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Agency

Office of
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Washington DC 20460

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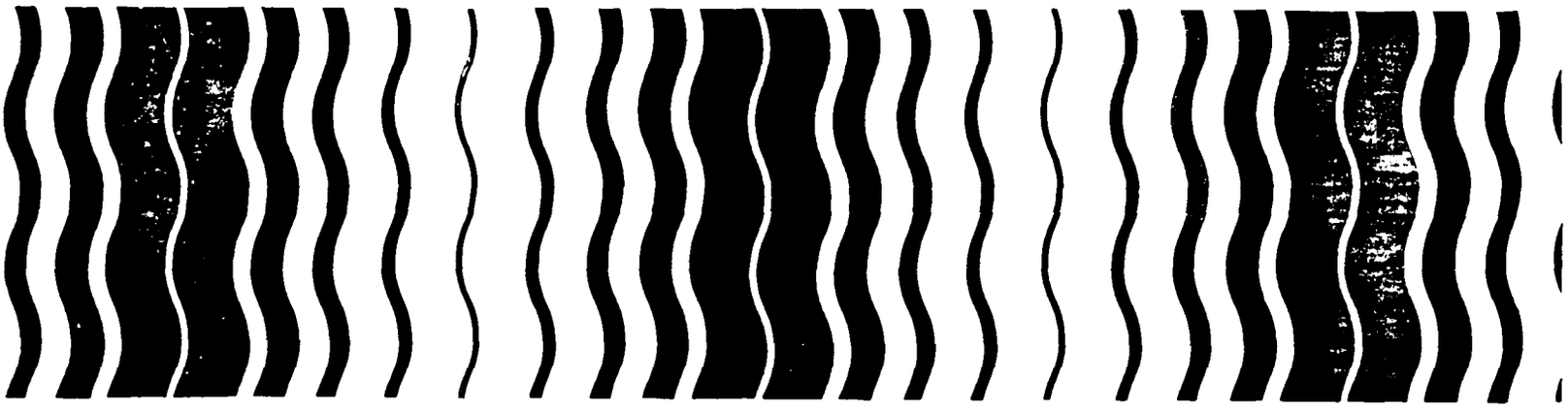
Pesticides

EPA

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



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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

ETHOPROP

AS THE ACTIVE INGREDIENT

Case Number 106

OPP (Shaughnessy) Number 041101

CAS Registry Number 13194-48-4

June 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI: Acceptable Daily Intake.

a.i.: Active ingredient.

ARC: Anticipated Residue Contribution.

CAS: Chemical Abstracts Service.

CSF: Confidential Statement of Formula.

DCI: Data Call-in.

EEC: Estimated Environmental Concentration.

EC: Emulsifible Concentrate

EP: End Use Product.

EUP: Experimental Use Permit

EPA: U.S. Environmental Protection Agency.

FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act.

FFDCA: Federal Food, Drug, and Cosmetic Act.

LC50: Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.

LD50: Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

LEL: Lowest Effect Level.

MPI: Maximum Permissible Intake.

MRID: Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.

MP: Manufacturing Use Product.

NPDES: National Pollutant Discharge Elimination System.

NOEL: No Observed Effect Level.

OPP: Office of Pesticide Programs.

FWS: U.S. Department of Interior, U.S. Fish and Wildlife Service.

PADI: Provisional Acceptable Daily Intake.

ppm: Parts per million.

RfD: Reference Dose.

TMRC: Theoretical Maximal Residue Contribution.

1. 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.

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.

A glossary of uses included in the "EPA Compendium of Acceptable Uses" and the detailed scientific review (neither of which are contained in this document), are available upon request[1]. The scientific review primarily presents the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide 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.

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[1]Scientific reviews and the EPA Compendium of Acceptable Uses may be obtained from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA. 22161. Phone: (703) 487-4650.

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

The following chemical is covered by this Registration Standard:

Common Name: Ethoprop

Chemical Name: O-ethyl S,S - dipropyl phosphorodithioate

CAS Number: 13194-48-4

OPP (Shaughnessy) Number: 041101

Chemical Class: Organophosphate

Empirical Formula: $C_8H_{19}O_2PS_2$

Molecular Weight: 242.307

Trade Names: Mocap®, VC 9-104

Description Of Physical Characteristics Of Chemical:

- Clear yellow tinted liquid with a strong mercaptan odor.
- Boiling point 86-91°C at 0.2 mm Hg.
- Solubility in water to 843 ppm at 21°C and soluble in most organic solvents.
- No corrosion observed on SAE type 1020 steel or aluminum foil of the type used to line a bag of granular formulation 332 hours at 21°C.

B. Use Profile

Type Of Pesticide: Insecticide, nematocide, and fungicide (suppression of white mold on peanuts).

Pests Controlled (In General): banana rootborer, nematodes, cutworms, rootworm, white mold, white grubs, flea beetle, aphid, mole crickets, wire-

Registered Uses (By General Groups): The registration is for use as an insecticide, nematocide, and fungicide.

Food crop application of ethoprop: bananas, broccoli (EUP), cabbage, cauliflower (EUP), corn grain, corn fodder and forage, cucumbers, mushrooms, okra, fresh corn including sweet corn (kernals plus cob with husk removed), lima beans, lima bean forage, snap beans, snap bean forage, peanuts, peanut hay, pineapples, pineapple fodder and forage, potatoes, soybeans, soybean forage and hay, sugarcane, sugarcane fodder and forage, and sweet potatoes (40 CFR §180.31 and §180.262). There are no international tolerances or Codex Maximum Residue Limits for residues of ethoprop. The ethoprop tolerances (40 CFR §180.262) should be revised to read, "pineapples, pineapple fodder and forage," instead of "pineapple fodder and forage."

Terrestrial non-food crop uses include tobacco, ornamental plants, and root dip treatments for citrus seedlings.

Domestic non-food crop uses on: Lawns [(24-c) registration for commercial applicator use only, FL800028].

Mode Of Activity: Contact.

Formulation Types Registered: Emulsifiable concentrate formulations containing 40% or more active ingredient are "Restricted Use" pesticide, and applicators must be certified or under the direct supervision of applicators certified to apply these products (44 CFR 45131, August 1, 1979). In addition, granular formulations 10% and greater have been proposed for "Restricted Use" classification on the basis of acute dermal toxicity and avian hazard (44 CFR 45218, August 1, 1979). These will be classified in accordance with the criteria for the "Restricted use classification groups" explained under 40 CFR 162.30, "Optional procedures for classification of pesticide uses by regulation", and hereafter known as "optional procedures of 40 CFR 162.30". There are no products for use or storage in or around the home.

Method Of Application: Ethoprop formulations are commonly applied by using ground equipment and are incorporated into the soil immediately after application with the use of cultivating equipment and/or

by irrigation. For the emulsifiable concentrate formulation, spray equipment (i.e., backpack sprayers) and watering cans may be used for application. The specific type of equipment is determined by site and equipment availability.

C. Usage Information

It is estimated that domestic annual usage of ethoprop ranges from 1.6-2.6 million pounds of active ingredient. Usage appears to be declining although data supporting this are limited. Ethoprop is registered for use as an insecticide, nematicide, and fungicide.

Domestic usage of ethoprop during 1985-86 was distributed among field corn (26-30%), tobacco (19-33%), potato (11-13%), soybean (11-13%), turfgrass (11-13%), peanut (5-6%), cabbage (3-4%), sweet potato (3-4%), sweet corn (1%), and lima and snap beans (<1%). Estimates are unavailable for ethoprop use on cirtus seedlings, cucumber, pineapple, and sugarcane. Estimates of the proportions of total crop acreage treated with ethoprop are presented for lima and snap beans (<3%), cabbage (15-20%), field corn (<1%), sweet corn (<5%), peanut (<5%), potato (<3%), soybean (<1%), sweet potato (18-22%), and tobacco (<15%).

III. AGENCY ASSESSMENT

A. Summary

As part of the registration process, the data base for ethoprop was first reviewed in 1983, and a Ethoprop Registration Standard was published. In that Standard, data gaps were identified according to policies then in place. Registrants were notified of the required studies and the time frames for submittal of data to the Agency. Data were submitted. The Agency has now evaluated all new data supporting the registration of Ethoprop, and reevaluated earlier studies especially in cases where the policy on criteria for acceptability has changed. This Standard summarizes, identifies, and discusses the Agency's concerns.

1. The Agency has identified a potential avian adverse effect concern. Precautionary statements are needed on manufacturing-use and end-use product labels to protect avian species.

2. The "Restricted Use" classifications for all ethoprop emulsible concentrate formulations containing 40% and greater will continue. Granular formulations 10% and greater have been proposed for "Restricted Use" classification on the basis of acute dermal toxicity and avian hazard (44 FR 45218, August 1, 1979). These will be classified in accordance with optional procedures of 40 CFR 162.30.

3. Tolerances are presently established (40 CFR §180.262, §180.31) at 0.02 ppm for residues of ethoprop per se. A major change in the tolerances for this chemical is not anticipated. A final reevaluation of the acceptable daily intake will be made when the requested new data are received and evaluated. In the interim, no new tolerances for ethoprop will be granted. There are no international tolerances or Codex Maximum Residue Limits for residues of ethoprop.

4. Due to the incomplete environmenal fate data base, no determination regarding the potential for ground water contamination can be made. Submission of ground water data is required. In the column study, ethoprop was very mobile. K_{des} values of ethoprop ranged from 1.97 to 14.18 in silt loam, a silty clay loam, and two sandy loam soils. The half-life of ethoprop was 84-112 days in the aerobic metabolism study in loam sand soils. In the anaerobic metabolism study, 79.1 to 58.2% of the applied [^{14}C]-ethoprop degraded during 56 days. Additional studies required to assess the potential of ground water contamination are: hydrolysis, photolysis in water and soils and leaching of soil degradates, and field dissipation.

5. The Agency has identified data necessary to fully evaluate the environmental and human risk associated with the use of ethoprop. The registrant must develop these data in order to maintain registration of products or register new products containing ethoprop. A summary of the data gaps appears in Table 1 (pages 12 and 13) and complete details are given in Appendix 1.

B. Health Risk Assessments

1. Acute Toxicity

Valid studies indicate that ethoprop is highly toxic (category I) to mammals when administered orally, dermally, or via inhalation. The oral LD50 for rats is as follows (mg/kg): Males, 61.03 (49.19 - 75.01); females, 32.8 (25.41-42. 24). The acute dermal LD50 for rabbits is 25.7 (14.44-45.83) mg/kg. The acute inhalation toxicity (LC50) for rats is 0.12 (0.08-0.17) mg/l. Application of 0.1 of undiluted ethoprop (technical) into rabbit eyes for the eye irritation test produced 100% mortality within one hour. A primary irritation index was not calculated for the rabbit dermal irritation test, because all the rabbits died within eight hours post exposure. The Agency does not have a sensitization study. Additional irritation studies, dermal and ocular, and a sensitization study are not required at this time because of the mortality observed in the test animals. No acute delayed neurotoxicity in hens was observed in a valid study performed with Mocap EC [approximately 70% active ingredient (ethoprop)

active ingredient (ethoprop) by weight)], and no further testing is required. The acute oral LD50 of Mocap EC in chickens is 9.9 (8.1-12.1) mg/kg.

2. Subchronic Toxicity

Subchronic oral (non-rodent): An acceptable 13-week study was conducted using the beagle dog. Ethoprop (technical) was tested using dietary dose levels of 1.0, 3.0, and 100 ppm. Cholinesterase inhibition was the only treatment-related effect noted. No toxicologically significant inhibition of plasma or erythrocyte cholinesterase was judged to have occurrred at the lowest dose tested (1.0 ppm; 0.075 mg/kg). The lowest effect level for cholinesterase depression was 3.0 ppm (0.225 mg/kg/day).

Subchronic oral (rodent): Three groups of 25 albino (Charles River Strain) rats per sex were fed ethoprop technical in the daily diet at doses of 0. 0.3, 1.0, or 100 ppm for 90 days. The pattern of cholinesterase inhibition suggests that the NOEL is approximately 0.3 ppm (0.015 mg/kg/day). The subchronic feeding study (rats) is considered supplemental, and has been used to establish a provisional acceptable daily intake (PADI). A new subchronic rat study is not required provided an acceptable rat chronic feeding study is conducted. The data obtained from the chronic study will suffice in this case for the information needed for a subchronic oral toxicity study.

Subchronic dermal: The 21-day dermal study showed no treatment related clinical signs of toxicity or mortality. However, brain cholinesterase inhibition was observed at all doses tested. This study is considered flawed, and an acceptable study is required. Large variations existed in plasma and erythrocyte cholinesterase levels observed among the animals on test. No additonal subchronic studies (90-day dermal, inhalation) are required, because the existing acceptable use pattern should not result in repeated or extended exposure. A study for subchronic neurotoxicity is not required, because the acute neurotoxicity data do not indicate a delayed neurotoxicity problem.

3. Chronic Toxicity

Beagle dogs were fed ethoprop in their diets at 0, 0.025, 1.0 and 10 mg/kg/day for 52 weeks. Plasma cholinesterase (ChE) was inhibited in females at all dose levels. Whereas, the mid- and high dose levels are effect levels for erythrocyte ChE inhibition, and the high-dose is an effect level for brain ChE inhibition. Also, all male dogs at all dose

levels exhibited less weight gain than the control group. No NOEL could be determined from the study. In order to determine a NOEL for plasma erythrocyte and and the issue of decreased male body weight gain in all test groups, the Agency is requiring an abbreviated study of 17 weeks.

In the chronic feeding study, Fisher 344 rats were fed 0, 4.5, 9.0 and 18 ppm of ethroprop for 12 weeks, and then placed on diets of 0, 49, 98 or 196 ppms for the remaining 52 weeks. Cholinesterase inhibition was observed at all the dose levels and a NOEl could not be determined. The MTD was considered to be the highest dose tested. The study is considered supplemental, and additional information is required.

The one year dog chronic feeding study is evaluated to be inadequate, but does not need to be repeated. The Agency is requiring specified special studies to resolve the deficiencies noted in the one-year dog chronic feeding study. The Agency review for chronic and oncogenic potential in rats (MRID 00138636) indicated that for the chronic feeding portion of this study the classification was core-supplemental. It cannot be upgraded since no NOEL for cholinesterase inhibition was observed. At all doses of ethoprop tested, cholinesterase inhibition of >20% was observed. Additional information must be submitted. In addition, the Agency is requiring summary incidence tables for clinical observations.

4. Oncogenicity

B6C3F1 mice were fed 0, 15, 30, and 60 ppm of ethoprop in their diet for 78 weeks. The study did not demonstrate oncogenic effects under the conditions of this study. However, the highest dose tested (60 ppm) is considered to be at least two times under the maximum tolerated dose. This study is considered supplemental and must be repeated.

Fisher 344 rats were fed 0. 4.5, 9.0, and 18 ppm of ethoprop for 12 weeks, and then placed on diets containing 0, 49, 98, or 196 ppm of ethoprop for the remaining 52 weeks. Under the conditions of this study, there was an increase in the number of C-cell adenomas of the thyroid in males receiving the high-dose when compared to controls, and there was a dose-related increase in the number of endometrial polyps in females. However, the total number of individual tissues examined histologically per group was not presented. Consequently, the incidence of these lesions cannot be determined or analyzed statistically, and an evaluation of the oncogenic potential of ethoprop cannot be performed from the reported study. This study is considered by the Agency to be supplementary. Additional data are required.

5. Mutagenicity

An acceptable battery of mutagenicty tests (gene mutation, chromosomal aberration, and DNA damage) are available. However, an acceptable bone marrow cytogenetic analysis in rats is needed to provide in vivo confirmation of in vitro findings in the chromosomal aberration studies submitted.

The results of the available mutagenicity studies are as follow:
1. Gene mutation: a) Reverse Mutation in Salmonella typhimurium (negative). b) In vitro CHO Sister Chromaid Exhange Assay (positive).
2. Chromosomal Aberration: a) In vitro CHO Cell Cytogenic Assay (positive). b) In vitro CHO Sister Chromaid Exchange Assay (positive).
3. DNA Damage Unscheduled DNA Synthesis In Primary Rat Hepatocytes (inactive in this assay).

6. Teratology

Ethoprop technical was adminstered by oral intubation to groups of Sprague-Dawley rats at doses of 0. 0.16, 1.6, and 16.0 mg/kg/day (MRID 00104532). However, based on the data presented and the current guidelines for examining teratology studies, the potential of the test material to cause developmental toxicity cannot be fully evaluated. More specifically, certain deficienceis were noted in the rat study at the time the initial registration standard was prepared (although occurrances of compound-related terata were not). At that time, a request was made for historical control data with regard to parameters such as delayed ossification. Apparently, these data were not submitted. Since then, new Agency guidelines have stressed that observations be made for all aspects of developmental toxicity, and not just occurrances of terata. For these reasons, complete historical control data for all measured fetal and maternal parameters (details in MRID 00104532) and individual litter data for all measured fetal parameters are now required. The issue of potential developmental toxicity in the rat needs to be addressed before the status of the study (now supplemental) can be upgraded.

A teratology study in New Zealand White rabbits was submitted in which ethoprop technical was administered by gavage to groups of animals at doses of 0, 0.125, 0.500, and 2.00 mg/kg. Since the data submitted in the study were not sufficient to fully evaluate such things as whether test material adminstration resulted in maternal toxicity or resulted in an increase in skeletal variations, a NOEL and LEL for maternal and developmental toxicity could not be determined. Additional data, including historical control data for fetal and maternal parameters, are needed for the resolution of these issues (MRID 00161619).

7. Reproduction

A three-generation study in Fisher 344 rats in which ethoprop technical was administered at dose levels of 0, 60.5, 131, and 262 ppm was not sufficient to satisfy the data requirements for reproductive toxicity (MRID 00162164). The data presented were considered insufficient to determine a NOEL and LEL for maternal and developmenal toxicity. Questions were raised with regard to culling procedures and the appropriateness of other parts of the protocol, animal illness, lack of food consumption and diet analysis data, inadequate data presentation, and descrepancies in data reporting.

8. Metabolism (§85-1; special study)

Available studies are not adequate to fulfill the requirement for metabolism data. An adequate study is required in the rat. Total [^{14}C] recovery in the three test groups accounted for 74 to 82 percent of the [^{13}C] dose. The low recoveries may have been associated with the volatility of the test material and its metabolites. However, an adequate intercomparison of [^{14}C] elimination data and levels of metabolites between sexes and test groups cannot be made because of the low recoveries. O-ethyl-S-propylphosphorothioic acid and O-ethyl-phosphoric acid were detected in urine as well as unchanged ethoprop (<0.7% of the dose) in animals receiving the low dose. Analysis for fecal metabolites was not performed. The study presented is classified as supplementary.

9. Other Special Studies (See pages 42 and 43 for additional information).

The following special studies are required in support of the registration standard to address questions generated from the evaluation of the submitted data:

a) A special study is required in rats for the purpose of determining a definitive NOEL for plasma, erythrocyte, and brain cholinesterase inhibition. A protocol should be submitted to the Agency for approval prior to commencement of this study.

b) A subchronic feeding study in dogs is required to address issues of decrease in animal body weight gain and the lack of a NOEL for cholinesterase inhibition in the present 1-year study. This study is required for purposes of determining a sensitive species for cholinesterase inhibition. A protocol should be submitted to the Agency prior to initiation of this study.

c) An acceptable rat bone marrow cytogenetic analysis study is required for in vivo confirmation of in vitro cytogenetic findings observed in the chromosomal aberration studies.

d) Two 60-day mouse studies are required in order to resolve the question of whether eye lesions observed in the 78-week mouse oncogenicity study were systemic effects of the test material administration. One test must be conducted by oral gavage in the B6C3F1 mouse, and the other one must be a dietary study in another mouse strain.

C. Other Science Findings

1. Ecological Effects

a. Avian Studies

Ethoprop technical is highly toxic (acute oral, dietary, and dermal) to bird species. There are sufficient data to characterize ethoprop as highly toxic to very highly toxic orally to upland game birds [ring-neck pheasants; 95% a.i.; LD50= 118 (103-134) mg/kg] & [bobwhite quail; 95% a.i.; LD50 = 33 (27-40 mg/kg]. Ethoprop is highly toxic to waterfowls [mallards; LC50 = 287 (215-382) mg/kg].

Acceptable acute and subchronic dietary toxicity studies are available. Pending the results of the field dissipation study, an avian reproduction study is required. Acute and simulated field studies show sufficient hazard to wildlife to require the following field studies: 1) One study with the emulsifiable concentrate (EC) on pineapple. 2) One study with the granular product on corn or potatoes.

b. Aquatic Studies

Technical ethoprop is very highly toxic to aquatic invertebrates. [Daphnia magna; 99.7% a.i.; EC50 = 0.093 (0.056-0.18) ppm].

Ethoprop is moderately to highly toxic to rainbow trout [92% a.i.; LC50 = 1.02 (0.56-2.10) mg/l], and highly toxic to bluegills [92% a.i.; LC50 = 0.30 (0.23-0.40 mg/l].

Ethoprop is highly toxic to crustaceans, and the data are as follow: a) Mysidopsis bahia (shrimp); LC50 = 23 ppb. b) Penaeus tylirostris (shrimp); LC50 = 7.2 ppb. c) Callinectes sapidus (blue crabs); 100% mortality at 24 hrs when exposed to 1 ppm.

For marine fish species, ethoprop is highly toxic. The 96 hour LC50s found during static testing with technical etho-18op wre 748.3 ppb for sheepshead minnows (Cyprinidon variegatus) and 32 ppb for spot (Leiostomus xanthurus). Flow-through procedures established 96-hour LC50s of 232.67 ppb for sheepshead minnows and 7.2 ppb for pinfish (Lagodon rhomboides).

Ethoprop is slightly toxic to embryo larvae of oyster species [95% a.i.; EC50 = 11.0 (5.6-32) ppm].

Further assessment of the potential hazards to aquatic organisms cannot be made until certain environmenal fate data are submitted and reviewed. At that time, an estimated environmental concentration (EEC) will be developed. Further aquatic data requirements will be developed. Further aquatic data requirements will be reserved until the EEC and environmental fate data are available.

2. Summary Of Data Gaps

The Agency has identified missing data required to fully evaluate the human and environmental risks associated with the use of ethoprop. Complete data gaps details may be obtained by referring to the tables in Data Appendices I. A summary of these data gaps has been made (Table 1).

Table 1: Summary Of Data Gaps.

Please refer to the tables in Data Appendices I for detailed information regarding these requirements.

Toxicology

°21 day dermal toxicity (rabbit).
°90 day feeding (rodent; not required if a chronic rat feeding study is performed).
°Chronic toxicity (rodent and nonrodent).
°Oncogenicity (mouse, rat).
°Teratogenicity (rat, rabbit).
°Reproduction (2-generation rat).
°Mutagenicity testing (structural chromosomal).
°Metabolism (§85-1).
°Special testing.

Environmental Fate/Exposure

°Hydrolysis.
°Leaching and adsorption/desorption.
°Soil dissipation.
°Soil dissipation, long term.
°Spray drift
°Photodegradation in air, soil, and water.
°Volatility (lab).
°Volatility (field).
°Rotational crops (confined; accumulation).
°Rotational crops (field; accumulation).
°Accumulation (fish).

Table 1: Summary Of Data Gaps Con't.

Fish & Wildlife

°Actual field testing with birds.

Residue Chemistry

°Nature of residue (metabolism, plants, and livestock).
°Residue analytical methods.
°Storage stability data.
°Magnitude of residue in meat, milk, poultry, and eggs.
°Residue Data

Product Chemistry

°All purity and composition.
°Analysis and certification of product.
°Physical and chemical characteristics; i.e. color, physical state, odor, boiling point, dissociation constant, stability.
°All analysis and certification of product ingredients.

D. TOLERANCE REASSESSMENT

Tolerances have been established (40 CFR §180.262, §180.31) at 0.02 ppm for residues of ethoprop per se in or on the raw agricultural commodities. A conclusive tolerance reassessment was not made at this time due to the lack of information on : a) The metabolism of ethoprop in plants and animals. b) Storage stability. c) Residue and toxicity studies. A final reevaluation of the tolerances and ADI will be made as soon as the requested data concerning storage stability, metabolism, residue, and toxicity are evaluated. No new tolerances for ethoprop will be granted in the interim. There are no international tolerances or Codex Maximum Residue Limits for residues of ethoprop. The ethoprop tolerances (40 CFR §180.262) should be revised to read, "pineapples, pineapple fodder and forage," instead of "pineapple fodder and forage." Temporary tolerances have expired for the following: grapes (12-31-84), Broccoli and cauliflower (4-28-88).

1. Evaluation Of Residue Data

a. Metabolism

Data on the metabolism of ethoprop in plants are not considered adequate. These data identified several plant metabolites of ethoprop, but did not quantitate them. Given the nature of this chemical, unusual or exceptionally toxic metabolites are not expected. Quantitation of known and/ or supposed metabolites will allow a more complete toxicological evaluation. Additional ^{14}C-radiolabeled experiments on corn,

potatoes, and cabbage are needed. Although not required previously, metabolism studies on ruminants and poultry are now needed to elucidate the pathway for metabolism of ethoprop in animals. Tolerances for ethoprop are currently expressed in terms of parent compound per se, and will be reassessed when the additional required studies are submitted and reviewed.

b. Analytical Enforcement Methods

Adequate analytical methodology is available for enforcement of the present tolerances in terms of ethoprop per se. Ethoprop is completely recovered by the multiresidue procedures in the Pesticide Analytical Manual, Vol. 1 (protocols II and III), and partially recovered by protocol I. No data are available for protocol IV. These data are required. If any metabolites of toxicological concern are identified in the metabolism studies required, additional validated methodology may be needed.

c. Storage Stability

Current guidelines require storage stability studies for appropriate raw agricultural commodities using weathered and fortified samples (40 CFR §158.120). This information and sample histories for previously submitted residue trials are required (see Appendix I).

d. Residues

The available data support the tolerances for ethoprop per se in potatoes, sweet potatoes, bananas, peanut nutmeats, and sugarcane. Based on available data, the established tolerance levels appear to be adequate. However, the available data are insufficient to fully assess the tolerances for residues in or on cabbage, lima beans, lima bean forage, snap beans, snap bean forage, soybeans, soybean forage, soybean hay, cucumbers, corn grain, sweet corn (kernel plus cob with husk removed), corn forage, and pineapples. Additional field residue data are required for these crops. There are no registered uses for mushrooms or okra, and the tolerances of .02 ppm are to be rescinded.

Food or feed additive tolerances may be required to cover possible residues of ethoprop and any metabolites of toxicological concern in the processed commodities of potatoes, soybeans, corn, peanuts, pineapples, and sugarcane. Processing studies on these commodities are therefore required in order to determine the need for these tolerances.

Tolerance proposals as well as appropriate supporting residue data are needed for the following raw agricultural commodities of crops having registered uses: bean hay (including snap bean, and lima hay), soybean straw, peanut hulls, and peanut vines. Consistent with current guidelines, these raw

agricultural commodities are now considered to be major feed items.

2. Evaluation of The ADI

The acceptable daily intake (ADI) for cholinesterase inhibition in man is usually determined on the basis of a no-observed effect level (NOEL) from a chronic feeding study. Because the chronic feeding studies evaluated for this standard were unacceptable, the Agency will continue to use the sub-chronic rat study to establish the Provisional Acceptable Daily Intake (PADI) as in 1983. The PADI of 0.000015 mg/kg/day is used for Tolerance evaluations and is based on a 90-day rat feeding study (MRID 00075239), a NOEL for cholinesterase inhibition estimated to be 0.015 mg/kg/day, and a safety factor of 1000.

A 200-fold safety factor is normally used when a 90-day study is substituted for a long-term study. In this case a safety factor of 1000 was used because the 90-day rat study only suggested a NOEL. It did not definitively support it. To assure safety, the larger safety factor was used.

A comparison of published tolerances to the PADI was conducted using the TAS Routine Chronic Analysis. The TAS analysis estimates the average dietary exposure for the U.S. population. The TMRC is 0.000073 mg/kg/day which occupies 489% of the PADI. The actual residues to which the public is exposed are likely to be considerably less than the Theoretical Maximum because:

a) as published in 40 CFR 180.262, the established tolerances on all but two minor crops are based on limits of detection for the analytical method used for ethoprop. Additionally, every crop having a tolerance is not treated;

b) processing and time-to-market often results in residue reduction;

c) not all crops contributing to the TMRC are likely to be consumed by an individual, and;

d) market basket surveys conducted by FDA indicate that little if any real pesticide residues of organophosphates actually remain in/on finished foods.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Position And Rationale

1. Special Review

The Agency is not initiating a special review of ethoprop at this time. The Agency has identified a potential avian adverse effect concern. As an interim measure, precautionary statements are required on manufacturing-use and end-use product labels to protect birds. The Agency is calling in all of the data identified as gaps in the Agency's ethoprop data base. When the new data are evaluated, the Agency will determine whether or not ethoprop meets or exceeds any of the special review criteria.

Rationale: Based on the review and evaluation of all available data for ethoprop, the Agency has determined that a special review of ethoprop is not warranted at this time.

2. Restricted Use

The "Restricted Use" classification of all ethoprop emulsifiable concentrate formulations containing 40% or greater under FIFRA §162.31 will remain in effect, and applicators must be certified or under the direct supervision of applicators certified to apply these products (44 FR, 45131, August 1, 1979). It is the Agency's position that these products must bear appropriate restricted use labeling in order to remain in compliance with FIFRA. In addition, granular formulations 10% and greater have been proposed for restricted use.

Rationale: All ethoprop emulsifiable concentrate formulations (40% or greater) have been classified for retricted use based on toxicity data. Technical ethoprop is in Toxicity Category I on the basis of acute oral and inhalation effects. Ethoprop can be acutely lethal from exposure to skin and/or eye(s). Due to the early deaths of the test animals from ethoprop by the ocular and dermal routes, the eye and dermal irritation tests could not be completed. Although there are numerous toxicology and ecological effects data gaps, available data are sufficient to show continuing concern. To enable the public and/or user to be aware of the reasons for the restricted use classification, a statement identifying the reasons for the restriction are to appear on the label. Granular formulations 10% and greater have been proposed for "Restricted Use" classification on the basis of acute dermal and avian hazard (44 FR 45218, August 1, 1979). These will be classified in accordance with the optional restricted use classification procedures of 40 CFR 162.30. There are no products for use in or around the home.

3. Tolerance And New Uses

The Agency will not grant any new tolerances or new uses for ethoprop until data required under this Standard have been received and all tolerances reassessed. The ethoprop tolerance of 0.02 for certain foods appears to be adequate. A final reevaluation of the tolerances and acceptable daily intake (ADI) will be made when the new data requested are received and evaluated.

Rationale: A conclusive tolerance assessment was not possible at this time due to the following: a) Metabolism of ethoprop in plants and animals is not fully understood. b) Storage stability. c) Residue and toxicity studies. A final reevaluation of the tolerances will be made when these concerns are resolved.

4. Groundwater

The Agency is unable to provide a quantitative estimate of the ethoprop potential for groundwater contamination.

Rationale: Ethoprop was found to be very mobile in columns of loamy sand and loam soil types. Additional studies required to assess the potential for groundwater contamination include hydrolysis, photolysis in water and soils, leaching of soil degradates, and field dissipation.

5. Nontarget Organism Labeling

In order to remain in compliance, updated label precautions are required by this Standard to address the hazard to fish and wildlife.

Rationale: Based on studies available to assess hazards to wildlife and aquatic organism, ethoprop is characterized as highly toxic to birds, marine/estuarine crustaceans, and marine/estuarine fish species. Ethoprop is slighly toxic to embryo larvae of oyster species. It is moderately toxic to honey bees.

6. Reentry Requirements

The Agency will reevaluate reentry protection when the requested data are received (40 CFR §158.140, Appendix I). In the interim, PR Notice 83-2 (March 29, 1983), and 40 CFR §170 pertaining to worker protection standards for agricultural pesticides must be followed.

Rationale: PR Notice 83-2 and 40 CFR §170 address worker protection standards for pesticides. The Agency has established for the present time a 24 hours reentry interval for all uses. The Agency is requiring soil dissipation data for those crops where agricultural practices involve human tasks, and where there would be direct exposure to pesticide treated soil (e.g., the harvest of potatoes). The reasons for the requirement of foliar and soil dissipation studes are as follow: 1) Ethoprop is in toxicity category I. 2) Ethoprop has a high vapor pressure (3.7×10^{-2} mmHg at 26°C). 3) Ethoprop is registered for food and non-food uses. 4) From 10-20% of applied ethoprop has been found on the surface of the soil. 5) Ethoprop exceeds both the criteria for toxicity and exposures as delineated in subdivision K of the Pesticide Assessment Guidelines.

7. Endangered Species

The U.S. Department Of Interior's Fish and Wildlife Service (FWS) has determined that certain uses of ethoprop may jeopardize the contined existence of endangered species or certain endangered species. EPA is develoing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed.

No new labeling is being required at this time. As explained below, labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn pending reissuance.

Rationale: In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to the FWS findings that certain pesticides, including ethoprop, jeopardized the continued existence of endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988, the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

8. Continuation Of Registration

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing ethoprop 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 sec. 3(c)(2)(B) and 3(c)(7). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, and then the Agency will determine if additional regulatory changes are necessary.

9. Review Of Data Submitted

The Agency has identified certain data that will receive priority 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.

§158.125 - Residue Chemistry

171-4 - Residue Analytical Method
171-4 - Nature of Residues (Metabolism)
171-4 - Magnitude of the Residues in Plants

§158.130 - Environmental Fate

161-1 - Hydrolysis
161-2 - Photodegradation - in water
161-3 - Photodegradation - in soil
161-4 - Photodegradation - in air
163-1 - Leaching and Adsorption/Desorption
163-2 - Volatility (Lab)
164-1 - Field Dissipation - Soil
165-1 - Confined Rotational Crop
165-2 - Field Rotational Crop

§158.135 - Toxicology

00-0 - Special Studies required on pages 10 and 11 of this Standard
83-1 - Chronic Toxicity (rodent)
83-2 - Oncogenicity - mouse, rat
83-3 - Teratology (rat, rabbit)
83-4 - Reproduction (rat)
85-1 - Metabolism

§158.145 - Wildlife and Aquatic Organisms

71-5 - Simulated and Actual Field Testing

§158.142 - Reentry Protection

132-1 - Foliar Dissipation
132-1 - Soil Dissipation

§158.142 - Spray Drift

202-1 - Drift Field Evaluation

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, manufacturing-use and end-use products must contain ethoprop as the sole active ingedient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section C below.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain ethoprop. 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 impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing ethoprop provided that the product labeling bears appropriate precautionary statements for the acute toxicity category into which each product falls.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below.

°Terrestrial, food uses on: bananas, broccoli (EUP), cabbage, cauliflower (EUP), corn grain, corn fodder and forage, cucumbers, fresh corn including sweet corn (kernals plus cob with husk removed), lima beans, lima bean forage, snap beans, snap bean forage, peanuts, peanut hay, pineapples, pineapple fodder and forage, potatoes, soybeans, soybean forage and hay, sugarcane, sugarcane fodder and forage, and sweet

potatoes (40 CFR §180.262). The ethoprop tolerances section (40 CFR §180.262) is being revised to read, "pineapples, pineapple fodder and forage," instead of "pineapple fodder and forage."

°Terrestrial, non-food uses on: citrus seedlings, ornamentals (including aglaonema, azalea, boxwood, bromeliads, cacti, caladium, camellia, Cape Jasmine, fern, gardenia, holly, philodendron, pothos, sanservieria, and yew), and tobacco.

°Domestic outdoor use on: lawns [Special Local Needs (24) (c)] registration for commerical applicator use only, Florida (FL)-800028.

°Greenhouse non-food use on: ornamentals (as specified above).

The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

D. Required Labeling

All products must bear appropriate labeling as specified in 40 CFR §162.10, PR Notices 83-2, 83-3, and below. Appendix II contains further information on label requirements.

Pesticide products containing ethoprop as an active ingredient may not be released for shipment by the registrant after July 1, 1989 unless the product bears amended labeling that complies with the requirements of this Standard. Five (5) copies of the labeling, revised in accordance with this Standard, must be submitted prior to release for shipment.

Pesticide products containing ethoprop as an active ingredient may not be distributed, sold, offered for sale, (having been so received) delivered or offered to be delivered by any person after July 1, 1990 unless the product bears amended labeling, five copies of which have been submitted to the Agency, that complies with the requirements of this Standard.

1. Use Pattern Statements

The ingredients statement for MPs must list the active ingredient as: Ethoprop, (O-ethyl S,S-dipropyl phosphate)... ___%. In addition, the total percentage by weight of all inert ingredients must be listed. All MPs must state that they are intended only for formulation into end-use products

for any of the use patterns listed agove. See the specify sites listed in Use Patterns listed on the pages 19 and 20. A limiting factor will be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or B for that use pattern.

2. Precautionary Statements

Labeling for all MP products containing ethoprop must bear statements reflecting the acute human toxicity of the compound. Ethoprop is in Toxicity Category I when administered orally, dermally, or via inhalation. Ethoprop can be acutely lethal if absorbed through the eye. The required precautionary statements associated with Toxiciy Category I are specified in 40 CFR 162.10.

3. Human Hazard Statement

In addition to the Toxicity Category I labeling requirements identifided above, the following human hazard statement, based on data reveiwed by the Agency, must appear on all manufacturing-use product labels: "Poisonous if absorbed through the eye(s). Do not get in eyes."

4. Manufacturing-use Products

The following revised environmental hazard statement must appear on all manufacturing-use product labels: "This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDS permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your local State Water Board or Regional Office of the EPA.

5. For Granular End-Use Products

The following label is required: "This pesticide is toxic to aquatic organisms (fish and invertebrates), and wildlife. Birds feeding in treated areas may be killed. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Do not contaminate water when disposing of equipment wash water."

6. For Non-granular End-Use Products

"This pesticide is toxic to aquatic organisms (fish and invertebrates) and extremely toxic to birds. Cover or disc spill areas. Birds in treated areas may be killed. Do not

apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff may be dangerous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

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 follow:

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

1. The restrictions upon use, composition, or packaging listed in Section IV.

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, and 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.

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

1. The data requirements listed in Table A.

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

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:

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

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

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

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 granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider

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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.

that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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 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. <u>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</u>. 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 as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. 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. <u>You request that EPA amend your registration by deleting the uses for which the data are needed</u>. You are not required to submit data for uses which are no longer on your label.

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

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. Good Laboratory Practices Standards must be followed (40 CFR, Part 160).

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert 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, 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.

G. 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 by the 90-day 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 data submission 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.

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.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

I. 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 VI.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 VI.D.1. (submit data) or VI.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 156.10 (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 156.10 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 (MPs) containing the subject pesticide 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.

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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.)

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).

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 the subject pesticide 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 9 months of receipt of this document, you must submit to the Product Manager:

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.

3. 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 the subject pesticide 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. End Use Products containing the subject active ingredient as one of multiple active ingredients

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

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).

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

Applications for full Federal registration of intrastate products are required to be submitted no later than July 31, 1988.

F. Addresses

The required information must be submitted to the following address:

William H. Miller (PM-16)
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 Assurance Division Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

TGUIDE-1

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.

TGUIDE-2

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 MRID 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 Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission 3/
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral Toxicity - Rat	TGAI	A	Yes	00078053	No	--
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00078035	No	--
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	Yes	00128218	No	--
81-4 - Eye Irritation	TGAI	A	Yes	0078036	No	--
81-5 - Dermal Irritation	TGAI	A	Yes	0048774	No	--
81-6 - Dermal Sensitization	TGAI	A	No	--	No 4/	--
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	Yes	0078037, 0078038	No	--
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent, and	TGAI	A	No	--	Yes 5/	15 Months
- Nonrodent (Dog)	TGAI	A	Yes	00075240	No	--
82-2 - 21-Day Dermal - Rabbit	TGAI	A	No	--	Yes 6/	12 Months

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission 3/
§158.135 Toxicology (cont'd)						
Subchronic Testing (cont'd)						
82-3 - 90-Day Dermal - Rabbit	TGAI	A	No	--	No 7/	--
82-4 - 90-Day Inhalation - Rat	TGAI	A	No	--	No 8/	--
82-5 - 90-Day Neurotoxicity	TGAI	A	No	--	No 9/	--
Chronic Testing						
83-1 - Chronic Toxicity - 2 Species						
- Rodent, and	TGAI	A	No	--	Yes	50 Months
- Nonrodent (Dog)	TGAI	A	Yes	00160179	Yes 10/	50 Months
83-2 - Oncogenicity - 2 Species						
- Rat (preferred), and	TGAI	A	Partial	00138636	Yes 11/	50 Months
- Mouse (preferred)	TGAI	A	Partial	00137496	Yes 12/	50 Months
83-3 - Teratogenicity - 2 Species						
- Rat	TGAI	A	Partial	00104532	Yes 13/	15 Months
- Rabbit	TGAI	A	Partial	00161619	Yes 14/	15 Months
83-4 - Reproduction - Rat 2-Generation	TGAI	A	Partial	--	Yes 15/	39 Months

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission 3/
§158.135 Toxicology (cont'd)						
Mutagenicity Testing (cont'd)						
84-2 - Gene Mutation (Ames Test)	TGAI	A	Yes	00160180, 00160181	No	--
84-2 - Structural Chromosomal Aberration	TGAI	A	Yes	00160183, 00160184	No[16]	12 Months
84-4 - Other Genotoxic Effects	TGAI	A	Yes	00160182	No	--
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A	No	--	Yes	24 Months
85-2 - Dermal Penetration	Choice	A	No	--	No	--
86-1 - Domestic Animal Safety	Choice	A	No	--	No[17]	--
Other Special Testing						
Rat Study[18]	TGAI	A	No	--	Yes[18]	14 Months
Subchronic Study[19]	TGAI	A	No	--	Yes[19]	18 Months
Rat Bone Marrow Cytogenetic analysis[20]	TGAI	A	No	--	Yes[20]	14 Months
Subchronic Studies (2)[21]	TGAI	A	No	--	Yes[21]	24 Months

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Footnotes

1/ Composition: TGAI = Technical Grade Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.
3/ Due dates refer to the number of months following the registrants receipt of this Registration Standard unless indicated.
4/ A study is not required because of the high acute dermal toxicity of technical grade Ethoprop.
5/ This study is not required if a chronic rat feeding study is performed.
6/ This requirement may be satisfied if questions raised about the study, such as too many hemolyzed blood samples and large variations in plasma and erythrocyte cholinesterase levels, are satisfactorily addressed.
7/ This study is not required because existing acceptable use patterns should not result in repeated or extended human skin contact.
8/ This study is not required because existing acceptable use patterns should not result in repeated or extended human contact by the inhalation route.
9/ This study is not required because the available acute delayed neurotoxicity data do not indicate a delayed neurotoxicity problem.
10/ This requirement may be satisfied if a special study resolves certain issues raised about the study (such as decreases in body weight gain and cholinesterase inhibition at the lowest dose tested).
11/ This requirement may be satisfied if additional data, needed to fully evaluate oncogenic potential, are supplied (such as the numbers of individual animal tissues and organs subjected to histopathological exam).
12/ This study does not fulfill requirements because a maximum tolerated dose was not attained or approximated. Additional supporting data are required prior to the final decision regarding the acceptability of this study. Two addtional special subchronic studies in the mouse are required to resolve the issue of eye lesions in the mouse oncogencity study.
13/ This requirement may be satisfied if issues regarding potential developmental toxicity (such as delayed ossification) are satisfactorily addressed.
14/ This requirement may be satisfied if additional data, including historical control data for fetal and maternal parametes, is submitted in order to satisfactorily resolve questions regarding such things as potential maternal toxiciy and possible increases in skeletal variations.
15/ This requirement may be satisfied if additional data is submitted in order to satisfactorily resolve questions regarding such things as animal illness, lack of food consumption and diet analysis, inadequate data presentation, discrepancies in data reporting, and the appropriateness of certain parts of the protocol.
16/ Generic data requirements for this type of testing are filled. However, an *in vivo* rat bone marrow cytogenetic assay is needed to confirm *in vitro* cytogenetic findings of genotoxicity.
17/ This study is not required at this time.

Table A (Con't)
Generic Data Requirements for Ethoprop

Footnotes

18. A special study in rats is requested in order to determine a definitive NOEL for plasm, eyrthrocyte, and brain cholinesterase (ChE) inhibition. A protocol must be designed by the registrant and submitted to the Agency for approval prior to commencement of the study. This study is requested for the following reasons: a) ChE activity inhibition by very low doses of ethoprop. b) Uncertainty of a NOEL in estimated for ChE inhibition in a 90-day rat study (MRID 0075239). c) Lack of a NOEL in an available rat chronic/oncogenicty study (MRID 00138636).

19. In order to determine the NOEL for female plasma cholinesterase and resolve the issue of decreases in male body weight gain in all test groups (MRID 00160179), an addditional study is required. It will not be necessary to repeat the comprehensive 1-year dog study in its entirety, but an abbreviated study of lesser complexity is required to resolve two issues. The new study should have a duration of approximately 17 weeks, because differences in body weight gain between males in the low-dose and control groups could not be discerned until approximately the 17 week of the study (MRID 00160179). Cholinesterase levels must be monitored until a plateau of at least 3 weeks duration is reached in which cholinester levels remain fairly constant. Plasma and erythrocyte cholinesterase levels in males and females must be monitored, and least two dose levels be employed. A protocol must be submitted to the Agency for approval prior to initating the study. The laboratory data (MRID 00160179) must be reexamined in order to determine whether a rationale exists that would mitigate the Agency's concern regarding the "across the board" decrease in mean body weight gain in all male test groups. If there is a rationale explaining the decrease in mean body weight gain in all male test groups, the duration of the requested study could possibly be shortened substantially.

20. Ethoprop, in the presence of a metabolic activation system, was found to be clastogenic in one and genotoxic in the other of two acceptable chromosomal abberrations studies (MRID 00160183 and 00160184). An acceptable rat bone marrow cytogenic analsysis is required for <u>in vivo</u> confirmation of the <u>in vitro</u> cytogenetic findings.

21. Eye lesions were noted in the 78 week mouse oncogenicity study (MRID 000137496). Since it could not be concluded whether or not the lesions noted were systemic effects of test administration, two special subchronic studies in the mouse, one an oral gavage study in B6C3F1 mouse and the other a dietary study in a stain of mouse other than B6C3F1 mouse, are required to resolve this issue (details are in MRID 00137496). The protocol should be submitted to the Agency for approval prior to commencement of the studies.

    An oral gavage study must be conducted with 30 male and 30 female mice in the control group, and 30 male and 30 female mice in the treated group. B6C3F1 mice must be used, but obained from a supplier

Footnotes

other than than Harley Industries of Indianapolis (used on previous test). A single daily dose of ethoprop (technical MCTR-60-78; lot no. 2225-62) must be administered for a period of 60 days and be sufficient to give biologically meaningful RBC and plasma cholinesterase depression. All animals must be observed daily, and five animals/sex/group be sacrificed on days 5, 11, 15, 20, 30, and 60. The sacrificed animals are to be only examined for gross and microscopic findings of the eye, and the investigator is to address those adverse findings previously noted (lesions). The results of the study must be reported in full to the Agency with a discussion to the findings and a conclusion.

A seperate study must be conducted with 30 male and 30 female mice in each of the test and control groups. The possibility of cross contamination must be eliminated between treated and control groups in this study and the above mentioned gavage study. The strain of mice used must be one other than the B6C3F1, and be obtained from a supplier other than Harlan Industries. The dose is to be adminstered in the feed for a period of 60 days, and be sufficient to give biologically meaningful RBC and plasma cholinesterase inhibition. The test material to be administered is Ethoprop (MCTR-60-78; lot no. 2225-62). All animals are to be observed daily. Five animals/sex/group are to be sacrificed on days 5, 10, 15, 20, 30, and 60, and only examined for gross and microscopic findings of the eye. The adverse effects previously noted (lesions, MRID 00137496) must be addressed. At 60 days, the experiment is to be terminated. The results of the study be reported to the Agency with a discussion of the findings and a conclusion drawn.

If the results of the gavage study are negative and the dietary study are positive, a scientifically sound argument must be presented as to the causation of the adverse eye effects previously noted and the probability of those effects occuring from topical exposure to ethoprop via the eye with time.

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 3/
§158.130 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	--	Yes- 4/	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	--	Yes	9 Months
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	00160171	No	--
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00160171	No	--
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	No	--	No	--
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	No	--	No	--
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	Partially	00160172/73	Yes 5/	12 Months
163-2 - Volatility (Lab)	TEP	A	No	--	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	--	Yes 6/	15 Months

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission 3/
§158.130 Environmental Fate (cont'd)						
Dissipation Studies - Field						
164-1 - Soil	TEP	A,B	No	--	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	A,B	No	--	No	--
164-3 - Forestry	TEP	N/A	No	--	No	--
164-4 - Combination and Tank Mixes	TEP	N/A	No	--	No 7/	--
164-5 - Soil, Long-Term	TEP	A	No	--	Yes 8/	--
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	--	Yes 9/	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	--	Yes 10/	--
165-3 - Irrigated Crops	TEP	N/A	No	--	No	--
165-4 - In Fish	TGAI or PAIRA	A,B	No	--	Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	N/A	No	--	No	--

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission 3/
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No	--	Yes	27 Months
132-1 - Soil Dissipation	TEP	A,B	No	--	Yes 11/	27 Months
133-3 - Dermal Exposure	TEP	A,B	No	--	Optional 12/	27 Months
133-4 - Inhalation Exposure	TEP	A,B	No	--	Optional	27 Months
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No	--	Yes	27 Months
201-1 - Drift Field Evaluation	TEP	A,B	No	--	Yes	27 Months
158.75 Human Exposure Data Other Exposure Data	TEP	A,B	No	--	Reserved 13/	27 Months

Table A (Cont'd)
Generic Data Requirements for Ethoprop

Footnotes

1/ Composition: TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, radiolabeled; TEP = Typical End-Use Product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard unless otherwise indicated.
4/ Registrant must repeat the hydrolysis study at pH 9 to confirm chemical degradation.
5/ Data on leaching of unaged ethoprop are acceptable. Additional data on leaching of soil degradates of ethoprop are required.
6/ Reserved pending results of the laboratory volatility study (163-2).
7/ Currently not being imposed for this product.
8/ All data are required if the results from the aerobic soil metabolism/field dissipation studies show that > 50% ethoprop remains in the soil prior to the recommended subsequent application.
9/ Supplementary data indicated [^{14}C] ethoprop residues accumulated in rotational crops. Therefore, a label restriction such as "Do not plant unregistered rotational crops for 8 months after last application" is needed. If ethoprop residue uptake in rotational crops occur after 12 months a tolerance petition must be submitted.
10/ Pending results of confined rotational crops study (165-1).
11/ Soil dissipation data are only required for those crops where agricultural practice involves human tasks where there wold be direct exposure to pesticide-treated soil, as in the harvest of potatoes.
12/ The Agency does not require the submission of reentry human exposure data, but will accept those data for review for establishment of field worker protection if submitted.
13/ Dependent on evaluation of poisoning incidence data and adequacy of worker stafety statement on product labeling.

Table A
Generic Data Requirements for Ethoprop

Data Requirement	Composition 1/	Use Patterns 2/	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)?
§158.145 Wildlife and Aquatic Organisms					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	Yes	00091247*, 05008363, 40378401	No
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	00022923	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,H	No	—	No 3/
71-4 - Avian Reproduction	TGAI	A,B,H	No	—	Reserved 4/
71-5 - Simulated and Actual Field Testing					
- Mammals and Birds					
(Level I)	TEP	A,B,H	Partial	00092113*,	Yes 5,9/
(Level II)	TEP	A,B,H	No	00161449	Reserved 6/
Aquatic Organism Testing					
72-1 - Freshwater FIsh LC_{50}	TGAI	A,B,H	Partial	40378201	No
	TEP	A,B,H	Partial	40663401 00048777*	No 7,9/
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	Yes	001610188	No
	TEP	A,B,H	Partial	40378202	No 7/

*Data submitted by Mobil Chemical Company, and subsequently transferred to Rhone-Poulenc Chemical Company, the current data owner. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Biblio-graphic Citation	Must Additional Data Submitted Under FIFRA Section 3(C)(2)(B)
§158.145 Wildlife and Aquatic Organisms (cont'd)					
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,H	Partial	00092111*, 00066341	Reserved[8,9/]
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A,B,H	Partial	00066341	Reserved[8/]
72-5 - Fish Life Cycle	TGAI	A,B,H	No		No[3/]
72-6 - Aquatic Organism Accumulation	TGAI, PAI, or Degradation Product	A,B,H	Reserved[8/]		
72-7 - Simulated or Actual Field Testing					
- Aquatic Organisms	TEP	A,B,H	Reserved[8/]		

*Data submitted by Mobil Chemical Company, and subsequently transferred to Rhone-Poulenc Chemical Company, the current data owner. These data may be compensable.

Table A (Cont'd)
Generic Data Requirements for Ethoprop

§158.145 Wildlife and Aquatic Organisms Footnotes

1/ Composition: TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, radiolabeled; TEP = Typical End-Use Product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ No requirement currently exists.

4/ Reserved pending submission of appropriate environmental fate data needed, such as field dissipation studies to better define expected residues on vegetable and soil for both crop and turf use.

5/ Actual field testing with birds (Level I) is required, as per 40 CFR 158.145, to support the use of end-use products containing ethoprop on corn or potatoes, and pineapples. For the pineapple use the EC formulation must be used and for the corn or potatoes study the granular must be tested. The design of the field studies must include appropriate methods, such as thorough carcass searching to determine whether there is pesticide-induced mortality and, if so, the extent of mortality. Acceptable protocols for conducting these field studies should be submitted to the Agency within 6 months from receipt of this document, for review and comment prior to the initiation of the study. A Guidance Document is available from the Agency, which outlines an acceptable approach to these studies. The Agency encourages registrants to consult with EEB staff for assistance as needed. If the terrestrial field studies on field crops indicate a hazard to wildlife then the Agency is reserving the option to require other terrestrial field studies where the use patterns require application rates of 2 lb ai/A or greater. If any of these use patterns are cancelled, then field studies (Level I) are still required for use patterns where the estimated environmental concentration (EEC) exceed the levels of the most sensitive species of avian wildlife.

6/ A level II field test with birds and mammals is reserved pending the results of the level I study. The level II study will be required where the Level I studies have identified a potential field effects on populations of birds and mammals. A Guidance Document is available from the Agency, which outlines an acceptable to these studies. The Agency encourages registrants to consult with EEB staff for assistance, as needed.

7/ Not applicable to this Manufacturing-Use Standard.

8/ Reserved pending the submission of the acute toxicity data on a warmwater fish species and a freshwater aquatic invertbrate along with appropriate environmental fate information (i.e., hydrolysis and photolysis in water). These data are needed to determine if hazardous concentration of ethoprop will reach the aquatic environment when prodcts are used as directed.

9/ All data citations are required to support the data requirement.

Table A
Generic Data Requirements for Ethoprop

Data Requirement	Composition 1/	Use Patterns 2/	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)? 3/	Timeframe for Submission
§158.155 Nontarget Insect						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Contact LD_{50}	TGAI	A,B,H	Yes	00011934** 000132710***	No 3/	--
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,H	No	--	No 3/	--
141-3 - Wild Bees Important in Alfalfa Pollination - Toxicity of Residues on Foliage	TEP	A	N/A	--	--	--
141-4 - Honey Bee Subacute Feeding Study	TEP	A,B,H	No	--	No 3/	--
141-5 - Field Testing for Pollinators	TEP	A,B,H	No	--	No 3/	--

**Data submitted by ICI Americas, Inc. These data may be compensable.
***Data submitted by Penick Corporation. These data may be compensable.
1/ Composition: TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ None of the registered uses will result in significant honey bee exposure.

Table A
Generic Data Requirements for Ethoprop

Data Requirement	Composition 1/	Use Patterns 2/	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)? 3/	Timeframe for Submission
§158.155 Nontarget Insect						
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects	--	A,B,H	Reserved 3/	--	--	--
142-2 - Aquatic Insect Life-Cycle Study	--	A,B,H	Reserved 3/	--	--	--
142-3 - Simulated or Actual Field Testing for Aquatic Insects	--	A,B,H	Reserved 3/	--	--	--
143-1 thru 143-3 - Nontarget Insect Testing - Predators and Parasites	--	A,B,H	Reserved 3/	--	--	--

1/Composition: TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.
2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/Reserved pending decision as to whether data requirement should be established.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHOPROP.

Data Requirement	Test substance[1]	Does EPA have data?	Bibliographic citation[2]	Must additional data be submitted?	Time frame for submission[3]
158.125 Residue Chemistry					
171-2. Chemical Identity[4]					
171-3. Directions for use		(See Index)			
171-4. Nature of the residue (Metabolism) - Plants	PAIRA	Partially	*00040380, 00075253, 00075254, 00075255, 00075256, 00092103, 00075252, 40653205,	Yes[5]	18 months
171-4. Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00092070.	Yes[6,7]	18 months
171-4. Residue analytical methods	TGAI and metabolites	Partially	00075245,*00075246, *00092079, 00092080, *00125395,*00125397, *00129928,*00145970, *00153065,*00153326, *00154203,*00160441,	Yes[8,9]	15 months
171-4. Storage Stability Data	TEP and metabolites	Partially	*00160441.	Yes[10]	15 months

(Continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Test substance[1]	Does EPA have data?	Bibliographic citation[2]	Must additional data be submitted?	Time frame for submission[3]
171-4. Magnitude of the residue in plants					
Root and Tuber Vegetables					
- Potatoes	TEP	Partially	*00153065,*40028502,	Yes[11]	24 months
- Sweet potatoes	TEP	Yes	00075252	No	
Brassica Leafy Vegetables					
- Cabbage	TEP	Partially	*00125397, 00092068	Yes[12]	18 months
Legume Vegetables					
- Beans (Phaseolus)	TEP	Partially	40653204	Yes[13]	18 months
- Soybeans	TEP	Partially	*00076720, 00092072, 00092074	Yes[14]	18 months
				Yes[15]	24 months
Foliage of Legume Vegetables					
- Beans (Phaseolus)	TEP	Partially	40653204	Yes[16,17]	18 months
- Soybeans	TEP	Partially	*00076720, 40653201	Yes[18,19]	18 months
Cucurbit Vegetables					
- Cucumbers	TEP	Partially	40653204	Yes[20]	18 months

(Continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Test substance[1]	Does EPA have data?	Bibliographic citation[2]	Must additional data be submitted?	Time frame for submission[3]
Cereal Grains					
- Corn	TEP	Partially	*00075249, 00075250, *00092108,*00092109, *00092135, 40653207	Yes[21],[22] Yes[23]	18 months 24 months
Forage, Fodder, and Straw of Cereal Grains					
- Corn	TEP	Partially	*00075249, 00075250, *00092108,*00092109, *00092135, 40653207.	Yes[24]	18 months
Miscellaneous Commodities					
- Bananas	TEP	Yes	40653206	No.	
- Peanuts	TEP	Partially	*00092106,*00092116, *00129928,*00141494, 40653202	Yes[25],[26] Yes[27]	18 months 24 months
Pineapples	TEP	Partially	00092070,*00154203.	Yes[28] Yes[29]	24 months 30 months
- Sugarcane	TEP	Partially	40653203	Yes[30]	24 months
Tobacco	TEP	Partially	*00145970,*00153065.	Yes[31],[32]	15 months
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	00092101	Yes[33]	15 months

(Continued, footnotes follow.)

TABLE A. Footnotes (continued).

1. Test substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = typical end-use product; EP = end-use product.

2. Asterisks indicate references submitted since completion of the ethoprop Residue Chemistry Chapter dated 2/28/83 or otherwise reviewed in this FRSTR. Other references listed here were reviewed in the interim Residue Chemistry Chapter.

3. Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

4. The same chemical identity data are required as under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

5. Data depicting the total terminal residue of radiolabeled ethoprop in three representative, dissimilar crops (we suggest corn, potatoes, and cabbage). Residues must be characterized in the raw agricultural commodities produced following application of formulated ethoprop to the crops under conditions representing normal cropping practices. Exaggerated rates may be necessary in order to have sufficiente ^{14}C-residues present for characterization. Multiple radiolabels (^{14}C, ^{32}P, ^{35}S) may be necessary for complete characteri

6. Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least three days with methylene-labeled [^{14}C]ethoprop at a level high enough to permit identification and quantitation of ^{14}C-residues. Milk and eggs must be collected for analysis twice daily during the dosing period. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using enforcement methods (including all FDA multiresidue protocols I-IV) to ascertain that the methods are capable of adequately recovering and quantifying all residues of toxicological concern.

7. Data depicting the nature of ethoprop residues in swine are also required if the metabolism studies required for ruminants and poultry reveal substantial differences in ethoprop metabolism between these animals and laboratory rats.

8. Residues of ethoprop occurring in or on raw agricultural commodities must be subjected to analysis by method 242.2 from PAM Vol. I (multiresidue protocol IV, available from the National Technical Information Service under Order No. PB 203734/AS).

TABLE A. Footnotes (continued).

9. The nature of the residue in plants and in animals is not adequately understood. If the requested plant and animal metabolism studies reveal the presence of additional residues of toxicological concern in plant and/or animal commodities, additional validated methods for data collection and tolerance enforcement may be required.

10. The storage conditions and intervals for all samples used to provide data previously submitted in support of the established tolerances and requested in this FRSTR must be submitted. This information must be accompanied by data depicting the percent decline in ethoprop residues under the storage conditions and for the intervals specified. Samples bearing field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data. Storage conditions for the samples must reflect data submitted previously and in response to requirements of this FRSTR. The chosen storage intervals must allow for reasonable unforseen delays in sample analysis. Upon receipt of these data, the adequacy of the established tolerances for ethoprop residues in raw agricultural commodities will be reevaluated.

11. A processing study depicting ethoprop residues in potato chips, granules or flakes, wet peel, and dry peel processed from potatoes bearing measurable weathered residues. If residues concentrate in any of these processed products, the registrant must propose appropriate food/feed additive tolerances.

12. Data depicting residues of ethoprop in or on cabbage heads with and without wrapper leaves harvested at normal crop maturity following pretransplant incorporated broadcast application of the 10-15% G or 6 lb/gal EC formulation at 5 lb ai/A. Tests must be conducted in the states of CA(8%), FL(16%) or GA(2%), MI(3%) or WI(9%), NJ(3%) or NY(15%) or PA(2%), and TX(16%) representing ca. 70% of U.S. cabbage production (1982 Census of Agriculture, Vol 1, Part 51, p. 338).

13. Data depicting residues of ethoprop in or on snap beans harvested at normal crop maturity following a single preplant application of the 6 lb/gal EC or a G formulation at 8 lb ai/A (broadcast) or 3.2 oz ai/1,000 ft of row (3 lb ai/field A, 36-inch row spacing) in a 12- to 15-inch band over the row. Tests must be conducted in MI(7%), NY(13%), OR(18%), and WI(35%) representing ca. 70% of 1985 U.S. snap bean production for processing (Agricultural Statistics 1986, p. 149). Short season varieties of snap beans must be included in the tests.

TABLE A. Footnotes (continued).

14. Data depicting Ethoprop residues in or on soybeans harvested at normal crop maturity following preplant incorporated application of the 6 lb/gal EC formulation at 4 oz ai/1,000 ft of row (3 lb ai/A, 42-inch row spacing; equivalent to 10.5 lb ai/treated A). Tests must be conducted in IL(18%) or IN(9%), IA(15%) or MN(8%), AR(5%) or MO(9%), and KS(2%) or NE(4%) representing ca. 70% of 1985 U.S. soybean production (Agricultural Statistics 1986, p. 126).

15. A processing study depicting residues of ethoprop in soybean meal, hulls, soapstock, crude oil, and refined oil processed from soybean seed bearing measurable weathered residues (obtained by using exaggerated field rates if necessary). If residues concentrate in any of these processed commodities, the registrants must propose appropriate food and/or feed additive tolerances.

16. Data depicting residues of ethoprop in or on snap bean vines harvested at normal crop maturity following a single preplant application of the 6 lb/gal EC or a G formulation at 8 lb ai/A (broadcast) or 3.2 oz ai/1,000 ft of row (3 lb ai/field A, 36-inch row spacing) in a 12- to 15-inch band over the row. Tests must be conducted in MI(7%), NY(13%), OR(18%), and WI(35%) representing ca. 70% of 1985 U.S. snap bean production for processing (Agricultural Statistics 1986, p. 149).

17. The registrant must propose an appropriate tolerance for residues of ethoprop in or on bean hay (to include both lima and snap bean hay) and submit appropriate supporting residue data.

18. Data depicting Ethoprop residues in or on soybean hay harvested at normal crop maturity and soybean forage harvested at several intervals following preplant incorporated application of the 6 lb/gal EC formulation at 4 oz ai/1,000 ft of row (3 lb ai/A, 42-inch row spacing; equivalent to 10.5 lb ai/treated A). Tests must be conducted in IL(18%) or IN(9%), IA(15%) or MN(8%), AR(5%) or MO(9%), and KS(2%) or NE(4%) representing ca. 70% of 1985 U.S. soybean production (Agricultural Statistics 1986, p. 126). The registrant must propose label restrictions establishing a pregrazing/preharvest interval for soybean forage that is reflected in the data requested above.

19. The registrant must propose a tolerance for residues of ethoprop in or on soybean straw and submit appropriate supporting residue data.

20. Data depicting ethoprop residues of concern in or on cucumbers harvested at maturity following a single preplant incorporated application of a 10-15% G or the 6 lb/gal EC formulation at 4.8 oz ai/1,000 ft of row (1.9 lb ai/field A, 7-ft row spacing) in a 12- to 15-inch band over the row. Tests should be conducted in

TABLE A. Footnotes (continued).

CA(11%), MI(19%), NC(14%), OH(9%), and WI(9%), states which account for ca. 62% of the total 1985 U.S. production of cucumbers (Agricultural Statistics 1986, p. 157).

21. Data depicting residues of ethoprop in or on field corn grain harvested at normal crop maturity following application of a 10-20% G formulation in the following treatments (separate tests): 6 lb ai/A broadcast preplant and incorporated; and 1.25 oz ai/1,000 ft of row (2 lb ai/field A, 20-inch row spacing) applied postemergence at layby in 3- to 4-inch bands on both sides of the row near the base of the plants. Short season varieties must be represented. Tests must be conducted in the states of IL(17%) or IA(19%), IN(9% or MI(3%) or OH(6%), KS(2%) or NE(11%), and MN(8%) or WI(4%) representing ca. 80% of 1985 U.S. field corn production (Agricultural Statistics 1986, p. 32).

22. Data depicting residues of ethoprop in or on sweet corn K+CWHR harvested at normal harvest intervals following application of a 10-20% G formulation in the following treatments (separate tests): 6 lb ai/A broadcast preplant and incorporated; and 1.25 oz ai/1,000 ft of row (2 lb ai/field A, 20-inch row spacing) applied postemergence at layby in 3- to 4-inch bands on both sides of the row near the base of the plants. Short season varieties must be represented. The registrant must propose a PHI for the postemergence use that is reflected in the data submitted. Tests must be conducted in the states of MN(20%) or WI(20%), OR(11%) or WA(10%), and IL(13%) representing ca. 70% of 1985 U.S. sweet corn production for fresh market and processing (Agricultural Statistics 1986, p. 156).

23. A processing study depicting residues of ethoprop in the following products processed from field corn grain bearing measurable weathered residues at or near the tolerance level: starch, crude oil, and refined oil from wet milling process; and grits, meal, flour, crude oil, and refined oil from dry milling process. If residues are shown to concentrate in any of these processed commodities, appropriate food or feed additive tolerances must be proposed.

24. Data depicting residues of ethoprop in or on corn (field or sweet) forage harvested at regular intervals and corn (field or sweet) fodder harvested at normal crop maturity following application of a 10-20% G formulation in the following treatments (separate tests): 6 lb ai/A broadcast preplant and incorporated; and 1.25 oz ai/1,000 ft of row (2 lb ai/field A, 20-inch row spacing) applied postemergence at layby in 3- to 4-inch bands on both sides of the row near the base of the plants. Short season varieties must be represented. Tests must be conducted in the states of IL(17%) or IA(19%), IN(9% or MI(3%) or OH(6%), KS(2%) or NE(11%), and MN(8%) or WI(4%) representing ca. 80% of 1985 U.S. field corn production (Agricultural Statistics 1986, p. 32). The registrant must propose label amendments establishing a pre-

TABLE A. Footnotes (continued).

grazing/pre-harvest interval for corn forage (in reference to the postemergence use) that is reflected in the data requested above.

25. The registrant must propose tolerances for the raw agricultural commodities, peanut hulls and peanut vines, and submit appropriate supporting residue data.

26. The registrants must propose label amendments establishing a maximum number of applications per season, a maximum seasonal use rate, and a PGI/PHI relative to at-pegging applications. These conditions must be reflected in the data submitted to support the tolerances, or additional data may be required.

27. Data depicting residues of ethoprop in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any of these processed commodities, appropriate food and/or feed additive tolerances must be proposed.

28. Data depicting residues of ethoprop in or on pineapple fruit and forage harvested 120 days after the last of eight applications (if a plant crop) or five applications (if a ratoon crop) of the 6 lb/gal EC formulation at 12 lb ai/A/application. Applications must be made by drip irrigation system. Tests must be conducted in the state of Hawaii.

29. A processing study depicting residues in bran and juice processed from pineapple fruit bearing measurable weathered residues. If residues concentrate in either of these processed products, the registrant must propose appropriated food and/or feed additive tolerances.

30. A processing study depicting residues of ethoprop in molasses, refined sugar, and bagasse processed from sugarcane bearing measurable weathered residues. If residues concentrate in any of these commodities, the registrant must propose appropriate food and/or feed additive tolerances.

31. Data characterizing and quantifying the pyrolysis products of radiolabeled ethoprop that occur in tobacco smoke. Multiple radiolabels (^{14}C, ^{32}P, ^{35}S) might be necessary for complete characterization.

32. Complete analytical methods must be submitted for detecting and quantifying ethoprop residues of concern in or on tobacco and in tobacco smoke.

TABLE A. Footnotes (continued).

33. Additional animal metabolism data have been requested in this FRSTR (see "Nature of the Residue in Animals" section for details). Upon receipt of those data the need for and nature of tolerances for residues of ethoprop in meat, milk, poultry, and eggs will be reevaluated.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT

Data Requirement	Composition[a]	Does EPA Have Data to Satisfy This Requirement?[b]	Bibliographic Citation[b]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[c]	6 months
61-3 - Discussion of Formation of Impurities	TGAI	Partial	00152115, Reg. Jacket	Yes[d]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	Partial	00152115.	Yes[d,e]	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes[f]	6 months
63-3 - Physical State	TGAI	No	N/A	Yes[f]	6 months
63-4 - Odor	TGAI	No	N/A	Yes[f]	6 months
63-5 - Melting Point	TGAI	N/A	N/A	No[g]	
63-6 - Boiling Point	TGAI	No	N/A	Yes[f]	6 months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00142272.	No	

(continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Composition[a]	Does EPA Have Data to Satisfy This Requirement?[b]	Bibliographic Citation[b]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry (continued)					
63-8 - Solubility		Yes	00142272.	No	
63-9 - Vapor Pressure	TGAI or PAI	Yes	N/A	No	
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[f]	6 months
63-11 - Octanol/Water Partition Coefficient	PAI	Yes	00142272.	No	
63-12 - pH	TGAI	Yes	00142272.	No	
63-13 - Stability	TGAI	No	N/A	Yes[f]	6 months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	N/A	No	

a Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient. The TGAI may also be used as a Manufacturing-use Product (MP). See also Table B, "Product Specific Data Requirements for Manufacturing-Use Product", for additional data requirements for registered technical products, including parts 61-1 (Product identity and disclosure of ingredients), 62-2 (Certification of ingredient limits) and 62-3 (Analytical methods to verify certified limits), and the physicochemical characteristics 63-14 (Oxidizing or reducing action), 63-15 (Flammability), 63-16 (Explodability), 63-17 (Storage stability), 63-18 (Viscosity), 63-19 (Miscibility), and 63-20 (Corrosion characteristics).

b Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable. Data submitted subsequent to the previous Product Chemistry Chapter in response to data requirements is evaluated and cited by MRID number.

TABLE A. (Continued).

c Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

d A detailed discussion of all impurities that are or may be present at >0.1% based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

e Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

f Physicochemical characteristics (color, physical state, odor, melting point, boiling point, vapor pressure, dissociation constant, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

g Data not required because TGAI is a liquid at room temperature.

Table B

Product Specific Data Requirements for Manufacturing-Use Products Containing Ethoprop

Data Requirement	Composition 1/	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)? 2/	Timeframe for Submission
§158.135 Toxicology					
Acute Testing					
81-1 - Acute Oral - Rat	MP	Yes	00078035	No	--
81-2 - Acute Dermal	MP	Yes	00078035	No	--
81-3 - Acute Inhalation - Rat	MP	Yes	00128218	No	--
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00078036	No	--
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00048774	No	--
81-6 - Dermal Sensitization Guinea Pig	MP	No	--	No 3/	--

1/Composition: MP = Manufacturing-Use Product.
2/A study is not required because of the high acute dermal toxicity of the MP.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS

Data Requirement	Composition[a]	Does EPA Have Data to Satisfy This Requirement?[b]	Bibliographic Citation[b]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	Partial	00152115, Reg. jacket	Yes[c]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[d]	6 months
61-3 - Discussion of Formation of Impurities	MP	Partial	00152115, Reg. jacket	Yes[e]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	Partial	00152115	Yes[f]	12 months
62-2 - Certification of Ingredient Limits	MP	Partial	00152115	Yes[g]	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	Partial	00152115	Yes[h]	12 months
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[i]	6 months
63-3 - Physical State	MP	No	N/A	Yes[i]	6 months
63-4 - Odor	MP	No	N/A	Yes[i]	6 months
63-7 - Density, Bulk Density, or Specific Gravity	MP	Yes	00142272	No	

(continued, footnotes follow.)

TABLE B. (Continued).

Data Requirement	Composition[a]	Does EPA Have Data to Satisfy This Requirement?[b]	Bibliographic Citation[b]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry (continued)					
63-12 - pH	MP	Yes	N/A	No	6 months
63-14 - Oxidizing or Reducing Action	MP	Yes	N/A	No	6 months
63-15 - Flammability	MP	Yes	N/A	No	6 months
63-16 - Explodability	MP	Yes	00152115	No	6 months
63-17 - Storage Stability	MP	Yes	N/A	Yes[i]	15 months
63-18 - Viscosity	MP	Yes	N/A	No	6 months
63-19 - Miscibility	MP	Yes	N/A	Yes[i,o]	6 months
63-20 - Corrosion Characteristics	MP	Yes	N/A	No	15 months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	N/A	No	

a Composition: MP = Manufacturing Use Product.

b Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

c The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

TABLE B. (Continued).

d Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

e A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

f Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

g Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. [We defer to the Toxicology Branch regarding the toxicological significance of (i) impurities associated with the active ingredient present at <0.1% (w/w) and (ii) impurities not associated with the active ingredient.] Certifications must be submitted on EPA Form 8570 Rev. 2-85.

h Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the TOX Branch regarding the toxicological significance of impurities and intentionally added inerts for which certified limits are required.]

i Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 156.10 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 156.10(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 156.10(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 156.10(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 156.10(g)]

SUMMARY-2

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 156.10(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 156.10(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 156.10(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 156.10(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 156.10(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 156.10(h)(2)].

SUMMARY-3

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 156.10(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 156.10(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 Part 152, Subpart I. You will be notified of the Agency's classification decision.

SUMMARY-4

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 156.10(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.

SUMMARY-5

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 156.10]

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

(& DOMESTIC ANIMALS)

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT

(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE

(reason for classifying)

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

PRODUCT NAME

ACTIVE INGREDIENT: _____ %

INERT INGREDIENTS: _____ %

TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED

IF INHALED

IF ON SKIN

IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY

TOWN, STATE

ESTABLISHMENT NO.

EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

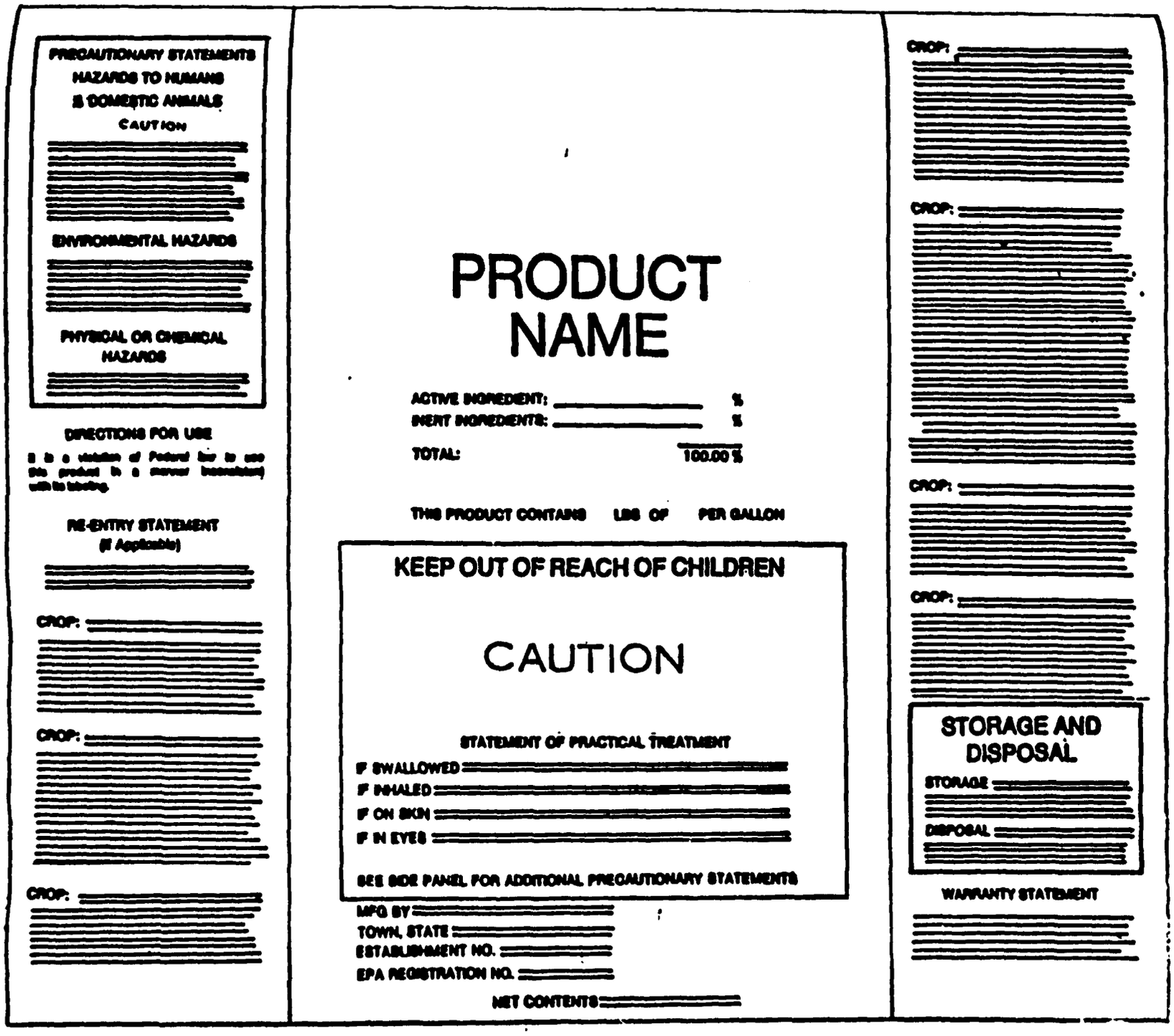
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
RE-ENTRY STATEMENT
(If Applicable)
CROP:
CROP:
CROP:
CROP:
PRODUCT
NAME
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS
CROP:
CROP:
CROP:
CROP:
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
WARRANTY STATEMENT

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products 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

scribed 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 semi-solid, 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 require 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 direc-

tions 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 required.

(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 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

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.

PEST/DIS-1

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.

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

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.

BIBGUIDE-2

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
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IV. FORMS APPENDICES

 OMB Approval No. 2070-0057
Expires 11/30/89

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

OMB Approval No. 2070-0057
Expires 11/30/89

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

(To qualify, certify ALL four items)

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:

GUIDANCE DOCUMENT DATE

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 [illegible]

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. 2070-0057
Expiration Date 11/30/89

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 Section 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 Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental 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 Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: _____
(Signature)

Dated: _____ _____
(Typed)

2070-0060

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. _____ Date of application _____

Name of Product _____

Applicant's Name and Address _____

_____

_____

_____

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is <u>not</u> an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; <u>or</u>

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

[ ] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (<u>Also sign the General Offer to Pay Statement below</u>.)

[ ] Those companies who have submitted the studies which I have cited (Selective method)

Date _____ Signature _____

Title _____

<u>General Offer to Pay</u>: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date _____ Signature _____

Title _____

EPA Form (April 1985)

EPA	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 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				
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				
Sec. 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				

Certification

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

Typed Name and Title	Signature	Date