Technical Information Service under Order No. PB 86 203734/AS. If the requested data regarding the nature of the residue in plants and animals reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

7/ Analytical methodology must be developed and submitted that is suitable for the enforcement of tolerances for propham in eggs, milk, and animal tissues. Also, residues of propham per se in or on crop samples must be subjected to analysis by the multiresidue protocols. Protocols for methods I,II,III, and IV are avialable from NTIS under order no. PB 86 203734/AS.

8/ The storage intervals and conditions must be reported for all samples used to support tolerances for residues of propham in or on raw agricultural commodities and in processed commodities. These data must be accompanied by data depicting the decline of residues during the intervals and under the conditions specified. On receipt of these data, the adequacy of the tolerances can be reevaluated. Residue data requested in this Standard must be accompanied by

Footnotes (cont'd)

information describing the storage conditions and intervals for all samples analyzed. These data must be accompanied by fortification recovery data depicting the stability of residues of concern in appropriate sample substrates under the storage conditions and for the time intervals specified. Any samples collected in the future must be stored at a temperature shown to reduce the loss of propham upon storage of treated samples; a temperature < 0 °C appears to be necessary. An acceptable analytical method must be used for analysis (see Residue Analytical Methods section). The method must include maceration of the sample, i.e., not merely surface washing. If the requested metabolism data indicate the presence of additional residues of toxicological concern, data depicting the storage stability of such residues will be required.

9/ It should be noted that the conclusions stated below are subject to change on receipt of the requested plant metabolism and storage stability data. Also, the crop group conclusions stated below address only the minimum residue chemistry data base acceptable for purposes of establishing a group tolerance. The registrant should consider the data requirements stated in 40 CFR 180.34 to propose group tolerances.

10/ The available data are insufficient to determine whether a group tolerance is appropriate. If the registrant seeks a crop group tolerance, additional data are required to support the established tolerance for residues of propham in or on the representative group member sugar beet roots (refer to the "Sugar beet roots" section for details of data requirements). Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members carrots, potatoes, and radishes.

11/ The following data are required, in conjunction with data required for sugar beet tops:

- Data depicting propham residues of concern in or on sugar beet roots harvested at the established PHI after postemergence application of, in separate tests, the 4 lb/a.i./gal FlC formulation at 6 lb ai/A as a directed shielded spray and the 15% active ingredient G formulation at 5.25 lb ai/A by ground or air equipment. Tests must be conducted in CA(23%), ID(15%), and MN(20%) or ND(10%) which represent 68% of U.S. sugar beet production (Agricultural Statistics, 1985, p. 76).

- Data depicting propham residues of concern in or on sugar beet roots harvested at the established PHI after postemergence application of the 4 lb/a.i./gal FlC formulation at 4 lb ai/A by air and through center pivot sprinkler irrigation (in separate tests). Tests must be conducted in ID, OR, or WA since this use is limited to these States.

Footnotes (cont'd)

- o Data depicting propham residues of concern in or on sugar beet roots harvested at the established PHI following postemergence application, in the irrigation water, of the 4 lb/a.i./gal FlC formulation at 6 lb ai/A. Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the irrigation water use permitted in CA under SLN CA-780196.

12/ Data from a processing study depicting propham residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beet roots bearing measurable weathered residues. If residues concentrate in any of these processed commodities, appropriate food and/or feed additive tolerances must be proposed.

13/ The registrant must also propose a label revision establishing an appropriate PHI. The data requested above (see footnotes 11 and 12) must reflect this revision or the Agency will impose an interval.

14/ The available data are insufficient to determine whether a group tolerance is appropriate. If the registrant seeks a crop group tolerance, additional data are required to support the established tolerance for residues of propham in or on the representative group member sugar beet tops (refer to the "Sugar beet tops" section for details of data requirements). Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group member turnip tops.

15/ The following data are required, in conjunction with data required for sugar beet roots:

- o Data depicting propham residues of concern in or on sugar beet tops harvested at the established PHI after postemergence application of, in separate tests, the 4 lb/a.i./gal FlC formulation at 6 lb ai/A as a directed, shielded spray and the 15% a.i. G formulation at 5.25 lb ai/A by ground and air equipment. Tests must be conducted in CA(23%), ID(15%), and MN(20%) or ND(10%), which represent 68% of U.S. sugar beet production (Agricultural Statistics, 1985, p. 76).

- o Data depicting propham residues of concern in or on sugar beet tops harvested after postemergence application of the 4 lb/a.i./gal FlC formulation at 4 lb ai/A by air and through center pivot sprinkler irrigation (in separate tests). Tests must be conducted in ID, OR, or WA since this use is limited to these States.

- o Data depicting propham residues of concern in or on sugar beet tops harvested at the established PHI following postemergence application in irrigation water of the 4 lb/a.i./gal FlC formulation at 6 lb ai/A. Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the irrigation water use permitted in CA under SLN CA-780196.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Footnotes (cont'd)

- o The registrant must also propose a label revision establishing an appropriate PHI. The data requested above must reflect this revision.

16/ The available data are insufficient to determine whether a group tolerance is appropriate. If the registrant seeks a crop group tolerance, additional data are required to support the established tolerance for residues of propham in or on the representative group members lettuce and spinach (refer to the "Lettuce" and "Spinach" sections for details of data requirements). Use directions must be proposed, and appropriate supporting residue data submitted for one additional representative group member (celery) or data supporting each crop will be required.

17/ Data must be submitted depicting the residues of propham in or on lettuce (with and without wrapper leaves attached) harvested at the proposed PHI following postemergence direct shielded application of the 4 lb/a.i./gal FlC fomulation at 6 lb ai/A. Tests must be conducted in the States of CA(73%) and AZ(17%) representing 90% of commercial U.S. lettuce production (Agricultural Statistics, 1985, p. 159). The registrant must propose a label revision establishing an appropriate PHI for the postemergence application or the Agency will set the PHI. The data requested above mustreflect this revision.

18/ Data must be submitted depicting the residues of propham in or on spinach harvested at the proposed PHI following postemergence application of the 4 lb/a.i./gal FlC formulation at 5 lb ai/A. Tests must be conducted in CA(24%), and OK (6%) or TX(25%), representing 55% of the commercial U.S. 1982 spinach acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 352). The registrant must propose revision of the label to establish an appropriate PHI for the postemergence application. The data requested above must reflect this proposed PHI. Residue data will not be required for spinach grown for seed unless all other uses on spinach are cancelled.

19/ The available data are insufficient to determine whether a group tolerance is appropriate. If the registrant seeks a crop group tolerance, additional data are required to support the existing tolerance for residues of propham in or on succulent and dried peas (see "Peas" section for details). The registered use pattern for peas (preplant and postemergence) is different from that for lentils (preplant). Use directions must be proposed and appropriate supporting residue data submitted for beans (Phaseolus spp.; one succulent variety and one dried variety) and soybeans.

20/ Data depicting the residues of propham in or on lentils harvested at normal crop maturity following preplant incorporated application of the 4 lb/a.i./gal FlC formulation by ground equipment at 4 lb ai/A must be submitted. Tests must be conducted in ID(31%) or WA(66%), which represent 97% of U.S. lentil production (1982 Census of Agriculture, Vol. 1, Part 51, p. 320). Since lentil forage and lentil hay are raw agricultural commodities, the registrant must propose tolerances and submit appropriate supporting residue data.

Footnotes (cont'd)

21/ Data depicting propham residues of concern in or on pea seed (succulent peas plus pods, and dry) harvested at the proposed PHI following postemergence broadcast application (by ground or aerial equipment) of the 15% a.i. G formula at 4 lb ai/A must be submitted. Succulent and dry varieties must be represented in separate tests. Tests must be conducted in MN(21%) or WI(26%) and OR(10%) or WA(22%) which represent 79% of U.S. pea production (Agricultural Statistics, 1985, p. 162). The registrant must propose a PHI which is reflected by the data requested above. Since pea vines and pea vine hay are raw agricultural commodities, the registrant must propose tolerances and submit appropriate supporting residue data. Alternatively, the registrant may elect to propose feeding restrictions for pea vines and pea vine hay.

22/ Data depicting propham residues of concern in or on grass forage and hay from three species including: (i) Kentucky bluegrass; (ii) Chewing's fescue, creeping red fescue or tall fescue; and (iii) orchardgrass, perennial ryegrass or bentgrass (Astoria/Highland) must be submitted. Grass forage in the various tests must be harvested 0 days after application (using ground equipment) of the 4 lb/a.i./gal FlC formulation at 4 lb ai/A. Hay should be harvested at the normal harvest time(s). Tests must be conducted in OR. Residue data will not be required for grass grown for seed unless all other grass uses are cancelled. The registrant must also propose a label revision designating propham use for either pasture (fenced, controlled grazing areas) or range (unfenced, grazing not controlled) grasses. If pasture use is designated, the registrant must propose an appropriate PGI and PHI (or delete the use patterns) after which grazing and harvesting of treated grass is restricted; the data request above must reflect that PHI. Alternatively, other specific label directions/limitations may preclude the need for a PGI and/or a PHI or we will assume that residues at any time are equal to residues at 0 day.

23/ A crop group tolerance is not appropriate for the nongrass animal feeds group at this time because additional data are needed to support the established tolerances for residues of propham in or on alfalfa and clover (see individual crop sections for details).

24/ Data depicting residues of propham in or on alfalfa forage and hay harvested 50 days after postemergence broadcas application of, in separate tests, the 4 lb/a.i./gal FlC formulation in 20 gal water/A and the 15% a.i. G formulation at 5 lb ai/A must be submitted. Ground and aerial applications must be represented in separate tests. Tests must be conducted in CA(7%), ID(5%) or MT(4%), IA(7%) or MN(7%), KS(4%) or NE(6%), ND(3%) or SD(6%), and WI(13%), which represent 62% of the U.S. alfalfa production (Agricultural Statistics 1985, p. 242). Note that residue data will not be required for alfalfa grown for seed unless all other uses on alfalfa are cancelled; if needed in the future, such data will be translated to clover. Data depicting residues in alfalfa forage and hay harvested 50 days following the postemergence broadcast application of, in separate tests, the 4 lb/a.i./gal FlC in 20 gal water/A and the 15% a.i. G at 6 lb ai/A must be submitted. Ground and aerial applications must be represe in separated tests. Tests must be conducted in CA, ID, NV, OR, and WA. Alternatively, the registrant may elect

Footnotes (cont'd)

to cancel this postemergence broadcast use permitted in CA under SLNs CA-780057 and CA-780058, in ID under SLN ID-830006, in NV under SLNs NV-780002 and NV-780003, in OR under OR-830005, and in WA under SLN WA-830002. Data depicting residues in or on alfalfa forage and hay harvested 8 days following postemergence broadcast application of the 4 lb/a.i./gal FlC formulation at 4 lb ai/A by center pivot sprinkler irrigation in 0.5-1.0 inch water must be submitted. The tests must be conducted in ID, OR and WA. Alternatively, the registrant may elect to cancel this postemergence broadcast use permitted in ID under SLN ID-830006, in OR under SLNs OR-770015 and OR-830005, and in WA under SLNs WA-770003 and WA 830002. Data depicting residues in or on alfalfa forage and hay harvested 50 days following the application of the 4 lb/ a.i./gal FlC formulation at 4 lb ai/A in irrigation water. Tests must be conducted in CA. Alternatively, the registrant may choose to cancel this irrigation water use permitted under SLN CA-780211.

25/ The submitted data are insufficient to assess the adequacy of the tolerances for residues of propham in or on clover and clover hay because data were not submitted for field dried hay samples and geographic representation of the acceptable data was inadequate. Residues of 530-1061 ppm were found in or on clover forage samples harvested at the implied PGI/PHI of 0 days from two OR tests treated at 1.5X the maximum registered use rate. Nevertheless, no additional data will be specifically required for clover because the data requested for alfalfa can be translated to support the clover tolerances since the uses are similar. However, the registrant must propose label revisions establishing a realistic PGI and/or PHI, and data translated from alfalfa must reflect this revision. Alternatively, other specific label directions/restrictions may obviate the need for a PGI and/or PHI. The translated data cannot be used to support a crop group tolerance.

26/ Data depicting propham residues of concern in or on flaxseed harvested at normal crop maturity following postemergence broadcast application of the 15% a.i. G formulation by ground or aerial equipment at 4 lb ai/A when the crop is 2-4 inches high must be submitted. Tests must be conducted in MN(9%), ND(69%), or SD(21%) which represent 100% of U.S. flaxseed production (Agricultural Statistics, 1985, p. 113). Since flax straw is a raw agricultural commodity, the registrant must propose a tolerance and provide appropriate supporting residue data. Alternatively, the registrant may propose label revisions restricting the feeding of flax straw to livestock.

27/ Data from a processing study depicting propham residues of concern in meal and hulls processed from flaxseed bearing measurable weathered propham residues must be submitted. If residues concentrate in either of these commodities appropriate feed additive tolerances must be proposed.

28/ Data depicting propham residues of concern in or on safflower seed harvested at normal crop maturity following preplant incorporated or preemergence application of the 4 lb/a.i./gal FlC formulation at 4 lb ai/A must be submitted. Tests must be conducted in CA(76%) and MT(17%), which represent 93% of U.S. safflower production (1982 Census of Agriculture, Vol. 1, Part 51, p. 317).

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Footnotes (cont'd)

29/ Data from a processing study depicting propham residues of concern in meal and oil processed from safflower seed bearing measurable weathered residues must be submitted. If residues concentrate in either of the processed commodities appropriate food and/or feed additive tolerances must be proposed.

30/ Due to inadequate understanding of plant metabolism of propham and the lack of established residue tolerances for several feed commodities which can contribute to the diets of livestock species, the interim tolerances for animal commodities cannot be assessed and dietary intake levels for animal feed studies cannot be determined. When a theoretical maximum dietary intake level for propham can be accurately estimated, appropriate feeding studies will be required. Also, the metabolism of propham in animals is not adequately understood (see "Nature of the Residue in Animals" section for details). Therefore, if the required metabolism studies reveal other residues of concern, additional residue data will be required from any required feeding studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	-	Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B	No	-	Yes	9 Months
161-3 On Soil	TGAI or PAIRA	A	No	-	Yes	9 Months
161-4 In Air	TGAI or PAIRA	A	No	-	Reserved 2/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	00115470	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	NA 3/				
162-4 - Aerobic Aquatic	TGAI or PAIRA	NA 3/				
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	?	No	-	Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Reserved 4/	
163-3 - Volatility (Field)	TEP	A	No	-	Reserved 4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate (cont'd)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A3/				
164-3 - Forestry	TEP	N/A3/				
164-4 - Combination and Tank Mixes						
164-5 - Soil, Long-term	TEP	A	No	-	Reserved5/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved6/	
165-3 - Irrigated Crops	TEP	N/A3/				
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	N/A3/				

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Footnotes

1/ Timeframes listed start on the issuance date of this document.

2/ Pending results of laboratory volatility data and review of reentry issues. These studies will be required if the chemical is volitile or use patterns/data warrant a reentry interval.

3/ No aquatic and forestry use pattern. These studies will be required if these use patterns are requested.

4/ Pending reentry issues. These studies will be required if the use patterns warrant the establishment of a reentry interval.

5/ Pending results of field dissipation study. These studies will be required if the chemical is long lived in the soil.

6/ Pending results of confined rotational crop study. This field study will be required if the confined study shows uptake by rotational crops.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	No	-	Conditional 1/
132-1 - Soil Dissipation	TEP	A	No	-	No 2/
133-3 - Dermal Exposure	TEP	A	No	-	Optional 3/
133-4 - Inhalation Exposure	TEP	A	No	-	Optional 3/

1/ Pending further toxicological evaluation when used as a post emergent herbicide.

2/ Soil Dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work, e.g., for use on potatoes or peanuts where hand harvesting will be performed.

3/ Human-exposure monitoring data may be submitted at the registrant's option. If Dermal Exposure data are submitted, Inhalation Exposure data must also be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	use pattern	Does EPA Have Data to Satisfy This Requirement (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission 1/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	A,B	Partially	160000	Yes	9 Months
71-2 - Avian Dietary LC_{50}	TGAI	A,B	No	-	Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B	No	-	No 1/	
71-4 - Avian Reproduction	TGAI	A,B	No	-	No 1/	
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B	No	-	No 1/	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	A,B	Yes	40094602, 00115433 GS0144-12	No	
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B	Yes	40094602	No	
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A	No		No 1/	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A	No		No 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission 1/
§158.145 Wildlife and Aquatic Organisms (cont'd)						
72-5 - Fish Life Cycle	TGAI	A	No		No1/	
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A	No		No1/	
72-7 - Simulated or Actual Field Testing - Aquatic Organism	TEP	A	No		No1/	
§158-150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A,B	No		No1/	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B	No		No1/	
122-1 - Vegetative Vigor	TGAI	A,B	No		No1/	
122-2 - Aquatic Plant Growth	TGAI	A,B	No		No1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission 1/
§158-150 Plant Protection						
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B	No		No 1/	
123-1 - Vegetative Vigor	TGAI	A,B	No		No 1/	
123-2 - Aquatic Plant Growth	TGAI	A,B	No		No 1/	
TIER III						
124-1 - Terrestrial Field	TEP	A,B	No		No 1/	
124-2 - Aquatic Field	TEP	D	No		No 1/	
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B	Yes	00036935	No	

1/ Available information on the chemical and its use patterns indicate that these studies are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158-155 Nontarget Insect						
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No	-	No[1/]	
141-4 - Honey bee subacute feeding study	[Reserved][2/]					
141-5 - Field testing for pollinators	TEP	A,B	No	-	No[1/]	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	[Reserved][3/]					
142-2 - Aquatic insect life cycle study	[Reserved][3/]					
142-3 - Simulated or actual field testing for aquatic insects	[Reserved][3/]					
143-1 thru 143-3 - NONTARGET INSECT TESTING PREDATORS AND PARASITES	[Reserved][3/]					

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Footnotes

1/ Data from this study is not required at this time. Requirement will depend on results of acute contact study. If the acute contact study demonstrates toxicity to the bees then the field study would be necessary.

2/ Reserved pending development of test methodology.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially?)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	TGAI	Yes	00115421	No	
81-2 - Acute Dermal	TGAI	Yes	00115422	No	
81-3 - Acute Inhalation - Rat	TGAI	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	No		No2/	
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent	TGAI	No		Yes - 15 Months	
Nonrodent	TGAI	No		Yes - 18 Months	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially?)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframes for submission 1/
§158.135 Toxicology (continued)					
82-2 - 21-Day Dermal	TGAI	No		Yes	12 Months
82-3 - 90-Day Dermal	TGAI	No		No 3/	
82-4 - 90-Day Inhalation - Rat	TGAI	No		No 3/	
82-5 - 90-Day Neurotoxicity	TGAI	No		No 4/	
CHRONIC TESTING:					
83-1 - Chronic Toxicity - Rodent	TGAI	No		Yes	50 Months
Nonrodent		No		Yes	50 Months
83-2 - Oncogenicity Study - Rat	TGAI	No		Yes	50 Months
Mouse		No		Yes	50 Months
83-3 - Teratogenicity - Rat	TGAI	Yes	00115434	No	
Rabbit		No		Yes	15 Months
83-4 - Reproduction	TGAI	No		Yes	39 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPHAM

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially?)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission 1/
§158.135 Toxicology (continued)					
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	No		Yes	9 Months
84-2 - Chromosomal Aberration	TGAI	No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI	No		Yes	12 Months
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	No		Yes	24 Months

1/ Timeframes listed start on the issuance date of this document.
2/ The compound is not an organophosphate. The test is not required.
3/ This test is not currently required, due to the lack of exposure data and may be required after the exposure data is submitted and reviewed.
4/ This test is not required because the acute hen test is not required and the compound has not shown neurotoxicity in a mammalian species.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPHAM

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially?)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral - Rat	MP	No		Yes - 9 Months
81-2 - Acute Dermal	MP	No		Yes - 9 Months
81-3 - Acute Inhalation - Rat	MP	No		Yes - 9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes - 9 Months
81-5 - Primary Dermal Irritation	MP	No		Yes - 9 Months
81-6 - Dermal Sensitization	MP	No		Yes - 9 Months

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

ISOPROPYL CARBANILATE

FINAL
DAI/SAT
047601

TABLE OF CONTENTS

FINAL
SAI/SAI
A047601

ISOPROPYL CARBANILATE*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
G (15%)
F1C (3 lb/gal or 31% a.i., 4 lb/gal or 43% a.i.)

GENERAL WARNINGS AND LIMITATIONS: A selective preplant, preemergence, and postemergence herbicide for control of certain annual broadleaf weeds and winter grasses. Keep out of lakes, ponds, or streams. Do not contaminate bodies of water by cleaning of equipment or disposal of wastes. This product breaks down rapidly in warm, moist soil, and, therefore is more effective on cool season crops where soil temperatures are below 55 F (12.8 C). Do not apply when wind speed favors drift. For strip or band treatments reduce dosages and water dilution rates proportionately. Maintain agitation during application of the flowable concentrate formulations.

Interim Tolerances: While petitions for tolerances for negligible residues are pending and until action is completed, interim tolerances are established.

Livestock Tolerances:

Cattle, fat	0.05 (I) ppm
Cattle, meat	0.05 (I) ppm
Cattle, mbyp	0.05 (I) ppm
Eggs	0.05 (I) ppm
Goats, fat	0.05 (I) ppm
Goats, meat	0.05 (I) ppm
Goats, mbyp	0.05 (I) ppm
Hogs, fat	0.05 (I) ppm
Hogs, meat	0.05 (I) ppm
Hogs, mbyp	0.05 (I) ppm
Horses, fat	0.05 (I) ppm
Horses, meat	0.05 (I) ppm
Horses, mbyp	0.05 (I) ppm
Milk	0.05 (I) ppm
Poultry, fat	0.05 (I) ppm
Poultry, meat	0.05 (I) ppm
Poultry, mbyp	0.05 (I) ppm
Sheep, fat	0.05 (I) ppm
Sheep, meat	0.05 (I) ppm
Sheep, mbyp	0.05 (I) ppm

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Disrupts normal cell division, inhibits protein and amylase synthesis, inhibits photolytic activity of isolated chloroplasts and affects the activity of messenger RNA.

*propham

ISOPROPYL CARBANILATE

BROADLEAF WEEDS CONTROLLED:

FGAEBF	Burning nettle
AZAAAC	Chickweed

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCACKBA	Annual bluegrass
CABSBJ	Barley (volunteer)
CACHBB	Canarygrass
PCABRBA	Common velvetgrass
CAATBM	Downy brome
CACUAA	Foxtail
PCABZBA	Italian ryegrass
PCACLBB	Rabbitfoot polypogon
CAEABE	Rattail fescue
CADFBA	Wheat (volunteer)
PCAAOBB	Wild oats
CACUBD	Yellow foxtail

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
TERRESTRIAL FOOD CROP	
(Agricultural Crops)	
123001AA Alfalfa	5.0 (I) ppm (alfalfa, hay) 2.0 (I) ppm (alfalfa) Do not graze or harvest for feed within 50 days after application. General Information: Irrigate within 5 days of application. Use the lower dosages on coarse and medium textured soils and the higher dosages on fine textured soils.
3-4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. Apply in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days of planting.
3-4 (4 lb/gal FlC)	Preemergence. Broadcast. Apply in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days after planting.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Alfalfa (continued)	
	3-5 (15% G) 000748-00211 (4 lb/gal FlC)	Postemergence. Broadcast. Apply in the winter or early spring. May be applied to established alfalfa or to seeding stands with 3 or more true leaves. Apply in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air.
	[SLN] 4-6 (15% G) (4 lb/gal FlC)	SLN - Use limited to CA, NV, OR, and WA. Postemergence. Broadcast application to new seeding and established stands. Apply in the late fall, winter, or early spring when alfalfa has at least 3 true leaves. Apply before April 15. Apply the flowable concentrate in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air.
	[SLN] 3-4 (4 lb/gal FlC)	SLN - Use limited to OR and WA. Postemergence. Broadcast. Apply water and product mixture by center pivot sprinkler irrigation. Apply 0.5 to 1 inch of water per acre.
	[SLN] 4 (4 lb/gal FlC)	SLN - Use limited to CA. Postemergence. Mix 1 part product to 4 parts water and meter into irrigation water. New seedling alfalfa should have at least 3 true leaves before application.
/33025AA	Bentgrass (Astoria/ Highland)	5.0 (I) ppm (grasses, hay) 2.0 (I) ppm (grasses)
/33024AA /33111AA /22030AA /22028AA /22035AA /22043AA	Chewing's Fescue Creeping Red Fescue Kentucky Bluegrass Orchardgrass Perennial Ryegrass Tall Fescue	General Information: Straw and plant residues should be removed before application. Avoid applying on warm, windy days. Reduce application rates in low spots where surface water may cause accumulation of the chemical injuring crops. Use on established fields which have been harvested at least once.
	3-4 (4 lb/gal FlC) 000748-00207	Use limited to OR, west of the Cascade Mountains. Broadcast. Apply in 20 or more gallons of water per acre. Spray in October after fall rains have started. Do not spray after October 31. For chewing's fescue and creeping red fescue, apply from October 1 to October 20.
	Chewing's Fescue	See Bentgrass (Astoria/Highland) cluster.

ISOPROPYL CARBANILATE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
'23003AA '23016AA 23016AA 23014AA '23017AA	Clover Crimson Clover Ladino Clover Red Clover White Clover	5.0 (I) ppm (clover, hay) 2.0 (I) ppm (clover) General Information: Irrigate within 5 days of application. Use the lower dosages on coarse and medium textured soils and the higher dosages on fine textured soils.
	3-4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. Apply in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days of planting.
	3-4 (4 lb/gal FlC)	Preemergence. Broadcast. Apply in 20 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days after planting.
	4.00-5.25 (15% G) 000748-00211	Postemergence. Broadcast. Apply in 20 to 60 gallons of water per acre in the winter or early spring. Seedling stands should have 3 or more true leaves. Apply by ground or by air.
	Creeping Red Fescue	See Bentgrass (Astoria/Highland) cluster.
	Crimson Clover	See Clover cluster.
'8009AA	Flax	0.1 (I) ppm (flax seed) General Information: Irrigate within 3 days of application.
	4 (15% G) 000748-00211	Postemergence. Broadcast. Apply when flax is 2 to 4 inches high and germinating weeds are less than 4 inches high. Apply by ground or by air.
	Ladino Clover	See Clover cluster.
5011AA	Lentils	0.1 (I) ppm
	4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. For control of barley (volunteer), wheat (volunteer), and wild oats. Apply in 10 to 20 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air. Spray mixture directly onto soil surface and immediately cross disk to a depth of at least 4 inches. Seed may be planted the same day but no later than 1 to 2 days after treatment.

ISOPROPYL CARBANILATE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/13020AA	Lettuce	0.1 (I) ppm General Information: Use the lower dosage on coarse textured soils and the higher dosage on fine textured soils.
	4-6 (4 lb/gal FlC) 000748-00207	Use limited to AZ and CA. Preplant. Broadcast. Apply in 20 to 40 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days of planting. Incorporate with a rotary tiller into the top 2 inches of soil. Furrow irrigation a few days after application is recommended for preplant treatments.
	3-4 (4 lb/gal FlC)	Use limited to AZ, CA, CO, and NM. Preplant. Broadcast. Apply in 40 to 60 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air. Incorporate with a rotary tiller or a double disk with harrow into the top 2 inches of soil. Furrow irrigation a few days after application is recommended for preplant treatments. Tank mix with benfluralin.
	3.75-6.00 (4 lb/gal FlC)	Preemergence. Broadcast. Apply in 20 to 40 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air within 2 days after planting. Irrigate by sprinkler (0.5 inch water) within a few days after application if there is no rainfall.
	4.5-6.0 (4 lb/gal FlC)	Postemergence. Directed (shielded) spray. Apply in 40 gallons of water per acre when the lettuce has at least 4 or more true leaves.
	Kentucky Bluegrass	See Bentgrass (Astoria/Highland) cluster.
	Orchardgrass	See Bentgrass (Astoria/Highland) cluster.
/15009AA	Peas (green or dry)	0.1 (I) ppm General Information: Irrigate within 3 days of application.
	4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. For control of barley (volunteer), wheat (volunteer), and wild oats. Apply in 10 to 20 gallons of water per acre by ground, or 5 to 10 gallons of total spray solution per acre by air. Spray mixture directly onto soil surface and immediately cross disk to a depth of

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Peas (green or dry) (continued)	
		at least 4 inches. Seed may be planted the same day but no later than 1 to 2 days after treatment.
	4 (15% G) 000748-00211	Postemergence. Broadcast. Apply when peas have 4 or more true leaves. Apply by ground or by air.
	Perennial Ryegrass	See Bentgrass (Astoria/Highland) cluster.
	Red Clover	See Clover cluster.
38034AA	Safflower	0.1 (I) ppm (safflower, seed) General Information: Use the lower dosage on coarse and medium textured soils and the higher dosage on fine textured soils.
	3-4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. Apply in 35 to 50 gallons of water per acre within 2 days of planting. Shallow incorporate 1 to 2 inches and follow with furrow irrigation within 2 days after application.
	3-4 (4 lb/gal FlC)	Preemergence. Broadcast. Apply in 35 to 50 gallons of water per acre within 2 days after planting. Sprinkler irrigation is essential after treatment if no rain occurs.
13024AA	Spinach	0.1 (I) ppm General Information: Irrigate within a few days of application. Use the lower dosage on coarse textured soils and the higher dosage on fine textured soils.
	4-5 (4 lb/gal FlC) 000748-00207	Preemergence. Broadcast. Apply in 20 to 40 gallons of water per acre after planting. Follow with 0.5 inch of water by sprinkler irrigation if no rain occurs within a few days.
	4-5 (4 lb/gal FlC)	Postemergence. Broadcast. Apply in 20 to 40 gallons of water per acre when spinach is in the 2 to 4 leaf stage. Follow with 1 inch of water by sprinkler irrigation if no rain occurs within a few days.

ISOPROPYL CARBANILATE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/28020AA	Sugar Beets	0.1 (I) ppm (beets, sugar (roots, tops)) General Information: Irrigate within 3 days after application. Use the lower dosages on coarse textured soils and the higher dosages on medium/fine textured soils.
	4 (4 lb/gal FlC) 000748-00207	Preplant. Broadcast. For control of barley (volunteer), wheat (volunteer), and wild oats. Apply in 10 to 20 gallons of water per acre. Spray mixture directly onto soil surface and immediately cross disk to a depth of at least 4 inches. Seed may be planted the same day but no later than 1 to 2 days after treatment.
	4.00-5.25 (15% G) 000748-00211	Postemergence. Broadcast. Apply when beets are between the 4 true leaf stage and the rosette stage but prior to tight crown development. Apply by ground or by air.
	4.5-6.0 (4 lb/gal FlC)	Postemergence. Directed (shielded) spray. Apply in 40 gallons of water per acre when beets have 4 to 8 true leaves.
	4 (4 lb/gal FlC)	Use limited to ID, OR, and WA. Preplant, preemergence, or postemergence. Apply by ground, by air, or by center pivot sprinkler irrigation. Use the air or center pivot sprinkler irrigation applications on preplant or preemergence only.
	[SLN] 4-6 (4 lb/gal FlC)	SLN - Use limited to CA. Postemergence. Apply in irrigation water when beets have at least 6 true leaves.
	Tall Fescue	See Bentgrass (Astoria/Highland) cluster.
	White Clover	See Clover cluster.

ISOPROPYL CARBANILATE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	(Noncrop, Wide Areas, and General Indoor/Outdoor Treatments)	
660020A	Fallowland	
		Do not graze or plant crops in treated areas within 8 months of application.
	3-4 (3 lb/gal FlC) 000748-00224	Broadcast. Apply in the fall or winter after soil temperatures have cooled to 50 F (10.0 C) at a depth of 1 inch. Apply in 20 or more gallons of water per acre by ground or 5 to 10 gallons of water per acre by air. Use the lower dosage for preemergence weeds and the higher dosage when weeds have 4 or more leaves.
	[SLN] 3-4 (3 lb/gal FlC)	SLN - Use limited to CO, OR, UT, and WA. Broadcast to fallowland to be planted to wheat (wheat-fallow-wheat). Apply in 10 or more gallons of water per acre by ground or 5 or more gallons of water per acre to stubble in fall or early winter but not after March 1. Tank mix with atrazine, metribuzin, paraquat, or 2-chlorsulfuron.
	TERRESTRIAL NON-FOOD CROP	
	(Agricultural Crops)	
/23001DA :3003DA	Alfalfa (seed crop) Clover (seed crop)	N.F.
	4-5 (15% G) 000748-00211	Postemergence. Broadcast. Apply when crops have 3 or more true leaves and the soil temperature has cooled to 55 F (12.8 C) or lower. Apply by ground or by air.
8066DA	Grasses Grown for Seed	N.F. General Information: Straw and plant residues should be removed before application.
	3-4 (4 lb/gal FlC) 000748-00207	Use limited to WA. Postemergence. Apply to established grasses between September 15 and October 15. Apply when grasses are in the 1 leaf stage.

ISOPROPYL CARBANILATE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/13024DA	Spinach (grown for seed)	N.F. Do not use treated crops or crop residue for food or feed. General Information: Irrigate 7 to 10 days following application. Crops, except wheat, may be rotated 3 months after application. Wheat may be planted 9 months after application.
	[SLN] 4-5 (4 lb/gal FlC)	SLN - Use limited to western WA. Preemergence. Broadcast. Soil surface treatment. Apply in 20 to 40 gallons of water per acre. Tank mix with diethatyl-ethyl.

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

/670000A	Noncrop Areas	Do not graze or plant crops in treated areas within 8 months of application. Do not apply after March 1. General Information: This site includes fencerows, roadsides, ditches, and lanes.
	3-4 (3 lb/gal FlC) 000748-00224	Broadcast. Apply in the fall or winter after the soil temperatures have cooled to 50 F (10.0 C) at a depth of 1 inch. Apply in 20 or more gallons of water per acre by ground or 5 to 10 gallons of water per acre by air. Use the lower dosage for preemergence weeds and the higher dosage when weeds have 4 or more leaves.

AERIAL AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application	
	—	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Alfalfa, Clover, Crimson Clover, Flax, Ladino Clover, Peas, Red Clover, Sugar Beets, White Clover (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Fallowland

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Aerial Application (continued)	
	TERRESTRIAL NON-FOOD CROP (Agricultural Crops) Alfalfa (seed crop), Clover (seed crop) (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Noncrop Areas
)900300 Tank Mix \AAAAAA	
—	Refer to
	TERRESTRIAL FOOD CROP (Agricultural Crops) Lettuce (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Fallowland
	TERRESTRIAL NON-FOOD CROP (Agricultural Crops) Spinach (grown for seed)

ISOPROPYL CARBANILATE

Listing of Registered Pesticide Products by Formulation

%015.0004 15% granular
isopropyl carbanilate (047601)
000748-00211

(000748-00211) CA780057 NV780003

%103.0014 3 lb/gal (31% a.i.) flowable concentrate
isopropyl carbanilate (047601)
000748-00224*
*currently unavailable for review

(000748-00224) CO810025 OR810067 OR810078 OR840049
WA810066 WA840072

%104.0014 4 lb/gal (43% a.i.) flowable concentrate
isopropyl carbanilate (047601)
000748-00207

(000748-00207) CA780058 CA780196 CA780211 NV780002
OR770015 OR830005 WA770003 WA830002
WA830004

)999999 State Label Registration

WA Reg. No.
000748-06004

Issued: 2-20-86 I-047601-11

ISOPROPYL CARBANILATE

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
080803	--	atrazine
084301	benfluralin (ISO)	N-butyl-N-ehtyl-alpha,alpha,alpha-trifluoro-2,6-dinitro-p-toluidine
118601	2-chlorosulfuron (ANSI)	2-chloro-N-[((4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino)carbonyl]benzenesulfonamide
116701	—	diethatyl-ethyl
101101	—	metribuzin
061603	—	paraquat

— Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

ISOPROPYL CARBANILATE

Auxiliary Documentation

Reg. No.	Cancellation Date
000748-00206	6/25/85

Registration Number 000748-00224 was extracted from the fiche because it could not be located at EPA.

TOLERANCE INDEX BY SHAUGHNESSY CODE: 047601 - H

CHEMICAL NAME: Isopropyl carbanilate

CFR	PPM	COMMODITY CODE	COMMODITY SEQUENCE	COMMODITY NAME
180.319	0.11	13020AA	633	LETTUCE
	0.11	13029AA	1112	SPINACH
	0.11	15011AC	622	LENTILS
	2.01	22000AA	519	GRASSES
	5.01	22000DA	530	GRASSES, HAY
	2.01	23001AA	1	ALFALFA
	5.01	23001DA	9	ALFALFA, HAY
	2.01	23003AA	267	CLOVER
	5.01	23003DA	293	CLOVER, HAY
	0.11	23009AA	153	BEETS, SUGAR, TOPS
	0.11	25002AA	150	BEETS, SUGAR, ROOTS
	0.11	27029AA	809	FLAX SEED
	0.11	27038AA	1016	SAFFLOWER SEED
	0.11	28016AA	806	PEAS
	0.051	50000AA	667	MILK
	0.051	53001MA	221	CATTLE, MBYP
	0.051	53001FA	209	CATTLE, FAT
	0.051	53001MA	228	CATTLE, MEAT
	0.051	53002DA	479	GOATS, MBYP
	0.051	53002FA	472	GOATS, FAT
	0.051	53002MA	485	GOATS, MEAT
	0.051	53003MA	504	HORSES, MBYP
	0.051	53003FA	504	HORSES, FAT
	0.051	53003MA	600	HORSES, MEAT
	0.051	53005MA	1048	SHEEP, MBYP
	0.051	53005FA	1040	SHEEP, FAT
	0.051	53005MA	1054	SHEEP, MEAT
	0.051	53006MA	503	HOGS, MBYP
	0.051	53006FA	556	HOGS, FAT
	0.051	53006MA	569	HOGS, MEAT
	0.051	55000MA	912	POULTRY, MBYP
	0.051	55000FA	906	POULTRY, FAT
	0.051	55000MA	919	POULTRY, MEAT
	0.051	55019AA	428	EGGS

Chem. Name: Propham (Isopropyl carbanilate) Date: _____

Chem No.: 047601

Product Total from Printout _____

Colleen

5/5

Total Jackets Requested	Total Received	Number Used	Number Not Used

	Reg. #	PM	RB	Date Requested	Recd	N/A	Fiche Copy Date	Not Used	Comments
1	748-206	25		Cancelled 6.25.85					
2	-207	25			✓				4lb/gal F&C
3	-211	25			✓				15% G
4	-224	25			✓	✓	wrong fiche		Donnie cannot find 3 lb/gal F&C
5	748-6004.5				✓				WA
6									
7									
8	SLN								
9	CA-780057				✓				
10	CA-780058				✓				
11	CA-780196				✓				
12	CA-780211				✓				
13	CO-810025				✓	✓			
14	NV-780002				✓				
15	NV-780003				✓				
16	OR-770015				✓				
17	OR-810067				✓				
18	OR-810078				✓				
19	OR-830005				✓				
20	OR-840049				✓	✓			

✓

	Reg. #	PH	RB	Date Requested	Rec'd	N/A	Fiche Copy Date	Not Used	Comments
21	WA-770003				✓				
22	WA-810066				✓				
23	WA-830002				✓				
24	WA-830004				✓				
25	WA-840072				✓				
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GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. 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, will be 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 attempted also 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 at any time 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 a 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Propham Standard

MRID CITATION

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

00038956 Chen, Y. (1979) Characterization of IPC Metabolites in Wheat: BR 21572. (Unpublished study received Sep 17, 1979 under 748-224; submitted by PPG Industries, Inc., Barberton, Ohio; CDL: 240987-N)

00082676 Paulson, G.D.; Jacobsen, A.M.; Zaylskie, R.G.; et al. (1973) Isolation and identification of propham (isopropyl carbanilate) metabolites from the rat and the goat. Journal of Agricultural and Food Chemistry 21(5):804-811. (Also in unpublished submission received Jan 2, 1974 under 2F1277; submitted by PPG Industries, Inc., Barberton, Ohio; CDL:095164-G)

00082681 Still, G.G.; Mansager, E.R. (1973) Metabolism of isopropyl carbanilate by soybean plants. Pesticide Biochemistry and Physiology 3(3):289-299. (Also in unpublished submission received Jan 2, 1974 under 2F1277; submitted by PPG Industries, Inc., Barberton, Ohio; CDL:095164-N)

00091226 Kennedy, G.; Jenkins, D.H. (1970) Report to PPG Industries, Inc.: Distribution of IPC in Milk and Tissues of a Lactating Cow: IBT No. J8629B. (Unpublished study received on unknown date under 1F1120; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Pittsburgh, Pa.; CDL: 090895-E)

00091227 Kennedy, G. (1970) Report to PPG Industries, Inc.: Tissue and Egg Residue Study of IPC in White Leghorn Chickens: IBT No. J8630B. (Unpublished study received on unknown date under 1F1120; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Pittsburgh, Pa.; CDL:090895-F)

00115396 Paulson, G.; Docktor, M.; Jacobsen, A.; et al. (1972) Isopropyl carbanilate (propham) metabolism in the chicken: Balance studies and isolation and identification of excreted metabolites. J. Agr. Food Chem. 20(4):867-876. (Also in unpublished submission received Oct 10, 1972 under 2F1277; submitted by PPG Industries, Inc., Barberton, OH; CDL:091814-I)

OFFICE OF PESTICIDE PROGRAMS
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Citations Considered to be Part of the Data Base Supporting
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MRID CITATION

00115398 PPG Industries, Inc. (1972) Propham: Residues in Various Subjects. (Compilation; unpublished study received Oct 10, 1972 under 2F1277; CDL:091814-K)

00115421 Terrell, Y.; Parke, G. (1977) Acute Oral Toxicity in Rats: IPC Technical: Laboratory No. 7E-6373. (Unpublished study received Apr 26, 1978 under 748-207; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL: 097066-B)

00115422 Quinn, R.; Paa, H. (1975) Report to PPG Industries, Inc.: Acute Dermal Toxicity Study with IPC Technical in Albino Rabbits: IBT No. 601-07378. (Unpublished study received Apr 26, 1978 under 748-207; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:097066-C)

00115433 Reinert, H.; Parke, G. (1975) Static 96-hour Toxicity Study of PPG Industries, Incorporated Sample: IPC Technical in Bluegill Sunfish and Rainbow Trout: Laboratory No. 5E-8036. (Unpublished study received Apr 26, 1978 under 748-207; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:097066-Q)

00115434 Ravert, J.; Parke, G. (1977) Investigation of Teratogenic and Toxic Potential of IPC 50.1% ... in Rats: Laboratory No. 6E-2504. (Unpublished study received Apr 26, 1978 under 748-207; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:097067-A)

00115437 Burt, M.; Corbin, F. (1978) Uptake, translocation, and metabolism of propham by wheat ..., sugarbeet ... and ... (Medicago sativa). Weed Science 26(3):296-303. (Also in unpublished submission received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-B)

00115439 Chen, Y. (1979) Quantitative Characterization of IPC Metabolites in Chicken Egg: BR 21501. (Unpublished study received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-D)

00115440 Paulson, G.; Jacobsen, A. (1974) Isolation and identification of propham ... metabolites from animal tissues and milk. J. Agr. Food Chem. 22(4):629-631. (Also in unpublished submission received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-F)

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Citations Considered to be Part of the Data Base Supporting
Registrations Under the Propham Standard

MRID CITATION

00115441 Paulson, G.; Jacobsen, A.; Still, G. (1975) Animal metabolism of propham ...: The fate of residues in alfalfa when consumed by the rat and sheep. Pesticide Biochemistry and Physiology 5:523-535. (Also in unpublished submission received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-G)

00115442 Smith, K. (1975) Ring-14C-labelled Propham Egg and Tissue Residue Study in Laying Hens: Laboratory No. 5E-7077. (Unpublished study received Jul 2, 1979 under 748-EX-15; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-I)

00115443 Still, G.; Mansager, E. (1975) Alfalfa metabolism of propham. Pesticide Biochemistry and Physiology 5:515-522. (Also in unpublished submission received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-K)

00115446 Zurqiyah, A.; Jordan, L.; Jolliffe, V. (1976) Metabolism of isopropyl carbanilate ... in alfalfa grown in nutrient solution. Pesticide Biochemistry and Physiology 6:35-45. (Also in unpublished submission received Jul 2, 1979 under 748-EX-15; submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-N)

00115447 Zurqiyah, A.; Jordan, L.; Jolliffe, V. (1975) Metabolism of Isopropyl Carbanilate ... in Alfalfa. Part II—Soil Application. (Unpublished study received Jul 2, 1979 under 748-EX-15; prepared by Univ. of California--Riverside, Dept of Plant Sciences, submitted by PPG Industries, Inc., Barberton, OH; CDL:098350-O)

00115448 Pittsburgh Plate Glass Co. (1960) A Progress Report on IPC and CIPC Residues in Cranberries. (Compilation; unpublished study received Apr 26, 1961 under 748-EX-167; CDL:119968-A)

00115470 Hardies, D.; Studer, D. (1979) Metabolism of Isopropyl Carbanilate on a Hanford Sandy Loam: BR 21566. (Unpublished study received Sep 17, 1979 under 748-224; submitted by PPG Industries, Inc., Barberton, OH; CDL:240988-G)

00119929 PPG Industries, Inc. (1970) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method: Propham. (Compilation; unpublished study received on unknown date under 1F1120; CDL:090893-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Propham Standard

MRID	CITATION
00134707	PPG Industries, Inc. (1973) Second Substantive Amendment to Pesticide Petition No. 2F1277 concerning Establishment of Tolerances for Propham on Several Crops: Chemistry Data. (Compilation; unpublished study received 1973 under 2F1277; CDL:091813-J)
00145691	Trainor, T. (1979) Isopropylcarbanilate Product Chemistry: Technical IPC and Chem Hoe-135 F1-3: BR 21592. Unpublished study prepared by PPG Industries, Inc. 14 p.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USDI Publication 137, Washington, D.C.

OMB Approval No 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements.

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-92)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE	
ACTIVE INGREDIENT	

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient.

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing the following required items or data

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 3580-6 (10-92)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date _____

Guidance Document for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468
Expiration Date 5/31/86

ATTACHMENT D

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name: _____

and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of generic data on the active ingredient named under FIFRA sec. 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product,

OR

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____
and their registration number(s) is/are _____

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA sec. 3(c)(2)(B).

Registrant's authorized representative: _____
Signature

Dated: _____ _____
(Typed)