REREGISTRATION ELIGIBILITY DOCUMENT
ISOPROPYL (2E,4E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
(REFERRED TO AS METHOPRENE)

LIST A

CASE 0030

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ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
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.
LC50	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.,m mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPT	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS CONT'D

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

The Environmental Protection Agency first registered methoprene in 1975 as a chemical pesticide, specifically as an insect growth regulator. It is registered for use on a variety of food and non-food sites including use in feed/mineral supplements for cattle, on rice, pastures, stored tobacco, mushroom cultures, in and around homes. It is also registered for use on non-crop aquatic areas to control the horn fly, mosquito, cigarette beetle, tobacco moth, sciarid fly, and flea larvae. Products which contain methoprene as an active ingredient are eligible for reregistration except the briquette (slow release) formulations.

The Agency issued a Registration Standard entitled, "Guidance for the Reregistration of Pesticide Products Containing Methoprene as the Active Ingredient" (NTIS PB87-109443) in February 1982. The Registration Standard continued to classify the compound as a conventional pesticide. Soon after the Registration Standard was issued, the Agency reclassified the compound as a biochemical pesticide. The classification of methoprene as a biochemical pesticide was based on information concerning the mode of action of methoprene and the chemical structure of methoprene. At that time the Agency also eliminated many of the environmental fate data requirements from the 1982 Registration Standard, since the tiered testing of Section M rather than Section N of the guidelines apply to biochemical pesticides.

The data base to support the reregistration of methoprene is substantially complete. However, two generic data requirements are being levied: octanol/water partition coefficient and an estuarine invertebrate life cycle study. Although the former study is not critical to the reregistration decision or environmental assessment of methoprene at this time, the Agency is requiring this data to satisfy this gap in the product chemistry data base for methoprene. The latter study is needed to assess the long term exposure to estuarine invertebrates. Although there is concern for the long term exposure to estuarine invertebrates, the Agency has determined that the reregistration of methoprene can precede at this time because most of the uses for methoprene do not involve significant exposure to estuarine invertebrates. Only the use as a briquette (slow release) formulation raises a concern. The other aquatic formulations are not expected to result in significant exposure because methoprene is short lived in the aquatic environment and does not have a high potential for bioaccumulation. The estuarine invertebrate life cycle study is required to confirm whether or not the estimated exposure from the briquette formulation is sufficient to pose an adverse effect on estuarine invertebrates.

The current data base is sufficient to allow the Agency to conduct a reasonable risk assessment for most registered uses of methoprene. The data the Agency has supports the conclusion that most uses of methoprene will not result in unreasonable effects to the environment. As mentioned above the only use of concern at this time is the long term exposure to estuarine invertebrates through the use of the briquette formulation.

EPA has determined that all products containing methoprene as an active ingredient are eligible for reregistration except the briquette formulation which will be considered for reregistration once the data requested in this document is submitted, reviewed, and determined to cause no unreasonable risk to nontarget organisms, specifically estuarine invertebrates.

Before reregistering each product, the Agency is requiring product specific data and revised labeling to be submitted within 8 months of the issuance of this document. After reviewing these data and the revised labels, the Agency will determine whether to reregister a product based on whether or not that product meets the requirements in Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration of methoprene. The document consists of five sections. Section I is this introduction. Section II describes methoprene, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration decision for methoprene and Section V discusses product reregistration. Additional details concerning the Agency's review of data are available on request.[1]

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[1] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401, M St., S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENT COVERED BY THIS REREGISTRATION DECISION

A. IDENTIFICATION OF ACTIVE INGREDIENT

The following active ingredient is covered by the Reregistration Eligibility Document:

Chemical Name: isopropyl (2E, 4E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate
(Referred to hereafter as methoprene)

Common Name: Methoprene

CAS Number: 40596-69-8

Office of Pesticide Programs Chemical Code Number: 105401

Empirical Formula: $C_{19}H_{34}O_3$

Trade Name: Altosid^R, ZR-515, and ENT-70460

Basic Manufacturer: Zoecon Corporation

B. USE PROFILE

Type of Pesticide: Biochemical Pesticide, Insect Growth Regulator

Pests Controlled: Horn fly, mosquito, cigarette beetle, tobacco moth, sciarid fly, flea larvae, mealy bug, and spider mite.

Registered Use Sites:

Terrestrial Food Crop - Rice
Terrestrial Feed Crop - Pastures
Terrestrial Non-Food Crop - Compost/compost piles, wide area/general outdoor treatment (public health use), ornamental herbaceous flowering/foliage/vine plants.
Aquatic Food Crop - Rice
Aquatic Non-Food Outdoor - Salt/brackish water sites, intermittently flooded areas/water, streams/rivers/channeled water, swamps/marshes/wetlands/stagnant water.
Aquatic Non-Food Industrial - Drainage systems, sewage systems.
Aquatic Non-Food Residential - Ornamental ponds/aquaria, swimming pool water systems.
Residential Outdoor - Compost/compost piles, ornamental herbaceous flowering/foliage/vine plants.
Indoor Food - food/feed storage area-full, cereals (manufactured), mushroom houses/mushroom casing soil,

eating establishments, commercial shipping containers-feed/food-empty, food processing plant premisses/equipment, dairy cattle (lactating), beef/range/feeder cattle (meat).
Indoor Non-Food - Stored tobacco, commercial transportation facilities, tobacco processing plant premises/equipment, commercial/institutional/industrial premises/equipment (indoor), horses (colts), ponies.
Indoor Medical - Hospitals/medical institutions premise (human/veterinary)
Indoor Residential - Kennels and/or pet sleeping quarters, household/domestic dwellings indoor premises, cats (adults/kitten) (pet), dogs/canines (adult/puppies) (pet).

Formulation Types Registered: Technical - 90% a.i.; Formulation Intermediates (5% - 90% a.i)

Formulations: Granular/Impregnated Material, Pelleted-Tableted; Emulsifiable/Soluble Concentrate, Pressurized Liquid (aerosol), Solution-Ready To Use.

Methods of Application: Ground spray, aerial spray, granular, mineral block/pellet, slow release briquette

C. REGULATORY HISTORY

The Agency first registered methoprene in 1975 for use in feed/mineral supplements for cattle, on rice, pastures, stored tobacco, mushroom cultures, in and around homes, and also on non-crop aquatic areas to control the horn fly, mosquito, cigarette beetle, tobacco moth, sciarid fly and flea larvae.

The Agency issued a Registration Standard entitled "Guidance for the Reregistration of Pesticide Products Containing Methoprene as the Active Ingredient" (NTIS PB87-109443) in February 1982. The Registration Standard classified the compound as a conventional pesticide. Subsequently the Agency issued an Errata Sheet for methoprene, classifying the compound as a biochemical pesticide. The classification of methoprene as a biochemical pesticide was based on information concerning the mode of action of methoprene and the chemical structure of methoprene compared to its naturally occurring counterpart. Methoprene is an insect growth regulator and exhibits a mode of action other than direct toxicity in the target pest. Also, the chemical structure of methoprene is substantially similar to natural juvenile insect hormone. Both chemicals are long-chain esters containing only carbon, hydrogen, and oxygen; have aliphatic ester groups; and similar molecular

weights. The major structural difference between the two chemicals is that the naturally occurring material has an epoxide (cyclic ether) ring while in methoprene this ring is converted to an open-chain methyl ether.

The Errata Sheet for methoprene eliminated environmental fate data requirements listed in the 1982 Registration Standard since they were no longer applicable to methoprene when classified as a biochemical pesticide. For biochemical pesticides, environmental fate studies comprise Tier II testing to be triggered by non-target organism concerns. At the time of the Errata Sheet, EPA did not believe further environmental testing was required. The following are the environmental fate data requirements that were eliminated:

- photodegradation in air and water
- aerobic soil metabolism
- aerobic and anaerobic aquatic metabolism
- leaching/adsorption/desorption
- laboratory and field volatility
- terrestrial field and long term soil dissipation
- confined and field rotational crops
- bioaccumulation in fish
- bioaccumulation in aquatic non-target organisms

The Errata Sheet still required, however, the remaining two studies that were listed in the 1982 Registration Standard for technical methoprene:

154-8 Fish Toxicity Study with Rainbow Trout

151-17 Octanol/Water Partition Coefficient

The ecological effects data requirement, Fish Acute LC50 in Rainbow trout (154-8), was satisfied at the time the Errata Sheet was issued in 1982 with MRID 00010643. Therefore this requirement no longer constitutes a data gap and was listed as satisfied in the Errata Sheet.

Product chemistry, acute toxicity and efficacy data on the formulated end use products that were listed in the 1982 Registration Standard were also still required in the Errata Sheet. However, the Errata Sheet stated that the Table C toxicological data requirement for primary eye irritation (152-13) for granular and pelleted tablet methoprene products was no longer needed. The Agency's rationale for originally requesting these data was the possibility of exposure to the dust of these granular products. Subsequently, information on the particle size of all of the currently registered granular methoprene products has been submitted to the Agency. The data showed that most of the particles exceed 150 microns in size and are too heavy to constitute a dust. Therefore, the Agency determined that this requirement was no longer needed.

III. AGENCY ASSESSMENT

A. PRODUCT IDENTIFICATION

Technical Methoprene is a pale yellow liquid with a faint fruity odor and has a boiling point of 100°C at 0.05 mm of Hg. Samples of methoprene stored in glass for 4 years at 70°F did not show any appreciable chemical decomposition. Technical Methoprene is soluble in water at 1.39 ppm and very soluble in all common organic solvents. The specific gravity of technical methoprene is 0.9261 at 20°C. Technical Methoprene is intended only for reformulation into an end-use pesticide and, therefore, is considered a "manufacturing-use" product.

The 1982 Registration Standard as modified by the Errata Sheet for Methoprene required additional product chemistry data for the Octanol/Water Partition Coefficient. Although this requirement is not critical to the reregistration decision or environmental assessment of methoprene at this time, the Agency is requiring this data to satisfy the gap in the product chemistry data base for this chemical.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Data Base

All current toxicological data requirements are satisfied. No further data were required in the 1982 Registration Standard as modified by the Errata Sheet for technical methoprene and no additional data have been submitted. All Tier I toxicological studies required for Methoprene have been submitted except for the Immunotoxicity Study (Guideline 152B-18). The required Tier I toxicological studies submitted for methoprene include the acute toxicity battery, a subchronic feeding study, a developmental toxicity study, and a mutagenicity study. The immunotoxicity study normally required for biochemical pesticides has been waived for methoprene since subchronic, chronic, teratology, and reproduction studies have already been submitted for methoprene and have shown no significant adverse toxicological effects. If the immune system were a sensitive target for methoprene toxicity, then this would have been expected to result in at least some signs of toxicity in some of the studies that comprise the extensive data base for methoprene. The results of the review of the toxicological data base are presented below:

a. Acute Toxicity

The acute oral LD_{50} value is determined to be greater than 10,000 mg/kg for rats and between 5,000 and 10,000 mg/kg for dogs. These data indicate a low acute oral toxicity potential and place

technical methoprene in toxicity category IV. The acute dermal LD_{50} for rabbits is determined to be greater than 2000 mg/kg and the acute inhalation LC_{50} in rats is greater than 20 mg/l. These data indicate a low human acute toxicity potential for methoprene and places it in toxicity category III for acute dermal toxicity and toxicity category IV for acute inhalation toxicity.

Sufficient data are available to assess the primary eye and dermal irritation potential of methoprene. In an eye irritation study, 0.1 ml of technical methoprene did not cause eye irritation or corneal opacity in rabbit eyes. Additionally, when rabbits were given 24 hour dermal exposure to 0.5 ml technical methoprene, on shaved, abraded and unabraded skin, no dermal irritation was observed for up to 72 hours. These data indicate that methoprene is not a primary eye or dermal irritant and places it in toxicity category IV for both eye and dermal irritation.

Several skin sensitization tests are available for technical methoprene. A skin sensitizing test was conducted in guinea pigs. Undiluted methoprene was administered by multiple intradermal injection. A positive reaction was obtained. However, when the test was subsequently repeated by topical application the results were negative. Additionally, a test was performed according to a standard Draize method on human subjects to determine the human contact sensitization potential of the test chemical. No positive responses were observed and it was determined that the test chemical is not a human skin sensitizer under the test conditions.

b. Subchronic Toxicity

A 90-day study was conducted in rats given 0, 250, 500, 1000, or 5000 ppm methoprene. A significant increase in liver weights was observed in both males and females at the highest dose. In addition, kidney weights in males at 5000 ppm were significantly increased. Renal tubular degeneration was observed in 7 out of 15 males at 5000 ppm and 3 out of 15 males at 1000 ppm. Based on these findings, a no observed effect level (NOEL) for systemic toxicity was established at 500 ppm. The lowest effect level was 1000 ppm.

A 90-day study was also conducted in dogs given 0, 250, 500, or 5000 ppm methoprene. The results showed that liver weights for males and females at 5000 ppm were significantly elevated. In addition, serum alkaline phosphatase (SAP) levels in males at 5000 ppm were elevated at the 4, 8, and 13 week testing intervals. Females at this dose had elevated SAP levels at the 8 week interval only. No other treatment related effects were observed. Based on these findings the no observed effect level (NOEL) for systemic toxicity was established at 500 ppm and the lowest effect level was 5000 ppm.

A 21-day dermal toxicity study in rabbits was conducted and

satisfies the requirement for subchronic dermal toxicity testing. Five groups of five male and five female Japanese rabbits were acclimated for 20 days and treated with undiluted Altosid® at 0, 100, 300, 900 or 2700 mg/kg/day for thirty days. The chemical was applied topically on the back of the animal which was previously clipped free of hair. Except for redness observed from day 4 to 29 at the application sites in the highest dose group, no treatment related effects were observed. The NOEL is considered to be 100 mg/kg of body weight. Higher doses caused a decrease in body weight gain.

In a 21-day inhalation study in rats, the NOEL was determined to be 20 mg/l (highest dose tested).

c. Chronic Effects

In a chronic feeding study, rats were fed diets containing 0, 250, 1000, or 5000 ppm methoprene (86.9% A.I.) for two years. No treatment related effects on body weight, food consumption, behavior, hematology, blood chemistry, urinalysis and organ weights were observed. Eye examinations did not indicate a treatment related effect. At the end of the study, survival was approximately 50% in all groups. At necropsy no treatment related gross pathological or histopathological lesions were observed. In addition, there was no increase in tumor incidence in treated groups. The NOEL from this study is indicated as 5000 ppm, which is the highest dose tested.

In another study, four groups of 50 male and 50 female Charles River CD-1 mice were fed diets containing 0, 250, 1000, or 2500 ppm methoprene for 18 months. No differences were observed in the tumor incidence between the control and treated groups. No treatment related effects on body weight, food consumption and general behavior were observed. At 18 months, survival was approximately 50% in all groups. At necropsy, no treatment related gross pathological changes were observed. However, histopathological examination indicated high incidence of brown pigmentation of liver at 2500 ppm. This finding was also observed in some mice at 1000 ppm but was absent at the 250 ppm level and in the control group. Amyloidosis was observed in various tissues at all dose levels including the control group. The incidence of this finding was approximately twice as great in the high dose test group compared to the controls. The NOEL for systemic toxicity was established as 250 ppm.

d. Oncogenicity

Data are available to assess the chronic toxicity and oncogenic potential of methoprene. In a 2-year feeding study with rats, the NOEL for systemic toxicity was determined to be 5000 ppm (highest dose tested). No indication of an oncogenic effect was

observed even at the highest dose level. In an 18-month oncogenicity study with mice no evidence of oncogenicity was observed at any dose level. The NOEL for systemic toxicity was established as 250 ppm.

e. Developmental Toxicity and Reproduction

Data are available to show that methoprene is not a developmental toxicant in rabbits at doses as high as 2000 mg/kg, when administered on gestation days 7 through 18. Maternal toxicity as demonstrated by a 38.4% reduction in body weight gain and a 20% incidence of abortion and fetotoxicity was observed at 2000 mg/kg/day. Based on the doses tested, the lowest effect level for maternal toxicity and embryolethality in utero is 2000 mg/kg/day and the NOEL is 200 mg/kg/day. A second teratogenicity study was conducted in mice given 0, 50, 200, or 600 mg/kg/day methoprene on days 7 through 14 of gestation. At 600 mg/kg/day (highest dose tested), no maternal toxicity, fetotoxicity or teratogenicity was observed. The data from this study support the conclusion that this chemical is not a developmental toxicant in mice and the NOEL for developmental effects is established at 600 mg/kg/day.

Data are available to assess the reproductive toxicity of methoprene in rats. In a three generation reproduction study, the NOEL was determined to be 2500 ppm (highest dose tested).

f. Mutagenicity

A bacterial assay and a dominant lethal study in rats presented sufficient evidence to indicate that methoprene is not mutagenic.

g. Metabolism

A series of studies investigating the metabolism of methoprene in the rat, mouse, guinea pig, steer and cow are available. These studies indicate rapid and extensive biodegradation of methoprene and its metabolites in mammalian species and that methoprene metabolites are incorporated into natural body constituents.

2. DIETARY EXPOSURE

a. Residue Data

~~There were~~ no residue chemistry data deficiencies identified in the 1982 Registration Standard as modified by the Errata Sheet for methoprene. The nature of the residue in plants and livestock is adequately understood. The residue of concern is methoprene *per se*. Adequate methodology is available for enforcement purposes and an adequate data base is available to support the present tolerance levels in the subject commodities.

Tolerances have been established in 40 CFR 180.359 for residues of methoprene, as well as Codex MRLs (Maximum Residue Levels) and Canadian tolerances in or on the following raw agricultural commodities as listed below:

Commodity	40 CFR 180.359 Tolerance (ppm)	Codex MRLs	Canadian Tolerance (ppm)
Cattle, fat	0.3		
Cattle, meat	0.1		
Cattle, meat byproducts	0.1		
Eggs	0.05	0.05	
Goats, fat	0.3		
Goats, meat	0.1		
Goats, meat byproducts	0.1		
Hogs, fat	0.3		
Hogs, meat	0.1		
Hogs, meat byproducts	0.1		
Horses, fat	0.3		
Horses, meat	0.1		
Horses, meat byproducts	0.1		
Milk	0.05		
Mushrooms	1.0	0.2	0.1
Peanuts	2.0	2.0	
Peanut hulls	40.00		
Poultry, fat	0.5		
Poultry, meat	0.5		
Poultry, meat byproducts	0.5		
Sheep, fat	0.3		
Sheep, meat	0.1		
Sheep, meat byproducts	0.1		
Meat, fat		0.1	
Cattle milk		0.05	
Edible Offal (mammalian)		0.1	

The U.S. Tolerances and Codex MRL's are expressed in terms of methoprene per se. The levels are identical for all of the pertinent commodities with the exception of mushrooms and meat fat. Lowering the meat fat (cattle, goat, hog, and horse fat) tolerance of 0.3 ppm to 0.1 ppm could result in residues of methoprene exceeding the tolerance level in this commodity because of current and pending feed uses. Thus the U.S. tolerance should not be changed to match the Codex MRL at this time. The difference in the mushroom Codex MRL and U.S. tolerance reflects differences in types of treatments and therefore, no correlation of the two limits could be accomplished at this time. There are no Mexican tolerances.

The mosquito vector control uses that were exempt from the requirement of a tolerance under 40 CFR 180.1033 and 185.4150, are now considered non-food uses. Thus the exemptions are no longer applicable and will be revoked.

It should be noted that there is a tolerance petition pending (PP#4F3103) for tolerances of 5, 10, and 25 ppm on cereal grains, grain milled fractions and rice hulls, respectively.

Methoprene as a feed additive may be safely used in accordance with the following prescribed conditions under 40 CFR 186.4150:

- It is used as a feed additive in the form of mineral and/or protein blocks or other feed supplements in the feed of cattle at the rate of 22.7 to 45.4 milligrams per 100 pounds of body weight per month.

- It is used to prevent the breeding of hornflies in the manure of treated cattle.

- To ensure safe use of the additive, the label and labeling of pesticide formulations containing this additive shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

b. Reference Dose

The following data were considered for establishing the Reference Dose (RfD) for methoprene:

Study	Species
Chronic Toxicity/Oncogenicity (18 months)	mice

The reference dose for chronic oral exposure was determined based upon an LEL for liver pigmentation at 150 mg/kg/day (1000 ppm) and a NOEL of 37.5 mg/kg/day (250 ppm) in the 18-month mouse feeding/carcinogenicity study. An uncertainty factor of 100 was used to account for inter- and intraspecies differences. The RfD therefore is 0.4 mg/kg/day.

The Agency determined the percent RfD utilized based upon current tolerances established for residues of methoprene. Approximately 0.29% of the RfD has been utilized considering the average American food consumption. None of the subgroups of Americans (e.g. infants, children) which are generally included in dietary risk assessments, have dietary intake of methoprene which exceeds the RfD.

c. Tolerance Reassessment

The data submitted have been determined to adequately support the existing tolerances established for methoprene as listed in Section III.B.2a of this document. The established tolerances are set at the appropriate levels and no new tolerances are required to cover the existing uses for the registered product. Exemptions for methoprene from use as a mosquito control vector have been determined to be unnecessary and will be revoked.

3. NON-DIETARY (OCCUPATIONAL) EXPOSURE

Methoprene does not meet the Agency's toxicity criteria for requirement of re-entry or mixer/loader/applicator exposure monitoring data because methoprene is in Toxicity Categories III and IV for acute dermal and inhalation toxicity, respectively, and there is no evidence of neurotoxic, oncogenic, reproductive, or developmental adverse effects associated with this chemical. Therefore, a quantitative risk assessment for occupational exposure was not necessary and was not required.

C. ENVIRONMENTAL ASSESSMENT

All environmental fate data requirements are satisfied. No further data were required in the 1982 Registration Standard as modified by the Errata Sheet for methoprene and no additional data have been submitted.

The 1982 Registration Standard as modified by the Errata Sheet for methoprene required one ecological effects data requirement, a Fish Toxicity study with rainbow trout (154-8). The study has been submitted and found acceptable.

The Agency has data to support the conclusion that most uses of methoprene will not result in unreasonable adverse effects to the environment. The Agency does have data, however, that show that methoprene is highly acutely toxic to estuarine invertebrates. The Agency also has some data indicating reproductive effects in these species, but there is no data on the effects of low concentrations over the full life cycle of an estuarine invertebrate species. The use of methoprene in a briquette formulation for application in estuarine areas raises a potential concern because the briquette is designed for slow release of methoprene into the water in order to control mosquito larvae. Thus, this one use of methoprene may result in significant exposure to estuarine invertebrates over an extended period of their life cycle. However, there are several mitigating factors that lead the Agency to the conclusion that methoprene could be reregistered at this time. Most of the uses for methoprene do not involve significant exposure to estuarine invertebrates. Only the briquette formulation raises a concern. The other aquatic uses are not expected to result in significant exposure because methoprene is short lived in the aquatic environment and does not have a high potential for bioaccumulation. (Methoprene dissipates rapidly in water. Over 90% dissipates within 3 days after treatment. Methoprene also dissipates rapidly in soil from submerged fields remaining at 0.002 ppm which is 1% of the initial concentration in the top 2 inches of soil 7 days after treatment). Therefore, although most uses of methoprene will not result in significant exposure to estuarine invertebrates, an estuarine invertebrate life cycle toxicity study (Guideline 154-13) is needed in order to confirm whether or not the estimated exposure from the briquette formulation is sufficient to pose an adverse effect on estuarine invertebrates.

1. ENVIRONMENTAL FATE DATA

Methoprene does not appear to be susceptible to hydrolysis under normal environmental conditions. It rapidly photodegrades in/on both aqueous and inert surfaces. In aqueous solutions exposed to natural sunlight, complete degradation occurs within days resulting in the formation of at least 50 minor photolysis

products. Photoisomerization of biologically active trans-2-methoprene to biologically inactive cis-2-methoprene rapidly yields an equimolar ratio of the two isomers. Other photoproducts included methoxycitronellic acid, (2E)-4,5-epoxy-11-methoxy-3,7,11-trimethyl-2-dodecenoate, and 8-methoxy-4,8-dimethyl-2-nonanone. Methoprene is also rapidly photodegraded on inert surfaces, forming methoxycitronellal.

Methoprene is rapidly metabolized in soil under both aerobic and anaerobic conditions (half-life 10-14 days). The major product is CO_2.

Degradation in the aquatic environment is due to both microbial metabolism and photolysis. Methoprene is rapidly degraded in both sterile and nonsterile pond water exposed to sunlight ($\geq$ 80% of applied methoprene is degraded within 13 days). The major microbial product is 7-methoxy-3,7-dimethyloctanoic acid (methoxycitronellic acid). Degradation is somewhat less rapid under sterile conditions than under nonsterile conditions indicating that, although photolysis may be the main degradation route, microbial metabolism contributes to methoprene degradation.

Methoprene degradation occurs at approximately the same rate in both freshwater and saltwater maintained in the dark. Degradation proceeds more rapidly at 20 degrees Celsius than at 4.5 degrees Celsius, with associated half-lives of 10-35 days and $\geq$ 35 days, respectively. Methoprene does not leach in soil and, combined with rapid microbial metabolism in soil, should not persist in soil or contaminate ground water. Similarly, methoprene dissipates rapidly from aquatic ecosystems, with over 90% of the initial methoprene, applied as emulsifiable concentrates or flowable concentrates, being dissipated from a variety of aquatic sites within 3 days of application. Uncharacterized methoprene residues accumulate in edible tissues of bluegill sunfish and crayfish at maximum bioconcentration factors of 457 and 75, respectively. Their rates of depuration are unknown.

2. ECOLOGICAL EFFECTS DATA

a. Effects on Birds

Methoprene was found to be practically non-toxic to mallard ducks with an acute oral LD_{50} value >2000 mg/kg and an 8-day dietary LC_{50} value for methoprene in bobwhite quails was found to be >10,000 ppm. Methoprene had no effects on quail reproduction at dietary concentrations of 30 ppm. Dietary concentrations of 30 ppm caused some reproductive impairment in mallard ducks, but concentrations of 3 ppm had no effect.

b. Effects on Fish

Methoprene is moderately toxic to warm water, freshwater fish. The 96-hour LC_{50} to bluegill sunfish was found to be 1.52 ppm. Under laboratory conditions, the edible portions of bluegill sunfish accumulated 550 and 950 times the ambient water concentrations of 0.005 and 0.31 ppm before reaching a plateau. Non-edible portions of the fish contained residue levels 12 times and 4 times greater than edible portions in the low and high concentrations, respectively. Almost 90% of the residue was found to be unmetabolized methoprene and fish removed from exposure excreted 93-95% of the residue within 14 days. Under simulated natural conditions, bluegills accumulated substantial amounts of the radiolabel, but only 4-5% of the total ^{14}C-residue was found to be methoprene or its metabolites.

In the 1982 Methoprene Registration Standard, a Fish Toxicity study with rainbow trout (Guideline No. 154-8) was required. The 96-hour LC_{50} to rainbow trout was found to be greater than 50 ppm. Methoprene is slightly toxic to coldwater, freshwater fish.

c. Effects on Aquatic Invertebrates

Methoprene can be characterized as very highly toxic to freshwater invertebrates. The 48-hour EC_{50} of technical methoprene to Daphnia magna was 89 ppb and the 42-day maximum acceptable tolerance limit was calculated to be between 27 and 51 ppb. Crayfish exposed to aged radiolabeled methoprene residues showed some tendency to accumulate the radiolabeled material to about 66 times the ambient water concentration, and to levels equal to the ambient soil concentration.

d. Effects on Estuarine and Marine Organisms

Technical methoprene is slightly toxic to very highly toxic on an acute basis to estuarine and marine invertebrates. Methoprene is slightly toxic to adult grass shrimp, very highly toxic to juvenile grass shrimp, and very highly toxic to larval mud-crabs. Technical methoprene may cause inhibition of gametogenesis in mud-crabs exposed to 1.3 ppm for 12-15 days. Marine organisms are not likely to be exposed to methoprene, but estuarine organisms are likely to be exposed. The hazards to estuarine invertebrates as a result of the use of methoprene as a mosquito larvicide are expected to vary depending upon the methoprene formulation used. (The long term exposure resulting from the slow release briquette formulation is of concern to the Agency).

An Estuarine Invertebrate Life Cycle Toxicity Study (Mysidopsis bahia) (154-13) is required to adequately characterize the chronic toxicity of methoprene to estuarine crustaceans. Methoprene is registered for direct application to salt and tidal

marshes, including a slow release briquette formulation which could result in longer term exposure of estuarine invertebrates. Because methoprene is an insect hormone that acts as an insect growth regulator there is a concern that important nontarget species may be adversely affected by chronic exposure to methoprene. Existing data are on the larval stage of the mud crab but no information is available on the entire life cycle. Because methoprene is highly toxic on an acute basis and is expected to be persistent in estuarine ecosystems as a result of the use of the briquette formulation (because of its slow release action over an extended period of time), the chronic toxicity test is required to fully assess this long term exposure.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

Section 4 (g) (2) (A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing methoprene as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing methoprene. Appendix A identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of methoprene, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix A are sufficient to allow the Agency to conduct a reasonable risk assessment for most registered uses of methoprene. The data the Agency has supports the conclusion that most uses of methoprene will not result in unreasonable adverse effects to the environment. As mentioned previously, the only use of concern at this time is the briquette formulation. The Agency therefore finds that all products containing methoprene as an active ingredient are eligible for reregistration except the briquette formulation which will be considered for reregistration once the data requested in this document is submitted, reviewed, and determined to cause no unreasonable risk to nontarget organisms, specifically estuarine invertebrates. Additional data are needed to fulfill the octanol/water partition coefficient data requirement, and data are needed to confirm whether or not the estimated long term exposure from the briquette formulations is sufficient to pose an adverse effect on estuarine invertebrates. The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix A. Although the Agency has found that products containing methoprene are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support reregistration of products containing methoprene, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing methoprene has been evaluated and the Agency has found that the following two additional studies are required to support reregistration of Methoprene:

151-17	Physical and Chemical Properties - Octanol/Water Partition Coefficient
154-13	Estuarine Invertebrate Life Cycle Toxicity Study

The Invertebrate Toxicity study is required to confirm whether or not the estimated exposure from briquette formulation is sufficient to pose an adverse effect on estuarine invertebrates.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHOPRENE

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

2. Based on the reviews of the generic data, the following additional label statements are required:

   a. In the directions for use, the following statement must appear:

      "Formulators using this product are responsible for obtaining EPA registration of their formulated products."

   b. In the directions for use, the following statement regarding acceptable use patterns must appear:

      "For formulation into end-use products intended only for (<u>list acceptable sites</u>)."

   c. In the Environmental Hazards section the following statment must appear:

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

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredient, methoprene, the products containing this active ingredient except the briquette formulation(s) are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are stated in the attached Data Call-In appendices.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING METHOPRENE

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

2. Based on the reviews of the generic data the following additional label statement is required:

"This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters."

APPENDIX A

Generic Data Reuqirements for Reregistration of Methoprene and Data Citations Supporting Reregistration

GUIDE TO APPENDIX A

Appendix A contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix 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.

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

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

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

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

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
151-10	Identification	ABCDEFGKLMNO	Data were obtained from the most recent confidential statement of formula submitted.
151-17	Color	ABCDEFGKLMNO	00010927
151-17	Odor	ABCDEFGKLMNO	00010927
151-17	Solubility	ABCDEFGKLMNO	00010925
151-17	Stability	ABCDEFGKLMNO	00010927
151-17	Physical State	ABCDEFGKLMNO	00010927

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry: (continued)			
151-17	Density or Specific Gravity	ABCDEFGKLMNO	00010927
151-17	Boiling Point	ABCDEFGKLMNO	00010927
151-17	Vapor Pressure	ABCDEFGKLMNO	00010927
151-17	pH	ABCDEFGKLMNO	00010927

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology:			
152-10	Acute Oral Toxicity	ABCDEFGKLMNO	00024607
152-11	Acute Dermal Toxicity	ABCDEFGKLMNO	00010914
152-19	Mutagenicity	ABCDEFGKLMNO	05018270, 00010545
152-20	Subchronic Oral Toxicity	ABCDEFGKLMNO	00024612
152-23	Teratogenicity	ABCDEFGKLMNO	00029250
152-26	Chronic Feeding	ABDLMNO	00010739
152-29	Oncogenicity	ABDLMNO	00010739, 00010600
S152-001	Subchronic 21-day Dermal Toxicity	ABCDEFGKLMNO	GS0030-0011
S152-002	Reproduction	ABCDEFGKLMNO	00010571
S152-003	Metabolism	ABCDEFGKLMNO	00010866, 05007755, 00010425 00010424, 00010379, 00010380 00011491, 00010879, 05008609 00010681, 00010626, 00010683

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Residue Chemistry:			
153-3	Metabolism in Plants	ABDKL	05007756, 00011031, 00010875 00010422, 00010369, 00010368 00010366, 05008622
153-3	Metabolism in Animals	ABDL	00012761, 00010682, 00010684 00010867, 00011098, 00010692 00011099
153-3	Analytical Methods	ABDKL	00011105, 00010687, 00010796, 00010938, 00011490, 00026940, 00010797
153-3	Residue Data: Crops	ABDK	00010827, 00010374, 00012782 00011493, 00010374, 00012782 00012787, 00012796, 00029673, 05007751
153-3	Residue Data: Meat and Milk	ABDL	00010682, 00010894, 00010898 00010832, 00010897, 00010619 00010896, 00010889, 00010895 00010680, 00012783, 00010833 00010893

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Ecological Effects:			
154-6	Avian Single-Dose Oral LD50	ABCDEFGKLMNO	00010633
154-7	Avian Dietary LC50	ABCDEFGKLMNO	00012754, 00012755
154-8	Fish Acute LC50	ABCDEFGKLMNO	00010388, 00010643
154-9	Aquatic Invertebrate Acute LC50	ABCDEFGKLMNO	00010856
S154-001	Avian Reproduction	ABCDEFK	00010634, 00010635
S154-002	Acute Toxicity to Estuarine and Marine Organisms	ABCDEFK	00010851, 00010852, 05010827 00010860, 00010859
S154-003	Aquatic Organism Accumulation	ABCDEFK	05008611, 00010903, 00010390
S154-004	Reptile and Amphibian LC50	ABCDEFGKLMNO	00010405

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF METHOPRENE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Environmental Fate:			
155-9	Hydrolysis	ABCDEFGK	00010439
S155-001	Field Dissipation Aquatic and Aquatic Impact	DEFGK	05008625, 00011485, 00010434 00010435, 00010436, 00010437 00010438, 00011484, 00010433 00010417, 00011091, 00011092 00012729

APPENDIX B

METHOPRENE BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX B

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 Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, 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 further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

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

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

As a last resort, the Agency has shown the first submitter as author.

b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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