United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-95-038 July 1995

Reregistration Eligibility Decision (RED)

Methyl Nonyl Ketone

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Rubis at (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Paul Lewis at (703) 308-8018.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

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

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

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

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

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

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

METHYL NONYL KETONE

LIST C

CASE 3094

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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METHYL NONYL KETONE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Doug Sutherland	Biological Analysis Branch
Art Grube	Economic Analysis Branch
Gabe Patrick	Biological Analysis Branch

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (hereafter referred to as the "Agency" or "EPA") has completed its reregistration assessment of the available information on the pesticidal active ingredient methyl nonyl ketone. The active ingredient has pesticidal activity as a dog and cat repellant/training aid and as an iris borer deterrent. Use sites include household/domestic dwelling contents, vegetable gardens, ornamental shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental woody shrubs and vines, paths/patios and refuse/solid waste containers. The Agency has reviewed the available data for methyl nonyl ketone and has determined that products registered for the uses described in this reregistration eligibility decision document as currently registered will not cause unreasonable risk to humans or the environment and that these products are eligible for reregistration.

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

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and 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.

FIFRA Section 4(g)(2)(A) 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 eligibility of the registered uses of methyl nonyl ketone. The document consists of six sections. Section I is the introduction. Section II describes methyl nonyl ketone, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for methyl nonyl ketone. Section V discusses the reregistration requirements for methyl nonyl ketone. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Methyl nonyl ketone
- **Chemical Name:** 2-Undecanone
- **Chemical Family:** Aliphatic ketone
- **CAS Registry Number:** 112-12-9
- **OPP Chemical Code:** 44102
- **Empirical Formula:** $C_{11}H_{22}O$
- **Basic Manufacturer:** McLaughlin Gormley King Company

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of methyl nonyl ketone is in Appendix A.

Type of Pesticide:
dog and cat repellent/training aid and iris borer deterrent

Use Sites:
Indoor Residential
household/domestic dwellings contents
Outdoor Residential
household/domestic dwellings outdoor premises
paths/pations

solid waste containers (garbage cans and bags)

Terrestrial Nonfood Crop

ornamental and/or shade trees
ornamental herbaceous plants
ornamental lawns and turf
ornamental woody shrubs and vines
around perimeters of vegetable plantings
paths/patios
refuse/solid waste containers (garbage cans and bags)

Target Pests:

dog, cat and iris borer

Formulation Types Registered:

pressurized liquid: 1.9% methyl nonyl ketone + 0.1% related compounds; 2.0% methyl nonyl ketone

granular: 1.9% methyl nonyl ketone + 0.1% related compounds; 0.08% methyl nonyl ketone + 0.42% cinnamaldehyde; 6.25% thiram, 6.25% methyl nonyl ketone and 5.50% castor oil (USP)

liquid ready-to-use (pump/sprayer): 1.8-1.9% methyl nonyl ketone + 0.1% related compounds; 2.0% methyl nonyl ketone

solid (crystalline): 1.8% methyl nonyl ketone + 0.1% related compounds

liquid for reformulating use only: 63.33% methyl nonyl ketone and 3.34% related compounds

Method of application:

Outdoor:

granular and crystals: band or broadcast to soil or ground as perimeter or border treatment, between rows or around base of ornamental plants and objects.

pressurized liquid or liquid ready-to-use: apply to bark of trees and base of shrubs. For surface treatments, spray a piece of cloth and attach it to item to be protected. The item may or may not be dry.

Indoor:

for a spot treatment, spray a piece of cloth and attach it to item to be protected. The item may or may not be dry.

Application equipment:

granular formulation: fertilizer spreader and by hand

pressurized liquid and liquid ready-to-use: pump sprayer and aersol can

Application timing:

Dog and cat:

granular and crystals: repels cats and dogs up to seven to ten days. Repeat until undesirable animal habits are broken. Repeat after rain. With crystal formulation, apply at three to four day intervals.

pressurized liquid or liquid ready to use: repels cats and dogs for 12-24 hours. Apply every day or two or as needed.

Iris borer:

spray in the spring, midsummer and at time of transplanting. Spray leaves after sunset or on cloudy days and soil around plants and between rows. Spray rhizomes when transplanting and the ground into which new rhizomes are set. Reapply if weather is cold or rain results in new growth of the host.

Application rate:

granular and crystalline formulation: sprinkle/scatter 4 lbs/1000 sq. ft. (1.28 oz. a.i.) or 1-2 cupfuls/100 sq. ft. on soil or ground area.

pressurized liquid and liquid ready-to-use: apply until surface is slightly moistened.

Use Practice Limitations:

Do not apply directly to ornamental or other plants unless instructed to because some vegetation may be damaged.
Pressurized liquid and liquid ready-to-use formulations may stain or soften some fabrics or plastics.
Do not use in commercial food processing or preparation areas.
Do not contaminate food or feedstuffs. Cover exposed food, food processing areas and food processing utensils.
Do not apply to food crops.
Do not apply to soft stemmed bodied plants.
Do not apply directly to water.

Estimated Usage of Pesticide

Due to a lack of usage for methyl nonyl ketone, the Agency cannot estimate the volume of use of this pesticide. However, it assumes the volume is relatively low.

C. Data Requirements

A Data Call-In was issued in 1992 for methyl nonyl ketone requiring the submission of additional product chemistry data.

D. Regulatory History

Methyl nonyl ketone was first registered in the United States in 1966 for use as a dog and cat repellant. Currently, there are 48 products registered to 65 companies. The Appendix B of this document includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Common name: Methyl nonyl ketone

Empirical formula: $C_{11}H_{22}O$

Molecular weight: 170.29

TGAI: Methyl nonyl ketone

Color: Colorless

Physical state: Clear liquid at room temperature

Odor: Slight acrid odor

Melting point: 11-14^{o} C

Boiling point: 233-234^{o} C

Density:	0.827 g/ml at 20^{o} C
Solubility:	in water: 18.0×10^{-3} g/l in organic solvents: is completely miscible with acetone, methanol, isopropanol, petroleum ether, vista LPA, Cyclo Solv (aromatic), and chloroethene.
Vapor pressure:	4.49×10^{-2} Torr at 25^{o} C
Octanol/water partition coefficient:	$k_{oc} = 16,601$
Stability:	Stable at room temperature. Slight discoloration was observed over an extended period of time.
Storage stability:	One year of storage at room temperature did not produce any significant change regarding purity, color, specific gravity, and refractive index.
Viscosity:	7.5 cps at 22^{o} C
Corrosion characteristics:	Methyl nonyl ketone is considered non-corrosive after 12 months of storage at room temperature.

B. Human Health Assessment

1. Toxicology Assessment

The methyl nonyl ketone toxicological data base is adequate and will support reregistration eligibility.

a. Acute Toxicity

Table 1 below describes the acute toxicity of methyl nonyl ketone.

Table 1: Acute Toxicity

TEST	MRID	RESULTS	CATEGORY
Oral LD50 - rat	41904101	>5,000 mg/kg males and females	IV
Dermal LD50 - rabbit	41904102 43163801	>2,000 mg/kg males and females	III
Inhalation LC50 - rat	41904103	>5.43 mg/L	IV
Eye irritation - rabbit *	41904104	mild conjunctival irritant	III
Dermal irritation - rabbit *	41904105	mild erythema/eschar and edema	III
Dermal sensitization - guinea pig *	41904106	weak sensitizer	N/A

* study is not required on technical grade active ingredient. Data are provided for informational purposes

In an eye irritation study, methyl nonyl ketone was observed to cause conjunctival irritation in 6/6 New Zealand white rabbits through 24 hours, 4/6 at 48 hours, 2/6 at 72 hours, 1/6 at 4 days and 0/6 at 7 days. In a dermal irritation study in New Zealand white rabbits, erythema and eschar formation were present in 6/6 animals through 72 hours and 3/6 at 7 days; edema was noted in 5/6 at 30-60 minutes, 2/6 at 24-72 hours and 0/6 at 7 days. There was the appearance of weak skin sensitization during the challenge phase of a dermal sensitization study in guinea pigs.

b. Subchronic Toxicity

In a 21-day dermal toxicity study, methyl nonyl ketone was administered at doses of 0, 30, 100, or 300 mg/kg/day (21 consecutive days) to young adult male and female New Zealand white rabbits. The systemic NOEL was equal to or greater than 300 mg/kg/day with the LOEL being greater than 300 mg/kg/day. The NOEL for dermal irritation was 100 mg/kg/day with the LOEL being 300 mg/kg/day based on moderate to severe dermal irritation (MRID 43110301).

c. Developmental Toxicity

In a developmental toxicity (teratology) study, methyl nonyl ketone was administered at doses of 0, 100, 300, or 1,000 mg/kg/day by gavage

to Charles River Crl:CD BR albino rats on gestation days 6 through 15. There was no evidence of maternal toxicity or developmental toxicity. Therefore, both the maternal and developmental NOELs were set at >1,000 mg/kg/day (the highest dose tested) (MRID 42225901, 42225902).

d. Mutagenicity

In a mouse lymphoma cell forward mutation study, dosing levels of 0, 0.0032, 0.0042, 0.0056, 0.0075, 0.010, 0.013, 0.018, 0.024, 0.032, or 0.042 μL/mL in the absence of S9, and 0, 0.013, 0.018, 0.024, 0.032, 0.042, 0.056, 0.075, 0.10, or 0.13 μL/mL in the presence of S9 were tested. The cultures were exposed to the methyl nonyl ketone for 4 hours. There was no evidence of induced forward mutation at the TK locus at any of the doses tested with or without the S9 activation (MRID 41740001).

In a Chinese hamster ovary study, dosing levels of 0, 0.0065, 0.013, 0.025, 0.05 or 0.10 μL/mL with and without S9 activation were tested. There was no evidence of induced chromosomal aberrations over the control values at any of the doses tested with or without the S9 activation (MRID 41783101).

In an unscheduled DNA synthesis (UDS) assay, primary rat hepatocytes were exposed to dosing levels of 0, 0.003, 0.01, 0.03, 0.1, or 0.3 μL/mL for 18 - 20 hours in the presence of tritiated thymidine. There was no evidence of UDS induction as measured by the incorporation of tritiated thymidine into DNA (autoradiography) (41774401).

e. Toxicology Conclusion

Based on available information, no toxicological endpoints of concern (such as short term or intermediate term) were identified.

2. Exposure Assessment

a. Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if certain toxicological criteria are met and if there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete.

<u>Handler (Mixer/Loader/Applicators) Exposures</u>

There is a potential for exposure to mixer/loader/applicators during the use-patterns associated with methyl nonyl ketone, specifically potential exposures arising from applying granulars by hand and lawn spreaders, and applying liquid sprays to ornamentals, furniture, and rugs.

Post-Application Exposures

There is a potential for exposure to persons entering treated sites after application of methyl nonyl ketone is complete, specifically potential post-application exposure arising from re-entering treated lawns, gardens, and residences.

Need for Assessment

While there is a potential for exposure to handlers as well as post-application exposure, an occupational and/or residential exposure assessment for methyl nonyl ketone is not required because there are no toxicological endpoints of concern.

3. Risk Assessment

a. Dietary

Based on the current use patterns and exposure profiles for methyl nonyl ketone, residues in/on food and/or feed are not expected to occur. Therefore, a dietary risk characterization is not required.

b. Occupational and Residential

As stated previously, no appropriate endpoints for short term or intermediate term occupational or residential risk assessment were identified. Therefore, a risk characterization is not required.

C. Environmental Assessment

The Agency has adequate data to assess the risk of methyl nonyl ketone to nontarget terrestrial organisms.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds: Acute and Subacute Toxicity.

In order to establish the acute and subacute toxicity of methyl nonyl ketone to birds, the following tests were required using the technical grade of the active ingredient (a.i.): one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail) and subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

The results of the studies summarized in Tables 2 and 3 below indicate that methyl nonyl ketone is practically nontoxic to avian species on an acute oral (Table 2) and subacute dietary (Table 3) basis. The guideline requirements for both the avian acute oral LD_{50} and the avian subacute dietary LD_{50} studies have been met.

Table 2. Avian Acute Oral Toxicity

SPECIES TESTED	% A.I.	LD_{50} (mg/kg)	MRID	CONCLUSION
Northern Bobwhite	100	> 2,250	41986501	Practically nontoxic
Mallard	100	> 2,250	41986502	Practically nontoxic

Table 3: Avian Subacute Dietary Toxicity

SPECIES TESTED	% A.I.	LC_{50} (ppm)	MRID	CONCLUSION
Northern Bobwhite	100	> 5,620	41947901	Practically nontoxic
Mallard	100	> 5,620	41947902	Practically nontoxic

(2) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Under the conditions of a range-finding and developmental toxicity study done for the Agency, as summarized in the Human Health Assessment, doses up to 1,000 mg/kg/day produced no apparent related maternal or developmental effects on rats. Based on these conclusions, wild animal testing was not required for methyl nonyl ketone.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of methyl nonyl ketone to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

The results of the acute toxicity studies summarized in Table 4 below indicate that methyl nonyl ketone is moderately toxic to both cold and warmwater fish. The guideline requirements for the freshwater fish toxicity studies have been met.

Table 4: Freshwater Fish Acute Toxicity

SPECIES TESTED	% A.I.	LC_{50} (ppm)	MRID	CONCLUSION
Rainbow trout	100	3.0	41909603	Moderately toxic
Bluegill sunfish	100	2.1	41909602	Moderately toxic

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of methyl nonyl ketone to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar Daphnia magna or early instar amphipods, stoneflies, mayflies, or midges.

The results of the freshwater aquatic invertebrate toxicity study summarized in Table 5 below indicate that there is sufficient information to characterize methyl nonyl ketone as highly toxic to aquatic invertebrates. The guideline requirement for the freshwater aquatic invertebrate toxicity study has been met.

Table 5: Freshwater Invertebrate Toxicity

SPECIES TESTED	% A.I.	EC_{50} (ppm)	MRID	CONCLUSION
Daphnia magna	97.9	0.54	41909604	Highly toxic

2. Environmental Fate

a. Environmental Fate and Transport

(1) Hydrolysis

In a study addressing the hydrolysis of methyl nonyl ketone, the data indicated that the pesticide does not undergo hydrolysis. Methyl nonyl ketone did not hydrolyze in sterile buffered aqueous

solutions (pH 5, 7, and 9) incubated in the dark at 25^0 C for 30 days. At the end of the study, methyl nonyl ketone was 84.7-98.9%, 94.0-103.1%, and 90.7-101.5% of the applied for the pH 5, pH 7, and the pH 9 buffered test solutions, respectively. Material balances ranged from 87.5 to 100.8% of the applied radioactivity. Therefore, the study was acceptable to support the Hydrolysis data requirement (MRID 41986401).

(2) Aerobic Soil Metabolism

The degradation of methyl nonyl ketone in soil appears to be microbiologically mediated under aerobic conditions (with a half-life of 0.5 day). In an aerobic soil metabolism study, methyl nonyl ketone, at 10 ppm, degraded with a half-life of approximately 0.5 days in sandy loam soil incubated aerobically at $25^0 \pm 1^0$ C. The major degradate was CO_2, which totalled 48.7% of the applied at 30 days. Other metabolites of methyl nonyl ketone were: 4-hydroxy-2-undecanone; 10-hydroxy-2-undecanone; 2,4-undecanone; 2,10-undecanone and; 4-hydroxypentanoic acid. None of these metabolites were present more than 3% of the applied at any sampling period. Therefore, the study was acceptable to support the Aerobic Soil Metabolism data requirement (MRID 42497201).

(3) Leaching-Adsorption/Desorption

In a Leaching-Adsorption/Desorption study, methyl nonyl ketone was observed to be relatively immobile in soil and have a low potential to leach into ground water or move offsite into surface water. Methyl nonyl ketone was determined to be relatively immobile in sodium azide-sterilized sandy loam, clay loam, sand, and silt loam soils (K_{ads}=18; K_{oc}=2,480). Therefore, the study was found to be acceptable to support the Leaching-Adsorption/Desorption data requirement.

Although the leaching-adsorption/desorption data requirement is satisfied, the Agency has concerns about the use of sodium azide as a chemical inhibitor for sterilization of soils. The Agency believes that physical or chemical sterilization (such as autoclaving or use of sodium azide) may subtly alter the soil chemistry, thus complicating the interpretation of the results obtained in the batch equilibrium studies. The Agency

acknowledges the difficulty of conducting a scientifically-sound batch equilibrium study for methyl nonyl ketone because it is unstable under aerobic conditions. Thus, no additional data are required (MRID 42208301).

b. Environmental Fate and Ground Water Assessment

Due to the low relative mobility and the rapid degradation of methyl nonyl ketone in soils, its low volume use, and use patterns, the Agency concludes that the potential for methyl nonyl ketone to leach into ground water or move offsite into surface water would be very low.

Methyl nonyl ketone is not very soluble in water (solubility in water is 18 ppm). It is not susceptible to hydrolysis at pH 5, 7, and 9 in the absence of light. Because of its extremely high vapor pressure (4.49×10^{-2} torr at 25°C), volatilization from soils will be an important route of dissipation. The high octanol/water partition coefficient (K_{ow}= 16,218) suggests that methyl nonyl ketone will have a high tendency to accumulate in fish. However, since methyl nonyl ketone products are not applied to surface or ground water and the current use patterns of methyl nonyl ketone products, exposure of the pesticide to fish is not anticipated.

Results from an aerobic soil metabolism study showed that methyl nonyl ketone degraded very rapidly in sandy loam soil (half-life=0.5 day). The major degradate was CO_2, which totalled 49% of applied at 30 days. Other nonvolatile metabolites identified at low concentrations were 4-hydroxy-2-undecanone, 10-hydroxy-2-undecanone, 2,4-undecanone, 2,10-undecanone, and 4-hydroxypentanoic acid. None of these degradates were present at more than 3% of the applied at any sampling period.

Methyl nonyl ketone is expected to be relatively immobile in the environment (K_{ads}=18; or K_{oc}=2,480).

Based on these properties, the Agency concludes that methyl nonyl ketone is expected to be relatively immobile and not persistent in the environment. The major routes of dissipation are volatilization (vapor pressure=4.49×10^{-2} torr) and biotic degradation under aerobic conditions (half-life=0.5 day).

3. Exposure and Risk Characterization

a. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

There is some concern that birds may ingest the granular formulation of methyl nonyl ketone while feeding. Therefore, a risk assessment on the granular product is included here.

As summarized in Table 6 below, the maximum application rate for the granular formulation is 49.5 lbs a.i. per acre. For broadcast applications, the LD_{50}/ft^2 for the northern bobwhite is 1.3 and for the mallard it is 0.21.

Table 6: Comparison of LD_{50}/ft^2 to the LOC for granular formulation

MAXIMUM APPLICATION RATE lbs a.i./A	APPLICATION METHOD	SPECIES (LD_{50}/ft^2)	LOC
49.5	Broadcast	Northern bobwhite (1.3)	High Risk > 0.5 Restricted use > 0.2 Endangered species > 0.1
49.5	Broadcast	Mallard (0.21)	

The LD_{50}/ft^2 shown in Table 6 are not based on a definitive LD_{50} value for birds. Both the bobwhite and the mallard studies failed to determine an LD_{50} because there was not 50% mortality at any of the test levels, including the highest. The information gained from both studies is that the LD_{50} is above 2,250 mg/kg. The LD_{50}/ft^2, the calculation being based upon an LD_{50} being equal to 2,250 ppm, are considered to be much greater than the actual acute values (which are unknown) and thus are overly conservative. These values should be viewed as the upper limit of what the actual values could be; the actual LD_{50}/ft^2 are unknown and could be much less. Thus, values greater than the LOC for high risk, restricted use, and endangered species do not necessarily mean that risk is presumed, but rather that acute risk to avian species, including endangered species, cannot be ruled out based on the limited information available. If product labeling is strictly adhered to, the likelihood of avian species being adversely impacted is minimized.

(2) Mammals

Methyl nonyl ketone is used as a dog and cat repellant. Because of the repellent nature of the product, mammals are not likely to ingest it directly. Also, according to the above range-finding and developmental toxicity study, doses up to 1,000 mg/kg/day produced no apparent related maternal or developmental effects on rats. Therefore, if mammals were to ingest the product, it would have to be in an amount greater than 1,000 mg/kg/day to have an adverse impact, and this is not likely.

b. Exposure and Risk to Nontarget Aquatic Animals

Methyl nonyl ketone displays moderate to high toxicity to most aquatic organisms tested to date. However, the use of methyl nonyl ketone is not likely to adversely impact aquatic organisms because this chemical is neither persistent nor mobile in the environment.

c. Endangered Species

The acute risk to endangered avian species cannot be dismissed because the use rate (49.5 lbs a.i./A) results in an LD_{50}/ft^2 that exceeds the endangered species LOC. However, based on the application method (broadcast by hand) it is unlikely that endangered avian species would be adversely impacted. Product labeling must be strictly adhered to in order to minimize adverse impacts to endangered avian species.

d. Exposure and Risk to Ground and Surface Water

Taking into account the relative immobility, the rapid dissipation in soils, and the use patterns, it is unlikely that methyl nonyl ketone will leach into groundwater or move offsite into surface water.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients 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 methyl nonyl ketone active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing methyl nonyl ketone. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of methyl nonyl ketone, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of methyl nonyl ketone and to determine that methyl nonyl ketone can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing methyl nonyl ketone as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of methyl nonyl ketone 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 the registration of products containing methyl nonyl ketone, 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. Determination of Eligibility

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all uses of methyl nonyl ketone are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for methyl nonyl ketone. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/ Applicators)

At this time there are no engineering control requirements, such as closed systems, currently required on labeling for methyl nonyl ketone products.

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects:

• In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

• These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

• The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Since there are no special toxicological concerns about methyl nonyl ketone, the establishment of active-ingredient-based handler PPE requirements is not warranted. PPE requirements, if appropriate, will be established based on the acute toxicity of the end-use product.

2. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered bird species to methyl nonyl ketone as discussed in the above environmental assessment. However, based on the application method of the pesticide, it is unlikely that endangered avian species would be adversely impacted.

The Endangered Species Protection Program is expected to become final in 1995. Limitations in the use of methyl nonyl ketone may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of the consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

V. ACTIONS REQUIRED OF REGISTRANTS

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

1. Manufacturing-Use Products

a. Additional Generic Data Requirements

The generic data base supporting the reregistration of methyl nonyl ketone for the above eligible uses has been reviewed and determined to be complete.

2. End-Use Products

a. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new

studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Entry Restrictions

The Agency is establishing minimum entry restrictions for all methyl nonyl ketone end-use products, as required for all pesticides, as described below.

a. **Entry Requirements:**

Labeling for sole-active ingredient end-use products that contain methyl nonyl ketone must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

The Agency is establishing the following entry restrictions for all homeowner uses of methyl nonyl ketone end-use products.

For liquid applications:

"Do not allow persons or pets to enter the treated area until sprays have dried."

For dry applications:

"Do not allow persons or pets to enter the treated area until dusts have settled."

Placement on labeling -- Place these statements near the beginning of the Directions for Use section of the labeling.

b. **Application Requirements:**

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

Placement on labeling -- Place this statement near the beginning of the Directions for Use section of the labeling.

c. **User Safety Requirements:**

• "Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

Placement on labeling -- Place this statement near the beginning of the Directions for Use section of the labeling.

d. **User Safety Recommendations:**

• "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

• "Users should remove clothing immediately if pesticide gets on or inside clothing. Then wash thoroughly with detergent and hot water separately from other laundry and put on clean clothing."

• "Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Placement on labeling -- Place these statements near the beginning of the Directions for Use section of the labeling.

3. Existing Stocks

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

The Agency has determined that registrants may distribute and sell methyl nonyl ketone products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain

obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
HOUSEHOLD/DOMESTIC DWELLINGS CONTENTS				Use Group: INDOOR RESIDENTIAL									
Soil treatment., When needed., Product container.	RTU	NA		UC	*	NS	NS	NS	NS	3	NS		
Spot treatment., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	0.5	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	1	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spot treatment., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	0.5	NS		
	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spot treatment., When needed., Sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	1	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., When needed., Sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES				Use Group: INDOOR RESIDENTIAL									
Spray., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL									
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS		
	G	NA	.08 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS		C93
Perimeter treatment., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	1	NS		
Soil broadcast treatment., When needed., Shaker can.	G	NA	.08 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS		
Soil treatment., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
Soil treatment., When needed., Sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES (con't)				Use Group: OUTDOOR RESIDENTIAL (con't)							
Spray., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	NS	NS	
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	C93
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Spray., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	NS	NS	
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD CROP							
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	C93
Broadcast., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	C93
Soil treatment., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	NS	NS	
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Bark treatment., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	AN	NS	
Bark treatment., When needed., Pump spray bottle.	RTU	NA		UC *	NS	NS	NS	NS	AN	NS	
Bark treatment., When needed., Sprayer.	RTU	NA		UC *	NS	NS	NS	NS	AN	NS	
Soil band treatment., When needed., Not on label.	FM/S	NA	.025 lb 1K linear ft	*	NS	NS	NS	NS	AN	NS	
Soil broadcast treatment., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	C93
Soil broadcast treatment., When needed., Shaker can.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	
Soil broadcast treatment., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	C93
Soil treatment., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	0.5	NS	

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL AND/OR SHADE TREES (con't)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)							
	PRL	NA		UC *	NS	NS	NS	NS	AN	NS	
Soil treatment., When needed., Product container.	RTU	NA		UC *	NS	NS	NS	NS	3	NS	
Soil treatment., When needed., Pump spray bottle.	RTU	NA		UC *	NS	NS	NS	NS	0.5	NS	
	RTU	NA		UC *	NS	NS	NS	NS	AN	NS	
Soil treatment., When needed., Sprayer.	RTU	NA		UC *	NS	NS	NS	NS	AN	NS	
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	C93
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP							
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	C93
Broadcast., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	C93
Soil treatment., Foliar., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
Soil treatment., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	NS	NS	
Spray., Fall., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
Spray., Foliar., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
Spray., Rhizome., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
Spray., Spring., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
Spray., Transplant., Mist sprayer.	RTU	NA		UC *	NS	NS	NS	NS	NS	NS	C67
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Perimeter treatment., When needed., Aerosol can.	PRL	NA		UC *	NS	NS	NS	NS	1	NS	
Perimeter treatment., When needed., Not on label.	FM/S	NA	.025 lb 1K linear ft	*	NS	NS	NS	NS	AN	NS	
Soil band treatment., When needed., Not on label.	FM/S	NA	.025 lb 1K linear ft	*	NS	NS	NS	NS	AN	NS	

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL HERBACEOUS PLANTS (con't)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)									
Soil broadcast treatment., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
Soil broadcast treatment., When needed., Shaker can.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
Soil broadcast treatment., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
Soil treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	0.5	NS			
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			
Soil treatment., When needed., Product container.	RTU	NA	UC	*	NS	NS	NS	NS	3	NS			
Soil treatment., When needed., Pump spray bottle.	RTU	NA	UC	*	NS	NS	NS	NS	0.5	NS			
	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS			
Soil treatment., When needed., Sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS			
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
ORNAMENTAL LAWNS AND TURF				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Broadcast., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Spray., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS			
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Soil broadcast treatment., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL LAWNS AND TURF (con't)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)									
Soil broadcast treatment., When needed., Shaker can.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
Soil broadcast treatment., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
Soil treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			
Soil treatment., When needed., Product container.	RTU	NA	UC	*	NS	NS	NS	NS	3	NS			
Soil treatment., When needed., Pump spray bottle.	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS			
Soil treatment., When needed., Sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS			
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
ORNAMENTAL NONFLOWERING PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Broadcast., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Soil broadcast treatment., When needed., By hand.	G	NA	.2 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
Soil broadcast treatment., When needed., Spreader.	G	NA	.04 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS			C93
Soil treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS			
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Broadcast., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			C93
Soil treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS			

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Soil band treatment., When needed., Not on label.	FM/S	NA	.025 lb 1K linear ft	*	NS	NS	NS	NS	AN	NS		
Soil broadcast treatment., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		C93
Soil broadcast treatment., When needed., Shaker can.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		
Soil broadcast treatment., When needed., Spreader.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		C93
Soil treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	0.5	NS		
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS		
Soil treatment., When needed., Product container.	RTU	NA	UC	*	NS	NS	NS	NS	3	NS		
Soil treatment., When needed., Pump spray bottle.	RTU	NA	UC	*	NS	NS	NS	NS	0.5	NS		
	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS		
Soil treatment., When needed., Sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS		
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		C93
PATHS/PATIOS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Soil treatment., When needed., Sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS		
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)				Use Group: OUTDOOR RESIDENTIAL								
Sprinkle., When needed., By hand.	G	NA	1.136 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		C93
REFUSE/SOLID WASTE CONTAINERS (GARBAGE CANS)				Use Group: INDOOR RESIDENTIAL								
Sprinkle., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS		C93
	G	NA	.2 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C93

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
REFUSE/SOLID WASTE CONTAINERS (GARBAGE CANS) (con't)				Use Group: INDOOR RESIDENTIAL (con't)							
Surface treatment., When needed., Aerosol can.	PRL	NA		UC	* NS	NS	NS	NS	NS	NS	
				Use Group: OUTDOOR RESIDENTIAL							
Spray., When needed., Aerosol can.	PRL	NA		UC	* NS	NS	NS	NS	AN	NS	
Spray., When needed., Sprayer.	RTU	NA		UC	* NS	NS	NS	NS	AN	NS	
Sprinkle., When needed., By hand.	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	
	G	NA	.08 lb 1K sq.ft	*	NS	NS	NS	NS	AN	NS	C93
	G	NA	.2 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	C93
Surface treatment., When needed., Aerosol can.	PRL	NA		UC	* NS	NS	NS	NS	NS	NS	
VEGETABLES (UNSPECIFIED)				Use Group: TERRESTRIAL NON-FOOD CROP							
Perimeter treatment., When needed., Not on label.	FM/S	NA	.025 lb 1K linear ft	*	NS	NS	NS	NS	AN	NS	
Perimeter treatment., When needed., Product container.	RTU	NA		UC	* NS	NS	NS	NS	3	NS	
Perimeter treatment., When needed., Pump spray bottle.	RTU	NA		UC	* NS	NS	NS	NS	AN	NS	

LEGEND
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HEADER ABBREVIATIONS
Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
FM/S : FORM NOT IDENTIFIED/SOLID
G : GRANULAR
PRL : PRESSURIZED LIQUID
RTU : LIQUID-READY TO USE

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C67 : Do not broadcast product over crops grown for food, feed or other purposes.
C93 : Do not apply directly to water.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methyl Nonyl Ketone

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	all	Satisfied
61-2A	**Start. Mat. & Mnfg. Process**	all	Satisfied
61-2B	**Formation of Impurities**	all	Satisfied
62-1	**Preliminary Analysis**	all	Satisfied
62-2	**Certification of limits**	all	Satisfied
62-3	**Analytical Method**	all	Satisfied
63-2	**Color**	all	Satisfied
63-3	**Physical State**	all	Satisifed
63-4	**Odor**	all	Satisfied
63-5	**Melting Point**	all	Satisfied
63-6	**Boiling Point**	all	Satisfied
63-7	**Density**	all	Satisfied
63-8	**Solubility**	all	Satisfied
63-9	**Vapor Pressure**	all	Satisfied
63-10	**Dissociation Constant**	all	Satisfied
63-11	**Octanol/Water Partition**	all	Satisifed
63-12	**pH**	all	Satisfied

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	all	Satisified
63-14	**Oxidizing/Reducing Action**	all	Satisfied
63-15	**Flammability**	all	Satisfied
63-16	**Explodability**	all	Satisfied
63-17	**Storage stability**	all	Satisfied
63-18	**Viscosity**	all	Satisfied
63-19	**Miscibility**	all	Satisfied

ECOLOGICAL EFFECTS

71-1A	**Acute Avian Oral - Quail/Duck**	C,I,M	41986501 and 41986502
71-1B	**Acute Avian Oral - Quail/Duck TEP**		
71-2A	**Avian Dietary - Quail**	C,I,M	41947901
71-2B	**Avian Dietary - Duck**	C,I,M	41947902
71-3	**Wild Mammal Toxicity**	C,I,M	42225902
71-4A	**Avian Reproduction - Quail**		
71-4B	**Avian Reproduction - Duck**		
71-5A	**Simulated Field Study**		
71-5B	**Actual Field Study**		

Data Supporting Guideline Requirements for the Reregistration of Methyl Nonyl Ketone

REQUIREMENT		USE PATTERN	CITATION(S)
72-1A	**Fish Toxicity Bluegill**	C,I,M	41909602
72-1B	**Fish Toxicity Bluegill - TEP**		
72-1C	**Fish Toxicity Rainbow Trout**	C,I,M	41909603
72-1D	**Fish Toxicity Rainbow Trout- TEP**		
72-2A	**Invertebrate Toxicity**	C,I,M	41909604
72-2B	**Invertebrate Toxicity - TEP**		
72-3A	**Estuarine/Marine Toxicity - Fish**		
72-3B	**Estuarine/Marine Toxicity - Mollusk**		
72-3C	**Estuarine/Marine Toxicity - Shrimp**		
72-3D	**Estuarine/Marine Toxicity Fish- TEP**		
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		
72-4A	**Early Life Stage Fish**		
72-4B	**Life Cycle Invertebrate**		
72-5	**Life Cycle Fish**		
72-6	**Aquatic Organism Accumulation**		
72-7A	**Simulated Field - Aquatic Organisms**		

REQUIREMENT		USE PATTERN	CITATION(S)
72-7B	**Actual Field - Aquatic Organisms**		
122-1A	**Seed Germination/Seedling Emergence**		
122-1B	**Vegetative Vigor**		
122-2	**Aquatic Plant Growth**		
123-1A	**Seed Germination/Seedling Emergence**		
123-1B	**Vegetative Vigor**		
123-2	**Aquatic Plant Growth**		
124-1	**Terrestrial Field**		
124-2	**Aquatic Field**		
141-1	**Honey Bee Acute Contact**		
141-2	**Honey Bee Residue on Foliage**		
141-5	**Field Test for Pollinators**		
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	C,I,M	**41904101**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	C,I,M	**41904102, 43163801**
81-3	**Acute Inhalation Toxicity - Rat**	C,I,M	**41904103**
81-4	**Primary Eye Irritation - Rabbit**	C,I,M	**41904104**
81-5	**Primary Dermal Irritation - Rabbit**	C,I,M	**41904105**
81-6	**Dermal Sensitization - Guinea Pig**	C,I,M	**41904016**

Data Supporting Guideline Requirements for the Reregistration of Methyl Nonyl Ketone

REQUIREMENT		USE PATTERN	CITATION(S)
81-7	**Acute Delayed Neurotoxicity - Hen**		
82-1A	**90-Day Feeding - Rodent**		
82-1B	**90-Day Feeding - Non-rodent**		
82-2	**21-Day Dermal - Rabbit/Rat**	C,I,M	**43110301**
82-3	**90-Day Dermal - Rodent**		
82-4	**90-Day Inhalation - Rat**		
82-5A	**90-Day Neurotoxicity - Hen**		
82-5B	**90-Day Neurotoxicity - Mammal**		
83-1A	**Chronic Feeding Toxicity - Rodent**	C,I,M	**Waived**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	C,I,M	**Waived**
83-2A	**Oncogenicity - Rat**		
83-2B	**Oncogenicity - Mouse**		
83-2B	**Oncogenicity - Mouse**		
83-3A	**Developmental Toxicity - Rat**	C,I,M	**42225902**
83-3B	**Developmental Toxicity - Rabbit**		
83-4	**2-Generation Reproduction - Rat**	C,I,M	**Waived**
84-2A	**Gene Mutation (Ames Test)**	C,I,M	**41740001**
84-2B	**Structural Chromosomal Aberration**	C,I,M	**41783101**
84-4	**Other Genotoxic Effects**	C,I,M	**Waived**
85-1	**General Metabolism**		

Data Supporting Guideline Requirements for the Reregistration of Methyl Nonyl Ketone

REQUIREMENT		USE PATTERN	CITATION(S)
85-2	**Dermal Penetration**		
86-1	**Domestic Animal Safety**		
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	C,I,M	**Satisfied**
132-1B	**Soil Residue Dissipation**	C,I,M	**Waived**
133-3	**Dermal Passive Dosimetry Exposure**	C,I,M	**Waived**
133-4	**Inhalation Passive Dosimetry Exposure**	C,I,M	**Waived**
231	**Estimation of Dermal Exposure at Outdoor Sites**	C,I,M	**Waived**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	C,I,M	**Waived**
233	**Estimation of Dermal Exposure at Indoor Sites**	C,I,M	**Waived**
234	**Estimation of Inhalation Exposure at Indoor Sites**	C,I,M	**Waived**
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	C,I,M	
161-1	**Hydrolysis**	C,I,M	41986401
161-2	**Photodegradation - Water**		
161-3	**Photodegradation - Soil**		
161-4	**Photodegradation - Air**		

Data Supporting Guideline Requirements for the Reregistration of Methyl Nonyl Ketone

REQUIREMENT		USE PATTERN	CITATION(S)
162-1	**Aerobic Soil Metabolism**	C,I,M	42497201
162-2	**Anaerobic Soil Metabolism**		
162-3	**Anaerobic Aquatic Metabolism**		
162-4	**Aerobic Aquatic Metabolism**		
163-1	**Leaching/Adsorption/Desorption**	C,I,M	42208301
163-2	**Volatility - Lab**		
163-3	**Volatility - Field**		
164-1	**Terrestrial Field Dissipation**		
164-2	**Aquatic Field Dissipation**		
164-3	**Forest Field Dissipation**		
164-5	**Long Term Soil Dissipation**		
165-1	**Confined Rotational Crop**		
165-2	**Field Rotational Crop**		
165-3	**Accumulation - Irrigated Crop**		
165-4	**Bioaccumulation in Fish**		
165-5	**Bioaccumulation - Aquatic NonTarget**		
166-1	**Ground Water - Small Prospective**		
166-2	**Ground Water - Small Retrospective**		
166-3	**Ground Water - Irrigated Retrospective**		

REQUIREMENT		USE PATTERN	CITATION(S)
201-1	**Droplet Size Spectrum**		
202-1	**Drift Field Evaluation**		
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	C,I,M	Waived
171-4B	**Nature of Residue - Livestock**	C,I,M	Waived
171-4C	**Residue Analytical Method - Plants**	C,I,M	Waived
171-4D	**Residue Analytical Method - Animal**	C,I,M	Waived
171-4E	**Storage Stability**	C,I,M	Waived
171-4F	**Magnitude of Residues - Potable H2O**	C,I,M	Waived
171-4G	**Magnitude of Residues in Fish**	C,I,M	Waived
171-4H	**Magnitude of Residues - Irrigated Crop**	C,I,M	Waived
171-4I	**Magnitude of Residues - Food Handling**	C,I,M	Waived
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	C,I,M	Waived
171-4K	**Crop Field Trials**	C,I,M	Waived
171-4L	**Processed Food**	C,I,M	Waived
171-5	**Reduction of Residues**	C,I,M	Waived
171-6	**Proposed Tolerance**	C,I,M	Waived

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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MRID	CITATION

00029517 Hotham, G.A. (1980) Efficacy Data for Hefty Dog/Cat Repellent. (Unpublished study including U.S. National Bureau of Standards special publication 412, received Apr 8, 1980 under 41847-1; prepared by Lasar Holography, Inc., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:242170-A)

00029519 Mobil Chemical Company (1979) Efficacy Data for Dog/Cat Repellents. (Unpublished study received Apr 8, 1980 under 41847-1; CDL:242171-A)

00049042 Voluntary Purchasing Group, Incorporated (19??) Examples of Performance. (Unpublished study received Dec 9, 1975 under 7401-285; CDL:229931-A)

00049043 Voluntary Purchasing Group, Incorporated (19??) Toxicology: Methyl nonyl ketone. (Unpublished study received Dec 9, 1975 under 7401-285; CDL:229931-B)

00049044 Voluntary Purchasing Group, Incorporated (19??) Miscellaneous Information. (Unpublished study received Dec 9, 1975 under 7401-285; CDL:229931-C)

00058129 Sterner, W.; Grahwit, G.; Chibanguza, G. (1977) Effect of MGK Dog and Cat Repellent, Lot 6623 on the Embryonic Development of Rats after Oral Applikation: Project No. 5-4-165-76. (Unpublished study received March 25, 1977 under 1021-873; prepared by International Bio-Research, Inc., West Germany, submitted by McLaughlin, Gormley, King Co., Minneapolis, Minn.; CDL:228757-A)

00060056 Herco Chemical Products Company (19??) Efficacy: Dog-Gon. (Unpublished study received Jan 26, 1971 under 11459-1; CDL:226784-A)

00071315 Vilkas, A.G.; Seminara, J. (1980) The Acute Toxicity of Sample # 12117902 MCTR-319-79 to the Rainbow Trout, Salmo gairdneri Richardson: UCES Project No. 11506-05-19. (Unpublished study received Jan 13, 1981 under 41847-1; prepared by Union Carbide Corp., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:244140-A)

00076140 Armour Industrial Chemical Company (19??) Unsymmetrical Ketones. Philadelphia, Pa.: Armour. (Product data bulletin; also In unpublished submission received Mar 22, 1966 under unknown admin. no.; submitted by McLaughlin, Gormley, King Co., Minneapolis, Minn.; CDL:102947-A)

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MRID **CITATION**

00076141 Wisconsin Alumni Research Foundation (1966) Assay Report: WARF # 5122135. (Unpublished study received Mar 22, 1966 under unknown admin. no.; submitted by McLaughlin, Gormley, King Co., Minneapolis, Minn.; CDL:102947-B)

00076142 Wisconsin Alumni Research Foundation (1966) Assay Report: WARF No. 5122134. (Unpublished study received Mar 22, 1966 under unknown admin. no.; submitted by McLaughlin, Gormley, King Co., Minneapolis, Minn.; CDL:102947-C)

00086697 Wo, C.; Shapiro, R. (1981) Acute Oral Toxicity: Report No. T-1794. (Unpublished study received Oct 27, 1981 under 46624-1; prepared by Nutrition International, Inc., submitted by Market-Tech Industries, Ltd., Plainview, N.Y.; CDL:246168-A)

00086698 Shapiro, R.; Wo, C. (1981) Acute Dermal Toxicity: Report No. T-1795. (Unpublished study received Oct 27, 1981 under 46624-1; prepared by Nutrition International, Inc., submitted by Market Tech Industries, Ltd.; Plainview, N.Y.; CDL:246168-B)

00086699 Wo, C.; Shapiro, R. (1981) Primary Skin Irritation: Report No. T- 1796. (Unpublished study received Oct 27, 1981 under 46624-1; prepared by Nutrition International, Inc., submitted by Market Tech Industries, Ltd., Plainview, N.Y.; CDL:246168-C)

00086700 Wo, C.; Shapiro, R. (1981) Modified Eye Irritation: Report No. T-1785. (Unpublished study received Oct 27, 1981 under 46624-1; prepared by Nutrition International, Inc., submitted by Market Tech Industries, Ltd., Plainview, N.Y.; CDL:246168-D)

00086701 Wo, C.; Shapiro, R. (1981) Acute Inhalation Study: Report No. T-1797. (Unpublished study received Oct 27, 1981 under 46624-1; prepared by Nutrition International, Inc., submitted by Market-Tech Industries,L Ltd., Plainview, N.Y.; CDL:246168-E)

00087093 ATI, Incorporated (1978) Confidential Statement of Formula. (Unpublished study received May 4, 1978 under 41847-EX-1; submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:233840-A)

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MRID **CITATION**

00087095 Armak Company (1966) Methyl Nonyl Ketone. (Unpublished study received May 4, 1978 under 41847-EX-1; submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:233840-C)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of

all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

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 (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms

as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of

extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as

that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study

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

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

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

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

METHYL NONYL KETONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Methyl Nonyl Ketone, please contact Paul Lewis at (703) 308-8018.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 8184.

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

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

RE: **Methyl Nonyl Ketone**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

INSERT PART A OF THE DCI HERE

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

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

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

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

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

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

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PAGE 1

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PAGE 4

THE EPA'S BATCHING OF PRODUCTS CONTAINING METHYL NONYL KETONE AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Methyl Nonyl Ketone, the Agency has batched products that can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., liquid, powder, aerosol, granular, etc.), and labeling (e.g., signal word, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so if the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by the EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. **Regardless of whether new data is generated or existing data is referenced, submissions must identify the test material by its EPA registration number.** If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms that are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, s4, 5 or 6.

However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient Methyl Nonyl Ketone.

Table 1, Batched Products:

Batch	Reg. No.	Active Ingredients	Form
1	4-356	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	15-8	Methyl Nonyl Ketone … 0.42% Cinnamaldehyde … 0.08%	granular
	16-153	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	192-182	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	270-293	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	572-209	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	769-599	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	1663-30	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	5887-78	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	11715-256	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	49585-23	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	59144-19	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular
	65636-85	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	granular

2	769-879	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	1769-362	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	2596-27	Methyl Nonyl Ketone … 2.0%	aerosol
	2596-28	Methyl Nonyl Ketone … 2.0%	aerosol
	7056-135	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	8220-17	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	10806-2	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	10900-77	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	11715-13	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	13799-1	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	44446-52	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
2A	769-603	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	65636-53	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	65846-8	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	68688-37	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
3	2596-53	Methyl Nonyl Ketone … 2.0%	pump spray
	2596-56	Methyl Nonyl Ketone … 2.0%	pump spray

4	10370-271	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	46515-33	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	59578-1	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
	59578-2	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	pump spray
5	2915-63	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
	5887-64	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
5A	11715-199	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	non-aerosol spray
	11715-285	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	non-aerosol spray
6	270-230	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	spray
	43591-4	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	spray

It is felt that data from another product within the same batch, or, better yet, the actual registration product are most representative of the potential acute toxicity of a product. However, the Agency will accept acute toxicity data conducted on the technical product (99.2% active ingredient) cited in the HED chapter of the Methyl Nonyl Ketone RED (see the Hazard Assessment) in support of the following products:

All products in batches 1, 2, sub-batch 2A, 3. Registration numbers 1021-873, and 4941-18.

It is felt that the inert ingredients contained in the above products are of low enough toxicity or in such low concentrations that they will not change the acute toxicity profile of the technical product.

Products in sub-batch 2A may cite either acute toxicity data conducted on a product from batch 2, sub-batch 2A or the technical. Either way, these products must cite a primary eye irritation study conducted on a product from sub-batch 2. Products in sub-batch 5A may cite either data conducted on a product from batch 5 or sub-batch 5A. However, products in sub-batch 5A must cite a primary eye irritation study conducted on a product of sub-batch 5A.

Table 2 lists the products the Agency was unable to batch. These products were not considered to be similar to other products for purposes of batching. With the exception of registrations 1021-873 and 4941-18, the registrant may only cite acute toxicity data conducted on that product itself and no other product in this RED. Registrations 1021-873 and 4941-18 may cite acute toxicity data from the technical product in HED's chapter of the RED. If the registrant of 1021-873 or 4941-18 choses not to cite the data on the technical, he/she must cite data conducted on the registration product.

Table 2, No Batch Group:

EPA Reg. No.	Active Ingredient	Formulation Type
1021-872	Methyl Nonyl Ketone … 63.33% Related Compounds … 3.34%	liquid
1021-873	Methyl Nonyl Ketone … 95.00%	liquid
1021-1637	Methyl Nonyl Ketone … 31.67% Related Compounds … 1.67%	liquid
4941-18	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
11715-286	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
20215-6	Methyl Nonyl Ketone … 6.25% Thiram … 6.25% Castor Oil … 5.50%	powder
28293-26	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	aerosol
63660-1	Methyl Nonyl Ketone … 1.9% Related Compounds … 0.1%	spray

Attachment 5. List of All Registrants Sent This Data Call-In Notice (insert)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA 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(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein 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.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

The following is a list of available documents related to Methyl Nonyl Ketone. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Methyl Nonyl Ketone and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Methyl Nonyl Ketone RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement