United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

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January 1996

EPA

Reregistration Eligibility Decision (RED)

Sodium Omadine

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 29 1996

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 sodium omadine. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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.

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

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 Bruce Kapner at (703) 308-8013. Address any questions on generic data to the Special Review and Reregistration Division representative, Judy Loranger at (703) 308-8056.

Sincerely yours,

Lois Rossi

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, 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

Sodium Omadine

LIST A

CASE 0209

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

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SODIUM OMADINE REREGISTRATION ELIGIBILITY DECISION TEAM

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Phyllis Johnson	Biological Analysis Branch
Frank Hernandez	Economic Analysis Branch

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Special Review and Reregistration Division

Judy Loranger	Reregistration Branch

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

Background

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide sodium omadine.

Sodium omadine is a broad spectrum antimicrobial compound used as a preservative in certain manufacturing materials and as an additive in process fluids which may otherwise be subject to deterioration through bacterial and/or fungal growth. Sodium omadine may be used as a biocide in: aqueous metalworking, cutting, cooling and lubricating fluids; latex emulsions used in adhesives, caulks, patching compounds, sealants, pastes and grouts; latex emulsions; aqueous fiber lubricants and inks; laundry rinse additives and detergents; carpet cleaners and analytical and diagnostic reagents. This RED does not address the use of sodium omadine as an in can preservative of water based chemical or mineral add mixtures used in concrete preparation, registered by the Agency on March 23, 1995. Currently there are 5 registered products that contain from 3.6 to 40 percent sodium omadine. These products, all end-use products, are formulated as liquid soluble concentrates. There are two registrants: Cincinnati Milacron and Olin Corporation, the primary registrant. There are no registered food uses.

Sodium omadine was first registered in the United States in 1968 for use as a biocide. The Registration Standard on sodium omadine (NTIS # PB86-173929) was issued in July 1985, and required submission of product chemistry, toxicology, ecotoxicity and environmental fate data to support continued registration of products formulated with sodium omadine. The 1987 Antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies.

Reregistration Eligibility

The Agency has now completed its review of the sodium omadine target data base, including data submitted in response to both the Registration Standard and the DCI, and has determined that the uses of sodium omadine as currently registered will not cause unreasonable adverse effects to humans or the environment. All generic data requirements have been satisfied for sodium omadine. All uses of sodium omadine registered prior to March 23, 1995 are eligible for reregistration.

Health Effects

The Agency's Office of Pesticide Program's Reference Dose (RfD) Peer Review Committee has classified sodium omadine as a Group D chemical (indicating insufficient weight of evidence of carcinogenicity for humans). Sodium omadine was assigned this classification because the dermal carcinogenicity study in mice was found to be unacceptable due to inadequate dose selection. The Agency has concluded that a repeat study is not required as long as the

product's use patterns do not dramatically change and the potential for human exposure remains low.

The Agency has used the following studies to derive toxicological endpoints for the occupational risk assessment described below: a dermal developmental study in rabbits was used to calculate short-term dermal exposures, and a 90 day dermal toxicity study in rats and a 90 day inhalation study in rats were used to calculate respective intermediate dermal and inhalation exposures. In the developmental toxicity study, no evidence of maternal or fetal toxicity was observed in rabbits given daily dermal applications of sodium omadine at doses of 0, 1, 2.5, or 5 mg/kg/day on days 6-19 of gestation.

In the 90 day dermal toxicity study, rats were given daily doses of sodium omadine at levels of 0, 5, 15 or 50 mg/kg/day. There was no evidence of dose-related dermal irritation. Dose related clinical signs seen in high dose females included emaciation, hunched posture, stiff hindlimbs, incoordination and tremors. Among the males, one high-dose rat was emaciated; there were no neurologic signs. The NOEL was 15 mg/kg/day in males and 5 mg/kg/day in females.

In the 90 day inhalation study, rats were administered sodium omadine at concentrations of 0, 0.00046, 0.0011 and 0.0038 mg/l (increased to 0.0081 mg/l at week 6). The systemic NOELs were 0.0081 mg/l in males and 0.0011 mg/l in females. The systemic LOEL was 0.0081 mg/l in females based on clinical signs of hindlimb dysfunction, skeletal muscle regeneration, decreased body weight and body weight gain.

Occupational Exposure

The Agency has concerns that workers may be exposed to sodium omadine through dermal or inhalation routes of exposure from pouring and pumping of sodium omadine in metal working fluids. Using exposure data from the CMA (Chemical Manufacturer Association) Antimicrobial Exposure Assessment Study, the Agency has conducted exposure and risk assessments for these activities and finds that margins of exposure (MOEs) for workers were greater than 100. Based on these calculations, the Agency has concluded that minimal risks exist to workers during the pouring and pumping of liquids that contain sodium omadine. The Agency has not evaluated occupational risk to machinists because these workers are regulated by the Occupational Safety Administration (OSHA). (Available information indicate that the amount of active ingredient (0.005 to 0.5%) present in the oil used by machinists would most likely be even lower than the amount to which the handler would be exposed. Therefore, it is presumed that exposure to sodium omadine treated fluids would represent a lesser hazard to the machinist than to handlers involved in pumping and pouring operations described in this document).

Environmental Fate and Ecological Effects

By their nature, industrial biocides are often toxic to aquatic organisms. While the hazard to aquatic organisms from exposure to sodium omadine has been characterized, a quantitative risk assessment has not been conducted. The Office of Pesticide Programs has established a policy that risks to aquatic environments from sodium omadine use as a biocide are best characterized and regulated under the NPDES permitting program of the Office of Water. All sodium omadine products are required to state on their labels that discharges to aquatic environments must comply with an NPDES permit.

Before reregistering the products containing sodium omadine, 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 sodium omadine. The document consists of six sections. Section I is the introduction. Section II describes sodium omadine, 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 sodium omadine. Section V discusses the reregistration requirements for sodium omadine. 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:** Sodium omadine
- **Chemical Name:** Sodium omadine exists as a mixture of two tautomeric forms: (I.) 1-hydroxy-2(1H)-pyridinethione, sodium salt and (II.) 2-pyridinethiol-1-oxide, sodium salt
- **CAS Registry Number:** (I.) 15922-78-8 and (II). 3811-73-2
- **OPP Chemical Code:** 088004 (chemical code only available for CAS number 15922-78-8)
- **Empirical Formula:** C_5H_4NOSNa
- **Trade and Other Names:** Omadine sodium, sodium 2-pyridinethiol 1-oxide, sodium 1-hydroxypyridine-2-thione, sodium 2-mercaptopyridine-N-oxide
- **Basic Manufacturer:** Olin Chemicals

B. Use Profile

Information on the currently registered uses of sodium omadine and application methods is presented below. A detailed table of the uses of sodium omadine is presented in Appendix A.

Type of Pesticide: Fungicide, microbiocide/microbiostat (for control of slime forming bacteria and fungi)

Use Sites:

Indoor Non-food:

Adhesives, Industrial
Emulsions, Resin/Latex/Polymer

Metalworking Cutting Fluids
Aqueous Synthetic Fiber Lubricants
Alkaline Aqueous Based Jet-Printer Inks
Laundry Rinse Additives, Detergents and Carpet Cleaners
Aqueous Analytical and Diagnostic Reagents

Target Pests: Bacteria (including slime-forming bacteria) and fungi

Formulation Types Registered: Soluble concentrate/liquid

Application types and rates:

Types of treatment:

Fungicide, microbiocide/microbiostat for: aqueous metalworking, cutting, cooling, and lubricating fluids and concentrates; latex emulsions used in adhesives, caulks, patching compounds, sealants, pastes, and grouts; vinyl acetate latex emulsions; aqueous synthetic fiber lubricants (spin finishes); aqueous based inks and jet-printer inks; laundry rinse additives; laundry detergent; carpet cleaners; aqueous analytical and diagnostic reagents used in chemical and clinical analysis - preservative treatment, industrial preservative treatment

Use Practice Limitations: NPDES (National Pollutant Discharge Elimination System) License Restriction

Rate and timing of Application:

Aqueous metalworking, cutting, cooling, and lubricating fluids - 27 to 499 ppm a.i. (initial, subsequent/maintenance); 72 to 128 ppm a.i. (timing not specified on labeling; registrants need to specify).

Metalworking, cutting, cooling, and lubricating concentrates (where end use dilution of metalworking, cutting, cooling, or lubricating fluid is 5%) - 1440 to 10,000 ppm a.i. (timing not specified on labeling; registrants need to specify).

Latex emulsions used in adhesives - 400 ppm a.i. (during manufacture).

Vinyl acetate latex emulsions - 46 to 400 ppm a.i. (during manufacture).

Aqueous synthetic fiber lubricants (spin finishes) - 64 to 499 ppm a.i. (timing not specified on labeling; registrants need to specify).

Alkaline aqueous based jet-printer inks - 320 to 5000 ppm a.i. (during manufacture).

Laundry rinse additives, laundry detergent, and carpet cleaners - 639 ppm a.i. (during manufacture).

Aqueous analytical and diagnostic reagents - 64 ppm a.i. (during manufacture).

C. Estimated Usage of Pesticide

Only proprietary information defining sodium omadine usage is available at this time. The Agency has concluded (not confidential) that sodium omadine is a minor use biocide that is primarily used in metalworking fluids. Other alternative products (also proprietary information) have a significantly larger market share than sodium omadine.

D. Data Requirements

Data requested in the July 1985 Registration Standard for sodium omadine include studies on product chemistry, toxicology, environmental fate and ecological effects. The 1987 Antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

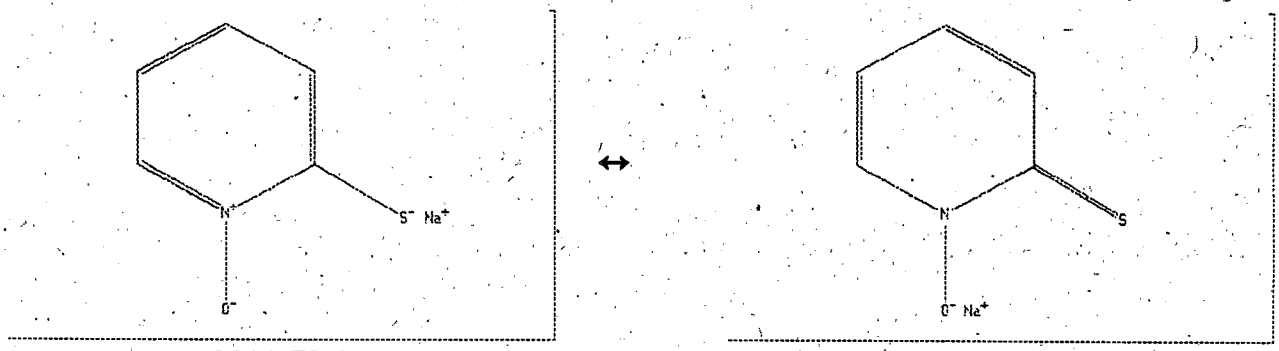
E. Regulatory History

Sodium omadine was first registered in the United States in 1968 for use as a biocide. The Registration Standard on sodium omadine (NTIS # PB86-173929) was issued in July 1985. The Registration Standard continued the registration of sodium omadine but required submission of product chemistry, toxicology, ecotoxicity and environmental fate data. As stated above, additional toxicology studies were required in the 1987 Antimicrobial Data Call-In (DCI). This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the DCI.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Technical sodium omadine is an off-white solid powder with a melting point of ~250° C and a vapor pressure of 7 x 10^{-8} torr at 22° C. The solubility of sodium omadine in water is ~54.7% w/w at 25° C. The following structures depict the resonance between the two tautomers:



3811-73-2 15922-78-8

Empirical Formula:	C_5H_4NOSNa
Molecular Weight:	149.2
CAS Registry No.:	3811-73-2 and 15922-78-8 (sodium omadine exists as a mixture of two tautomers, refer to Section II, A for chemical names for each tautomers)
Chemical Code:	088004

B. Human Health Assessment

1. Toxicology Assessment

The generic toxicological data base for sodium omadine is complete and will support reregistration eligibility. The Agency has identified data gaps (primary eye irritation, acute inhalation and dermal sensitization) for end use products that will be required in the product specific Data Call-In notice.

a. Acute Toxicity

The 40% sodium omadine formulation has been evaluated for a variety of acute toxicity effects. The results are summarized in the table below.

Test	Results	Category
81-1 Acute Oral LD_{50} (rat)[1]	LD_{50} = 2000 mg/kg ♂ LD_{50} = 1100 mg/kg ♀ LD_{50} = 1500 mg/kg ♂+♀	III
81-2 Acute Dermal LD_{50} (rabbit)[2]	LD_{50} = 1900 mg/kg ♂ LD_{50} = 1800 mg/kg ♀ LD_{50} = 1800 mg/kg ♂+♀	II
81-3 Acute Inhalation LD_{50} (rat)[3]	LC_{50} = 1.26 mg/l ♂ LC_{50} = 0.81 mg/l ♀ LC_{50} = 1.08 mg/l ♂+♀ (4-hour analytical)	III
81-4 Primary Eye Irritation (rabbit)[4]*	Data gap	
81-5 Primary Dermal Irritation (rabbit)[5]*	Slight transient erythema and edema.	IV
81-6 Dermal Sensitization (guinea pig)[6]*	Not a sensitizer in a maximization test (Magnusson-Kligman) up to dose levels which were irritating.	
81-6 Dermal Sensitization (human)[7]*	Not a sensitizer in humans challenged 4 days per week for 3 weeks, then challenged after a 1-week hiatus.	

[1] MRID No. 40247801
[2] MRID No. 40247802
[3] MRID No. 40339001
[4] No MRID
[5] MRID No. 40247803
[6] MRID No. 40247804
[7] MRID No. 40387401

*Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

b. Subchronic Toxicity

In a subchronic toxicity/neurotoxicity study, sodium omadine (41.2% purity) was administered by oral gavage to groups of 20 male and 20 female Sprague-Dawley rats for 13 weeks at doses of 0, 0.5, 2.0, or 8.0 mg/kg/day. In-cage clinical observations for signs of neurotoxicity were made prior to dosing, at 1 and 6 hours after dosing, and daily before dose administration throughout the study. Prior to initiation and during weeks 5 and 13, all animals were given functional tests for potential neurotoxicity (hindlimb grip strength, hindlimb tactile placing response, and landing hindfoot spread test).

At 2.0 mg/kg/day, slight atrophy of the hindlimb skeletal muscle was observed in 5/20 males and 5/20 females, and minimal atrophy was seen in one female. Atrophy of the panniculus muscle was observed in 3/20 females receiving 2.0 mg/kg/day; the atrophy was considered a neurotoxic effect (neurogenic atrophy).

Both males and females dosed at 0, 0.5, and 2.0 mg/kg/day had similar body weights throughout the study. The 8.0 mg/kg/day groups consistently gained less weight than the other groups, and weighed as much as 21% and 22% less than controls for males and females, respectively. Significant decreases in weight gains were seen for males (30%) and females (47%). The body weight and clinical observation data suggest a steep dose response.

In the high-dose groups, minimum to marked hindlimb atrophy was observed in 95-100% of the males and females (more severe in females), minimal paravertebral muscle atrophy was seen in 2/20 males and 17/20 females, and atrophy of the subcutaneous panniculus muscle was seen in 20/20 males and 17/20 females. Treatment-related neurotoxic signs observed in the high-dose animals consisted of slight hypoactivity, piloerection, ataxia (hindlimb), slight head searching, emaciation, hindlimb paralysis, and hunched posture. As a consequence of severe hindlimb motor dysfunction, 10 high-dose females were sacrificed *in extremis*. Effects on neuromuscular function included significant decreases in landing foot spread, hindlimb grip strength, and hindlimb tactile placing response.

The study LOEL was 2.0 mg/kg/day based on evidence of neurotoxicity in males and females (neurogenic skeletal muscle atrophy) and the NOEL was 0.5 mg/kg/day.

The neurotoxicity portion of the study was classified as supplemental because cage observations were limited, many of the usual functional observation battery (FOB) parameters were not performed, grip strength measurements and motor activity were not quantified, guideline procedures for preparation of neural tissues (including perfusion) were not followed, and the histological examination of neural tissues was inadequate. (MRID No. 40756901)

In a subchronic dermal toxicity study, Sprague-Dawley rats were administered sodium omadine (41.2% purity, 20/sex) daily for 90 days at dosage levels of 0, 5, 15, or 50 mg/kg body weight/day. There was no evidence of dose-related dermal irritation. Dose-related clinical signs seen in high-dose females included emaciation, hunched posture, stiff hindlimbs, incoordination, and tremors. Among the males, one high-dose rat was emaciated; there were no neurologic signs.

Males and females dosed at 0, 5, and 15 mg/kg/day had similar body weights throughout the study. The 50 mg/kg/day males and females consistently gained less weight than the other groups, and weighed as much as 14% and 23% less than controls, respectively. At termination, high-dose body weights were 9%

and 17% less than controls for males and females, respectively. Food consumption was not affected.

There were no dose-related effects on eye health or clinical pathology. Statistically significant increases in relative brain, pituitary, heart, lung, liver, kidney, and spleen weights in the high-dose males and females were attributed to retarded growth. There were no dose-related effects on absolute organ weights. The only dose-related gross lesion was wasting of the hindlimb skeletal muscle in 3/20 mid-dose females, and in 2/20 males and 19/20 females in the high-dose.

The gross findings were confirmed histopathologically as a reduction of muscle fiber diameter, fatty replacement, and an increase in the number of sarcolemmal nuclei. The subcutaneous panniculus muscle displayed atrophy in the mid-dose females and the high-dose males and females. In addition, degeneration of sciatic nerve fibers and minimal atrophy in the paravertebral muscles was seen in 10/20 high-dose females. Degenerated fibers showed a loss of myelin. The LOEL was 50 mg/kg/day in males and 15 mg/kg/day in females, based on atrophy of the hindlimb muscles and subcutaneous panniculus muscles. The NOEL was 15 mg/kg/day in males, and 5 mg/kg/day in females.

At 50 mg/kg/day, both sexes had decreased weight gain compared to controls, and females showed minimal atrophy of the paravertebral muscle, neurotoxic symptoms, and degeneration of some sciatic nerve fiber bundles. (MRID No. 40936201)

In the rat inhalation toxicity study, sodium omadine (40% aqueous solution) was administered by whole-body inhalation to male and female Sprague-Dawley rats for 6 hours/day, 5 days/week, for 13 weeks at analytical concentrations of: 0, 0.00046, 0.0011, and 0.0038 mg/l. The high concentration of 0.0038 mg/l was increased to 0.0081 mg/l at week 6 because of the lack of signs of toxicity. Air control groups were included. The systemic NOEL(s) were 0.0081 mg/l in males and 0.0011 mg/l in females. The systemic LOEL was 0.0081 mg/l in females, based on clinical signs of hindlimb dysfunction, histopathologic skeletal muscle regeneration, and decreases in female body weight and body weight gain. (MRID No. 41178201)

c. Chronic Toxicity

Sodium omadine (41.41% and 40.5% purity) in 40% aqueous solution was administered in water by gavage to groups of 5 male and 5 female Cynomolgus monkeys for 1 year at dose levels of 0, 5, 25, or 150 mg/kg/day. The dose level of 150 mg/kg/day was lowered to 75 mg/kg/day at week 6 because of adverse effects on survival.

No evidence of toxicity was seen at the 5 mg/kg/day dose other than emesis in some monkeys. Emesis was observed in all monkeys at higher doses. Male body weights were unaffected by dosing, but female body weights were decreased as much as 8%, 17%, and 23% at the 5, 25, and both 75 and 150 mg/kg/day doses, respectively. At 150 mg/kg/day, one female was sacrificed *in extremis* at week 6. At 75 mg/kg/day, one male and one female died at weeks 13 and 35, respectively; the cause of death was not apparent for either animal. Clinical signs noted prior to death in the dead and sacrificed females included prostration, decreased activity, emesis, thinness, weakness, and cold extremities. Emesis and ptyalism were seen in the male that died. Hematologic changes (i.e., decreases in erythrocyte count, hemoglobin, and hematocrit levels) were slight and considered of minor toxicological importance. The NOAEL was 5 mg/kg/day. The LEL was 25 mg/kg/day based on emesis and decreased female body weight. (MRID No. 41178101)

d. Carcinogenicity

In an 80-week dermal carcinogenicity study, sodium omadine 40% aqueous solution (41.2% purity) was administered topically to groups of 50 male and 50 female CD-1 mice at dosage levels of 0, 5, 15, or 40 mg/kg/day.

At 40 mg/kg/day, an increase in the incidence of epidermal hyperplasia at the application site was seen in males (20% compared to 0% in controls, $p < 0.01$) and in females (20% compared to 6% for controls; nonsignificant by pairwise comparison but a significant trend, $p < 0.05$). No systemic toxicity was observed. Under the conditions of the study, dermal application of sodium omadine did not induce any benign or malignant neoplasms.

The 40 mg/kg/day dose is defined as a free-standing systemic NOEL, based on the range-finding study. The dermal NOEL was 15 mg/kg/day. The dermal LEL (lowest effect level) was 40 mg/kg/day based on an increase in epidermal hyperplasia at the skin application site. The high-dose was considered inadequate to assess carcinogenicity. (MRID No. 42100801)

Sodium omadine 40% aqueous solution (41.2% purity) was administered daily by oral gavage to groups of 70 Crl:CD(SD)BR Sprague-Dawley rats/sex at dosage levels of 0, 0.5, 1.5, or 5.0 mg/kg/day for 2 years. The highest dose was reduced to 3.5 mg/kg/day after 12 weeks because of excessive weight loss in females. At the highest dose tested (5.0/3.5 mg/kg/day) there was a significant decrease in mean body weight (as much as 10%) and body weight gain in females throughout the study; a marked increase in nerve fiber degeneration in the sciatic nerve and spinal cord in both sexes; and an increased incidence of retinal atrophy

in both sexes. Under the conditions of the study, an increase in neoplasia was not observed at any site. Dosing was considered adequate to assess carcinogenicity. The NOEL was 0.5 mg/kg/day. The LOEL was 1.5 mg/kg/day, based on significant increases in the incidence of degeneration of the skeletal muscle of the hindlimbs in both sexes. (MRID No. 42100901)

The OPP RfD/Peer Review Committee met on 3/30/95 to discuss the adequacy of the carcinogenicity studies described above. The rat carcinogenicity study was found to be acceptable. The dermal carcinogenicity study in mice was found to be inadequate because the chemical was not tested at a sufficiently high dose level. However, the Agency concluded that a new study will not be required as long as the use patterns do not dramatically change and the potential for human exposure remains low. Sodium omadine was classified as a Group D carcinogen (insufficient weight of evidence).

e. Developmental Toxicity

In a developmental toxicity study, New Zealand White rabbits were given sodium omadine by daily dermal application for 6 hours at doses of 0, 1, 2.5, or 5 mg/kg/day on gestation days 6-19, inclusive. There was no evidence of maternal or fetal toxicity at any dose. Since there was no LEL in this study, and a range-finding dose of 7.5 mg/kg/day resulted in substantial toxicity, it is reasonable to define 5 mg/kg/day as a free-standing NOEL." (MRID No. 40487201)

f. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD(SD)BR rats received sodium omadine 40% aqueous solution (41.2% purity) by gavage at dose levels of 0, 0.5, 1.5, or 3.5 mg/kg/day. The highest dose level was changed from 4.5 mg/kg/day to 3.5 mg/kg/day after 3 weeks of dosing because of marked toxicity at 4.5 mg/kg/day.

The parental NOEL was 0.5 mg/kg/day. The parental LOEL was 1.5 mg/kg/day in females, and 3.5 mg/kg/day in males, based on increased incidence of histologic atrophy in the upper hindlimb skeletal muscles (reduction in fiber diameter) in F_1 females (3/25), F_0 males (7/23), and F_1 males (9/25). Additional parental effects seen at 3.5 mg/kg/day included increased histologic atrophy in the upper hindlimb skeletal muscles in F_0 females (19/24), and F_1 females (20/23); and significantly decreased body weight in F_0 and F_1 females.

The reproductive NOEL was 1.5 mg/kg/day. The reproductive LEL was 3.5 mg/kg/day, based on slightly decreased number of pups per litter born in both

generations (possibly a consequence of reduced mating success due to hindlimb atrophy), delayed development in pups from both generations (including open ears and eyes and startle response), and decreased pup body weight and weight gain in both sexes. (MRID No. 41097201)

g. Mutagenicity

Sodium omadine 40% aqueous solution (41.4% purity) did not induce forward gene mutations at the HGPRT locus in cultured Chinese hamster ovary (CHO) cells at concentrations of up to ≥0.08 µg/ml without S9 activation or 27 µg/ml with S9 activation. These concentrations were found to be severely cytotoxic (i.e., <10% cell survival). (MRID No. 40411501)

In the in vivo Micronucleus Assay, sodium omadine 40% aqueous solution (41.4% purity) did not cause micronucleus induction in the bone marrow cells of male or female CD-1 mice at 30, 48, or 72 hours after the intraperitoneal administration of 575 mg/kg (238 mg/kg/active ingredient). Clinical signs of toxicity (decreased body tone, body drop, abnormal gait, ptosis, lacrimation, and tremors) and target cell cytotoxicity were observed at this level. (MRID No. 40343701)

Sodium omadine 40% aqueous solution (41.4% purity) did not induce unscheduled DNA synthesis (UDS) in primary rat hepatocytes treated with doses up to 220 ng/ml (300 ng/ml, based on analytical determinations). Concentrations ≥71 ng/ml (≥80 ng/ml) were cytotoxic. (MRID No. 40387501)

h. Metabolism

The absorption, distribution, metabolism, and excretion of sodium omadine were studied in groups of Sprague-Dawley rats administered a single oral dose of 0.5 or 25 mg/kg ^{14}C-sodium omadine, 0.5 mg/kg/day of sodium omadine for 14 days followed by a single oral dose of ^{14}C-sodium omadine (0.5 mg/kg), or a single (IV) dose of 0.5 mg/kg ^{14}C-sodium omadine.

Sodium omadine in rats was rapidly absorbed, metabolized, and excreted at all dosing levels. Total recovery of administered radioactivity was 85%-95% at 4 days postexposure. The urine is the major route of excretion of sodium omadine (73-85% of the dose); the feces are only a minor route of excretion (5-12% of the dose). Sodium omadine and its metabolites were not excreted in expired air.

In the single oral low-dose group and the IV-dose group, most of the administered radioactivity was excreted within the first 12 hours postdosing. In

the repeated oral low-dose group and in the single oral high-dose group, the majority of the administered radioactivity was excreted within 24 and 48 hours postdosing, respectively. There was no evidence of bioaccumulation of sodium omadine or its metabolites in the tissues.

The metabolic profiles in the urine were similar in all dose groups; 12 urinary metabolites (A-L) were characterized. The major metabolite in rat urine was 2-pyridinethiol-1-oxide-S-glucuronide (Metabolite K) (41.4%-67.2% of the recovered radioactivity), while unchanged parent compound was not detected in the urine. (MRID No. 41269001)

i. Neurotoxicity

Results of a 13 week oral subchronic toxicity/neurotoxicity study were previously described in detail in section III, B, 1, b. Although the neurotoxicity portion of this study was found to be supplemental due to reporting deficiencies, enough information was provided to derive a LOEL of 2.0 mg/kg/day based on evidence of neurotoxicity in male and female rats (neurogenic skeletal muscle atrophy). The NOEL was found to be 0.5 mg/kg/day. In the subchronic dermal toxicity study, dose-related clinical signs seen in high-dose female rats included emaciation, hunched posture, stiff hindlimbs, incoordination, and tremors. Among the males, one high-dose rat was emaciated; there were no neurologic signs. The LOEL was 50 mg/kg/day in males and 15 mg/kg/day in females, based on atrophy of the hindlimb muscles and subcutaneous panniculus muscles. The NOEL was 15 mg/kg/day in males, and 5 mg/kg/day in females.

j. Toxicological Endpoints

The endpoint for risk assessment of short-term (1 to 7 days) dermal exposure to the active ingredient is a NOEL of 5 mg/kg/day based on the dermal developmental toxicity study in rabbits. The endpoint for risk assessment of intermediate term (1 week to several months) dermal exposure is a NOEL of 5 mg/kg/day based on the 90-day dermal toxicity study in rats. The endpoint for risk assessment of intermediate term inhalation exposure is a systemic NOEL of 0.0011 mg/l, based on the 90-day inhalation study in rats. Sodium omadine was not found to be a dermal sensitizer in the tests conducted.

k. Reference Dose

The RfD for sodium omadine was determined to be 0.005 mg/kg/day based on a NOEL of 0.5 mg/kg/day and an uncertainty factor of 100. The NOEL was obtained from a chronic rat study. The rat reproduction study with a parental NOEL of 0.5 mg/kg/day supports the RfD as a co-critical study. This pesticide

has not been reviewed by the FAO/WHO Joint Committee on Pesticide Residues (JMPR).

2. Exposure Assessment

a. Dietary

Sodium omadine is not registered for food use. Currently, because there are no known dietary exposures to sodium omadine, a dietary exposure assessment is not required.

b. Occupational and Residential

The registrant Olin Chemicals, is a participant in the CMA (Chemical Manufacturer Association) Antimicrobial Exposure Assessment Study. Based on the results of this study, the Agency has sufficient data to assess mixer/loader/applicator (M/L/A) exposure.

Because sodium omadine is used primarily as a preservative in metalworking and cutting fluids, the main focus of this occupational exposure assessment is on the metalworking uses (mixing and loading). Although sodium omadine may also be used as a preservative in numerous manufacturing materials and fluids (listed in Section II, B), these uses were not discussed in detail in this assessment because they most likely represent very limited use and the metal-working uses represent a reasonable worse case exposure assessment. There are no registered residential uses for sodium omadine; thus, an exposure assessment of residential use is not required in this document.

This assessment of occupational exposure addresses only the potential for handler exposure to pesticide products during loading of the products which contain sodium omadine, into metal-working and -cutting fluids. The products are loaded using either open-pouring or metering-pump techniques. Although Agency representatives continue to discuss, through an interagency workgroup (EPA, Occupational Safety and Health Administration (OSHA), and National Institute for Occupational Safety Health (NIOSH)), the roles and responsibilities of regulating the uses of metalworking fluids, paints and other products in the industrial setting, OSHA is most appropriately responsible for regulating machinists safety and exposure. Therefore, machinists exposures will not be addressed in detail in this document. Available information indicate that the amount of active ingredient (0.005 to 0.5%) present in the oil used by machinists would most likely be even lower than the amount to which the handler would be exposed. Therefore, it is presumed that exposure to sodium omadine treated fluids,

would represent a lesser hazard to the machinist than to handlers involved in pumping and pouring operations described in this document.

Background

Machine shops are the major site in the U.S. where sodium omadine is used as a preservative in metalworking and cutting fluids. It is estimated that sodium omadine may be poured or pumped into metalworking or cutting fluids between 2 and 26 times per year. A worst case scenario for the use of sodium omadine would be pouring or pumping of sodium omadine solutions (40% a.i.) into metal-working or -cutting fluids. Approximately 80% of the U.S. use for metal-working and -cutting fluids are small machine shops.

The Agency has determined that an occupational and residential exposure assessment is required for active ingredients if: (1) certain toxicological criteria are triggered and (2) there is a potential exposure to handlers (mixers, loaders, applicators, etc.) during use or for persons entering treated sites immediately after completion of product applications/use. Based on toxicity and exposure criteria, an occupational exposure assessment is required for sodium omadine use as a metalworking additive.

Handler (M/L/A) Exposure

As stated earlier, the registrant, Olin Chemicals, is a participant in the CMA (Chemical Manufacturer Association) Antimicrobial Exposure Assessment Study. The MCS (Maximum Credible Sum) unit of exposure developed in the Antimicrobial Exposure Assessment Study is applicable to assess exposure in this document.

According to the product labels the highest level of sodium omadine (EPA Reg. 1258-843) in a formulated product is 40% sodium omadine active ingredient in aqueous solution. Based on label use information, a maximum of 12.5 pounds of the formulated product is added to 10,000 pounds of water-based fluids to make metal-working, -cutting and -cooling fluids. On this basis, a total of 5 pounds of the active ingredient is handled during this mixing process (12.5 pounds X 0.4 = 5 pounds).

The vinyl acetate emulsion use of sodium omadine was selected to estimate the amount of active ingredient used as a preservative in an industrial setting. Based on label use information, 1.15 pounds of the 40% sodium omadine product is added into 10,000 pounds of compound to be preserved. This is equal to 0.46 pounds of active ingredient handled (1.15 pounds x 0.4 = 0.46 pounds).

The Agency is concerned about the potential for exposure to those small machine shop operators (handlers) who both load this pesticide into the metalworking fluid and use the treated metal-working and -cutting fluids on a daily basis. The primary handler exposure would be limited to dermal and inhalation exposure routes during open-pouring and meter-pump loading of the pesticide into metal-working and -cutting fluids. However, the total exposure to the active ingredient may vary widely depending on the amount of coolant used, as well as upon how frequently the individual uses metal-working and -cutting fluids. The following tables show the estimated daily exposure and margin of exposure values for handlers exposed to liquid sodium omadine through open pouring and pump-metering when used as an industrial preservative (nonmetalworking uses) or as a metal-working or cutting fluid. Note: mean unit exposure values used in these calculations were obtained from the previously cited CMA study. Workers wore gloves, long-sleeve shirt and long pants for this study.

ESTIMATED HANDLER EXPOSURE AND MOE(s) DURING LIQUID POURING

Use Setting	UE* (μg/lb ai)	lb ai/ used	BW** (kg)	Estimated Daily Exposure (μg/kg/day	MOE
Preservative	140	0.46	60	1.07	4700
Metalworking Cutting Fluids	133	5	60	11.08	450

* UE = Unit Exposure for combined dermal and inhalation exposures. Mean UE (cited above) was derived from the CMA Study.

** BW = Body Weight (average 60 kg for female worker based on the developmental toxicity endpoint).
Actual Daily Exposure (μg/kg/day) = (UE X lb ai/used)/BW
NOEL = 5 mg/kg/day based on rabbit developmental toxicity and rat subchronic dermal toxicity studies.
MOE = NOEL ÷ Daily Exposure

ESTIMATED HANDLER EXPOSURE AND MOE(s) DURING LIQUID PUMPING					
Use Setting	UE* (μg/lb ai)	lb ai/ used	BW** (kg)	Estimated Daily Exposure (μg/kg/day)	MOE
Preservative	7.5	0.46	60	0.06	83,000
Metalworking Cutting Fluids	325	5	60	27.08	185

* UE = Unit Exposure for combined dermal and inhalation exposures. Mean UE (cited above) was derived from the CMA Study.

** BW = Body Weight (average 60 kg for female worker based on the devel opmental toxicity endpoint). Actual Daily Exposure (μg/kg/day) = (UE X lb ai/used)/BW
NOEL = 5 mg/kg/day based on rabbit developmental toxicity and rat subchronic dermal toxicity studies.
MOE = NOEL ÷ Daily Exposure

The exposure estimates presented above for metalworking operations were calculated assuming that exposures occurred in small machine shops, where approximately 80% of U.S. use for metalworking and cutting fluids take place, rather than in a large industrial setting. The exposure tables above indicate that worker exposure may be higher for pumping than for pouring operations. This is possible because activities in a small machine shop routinely require more pumping operations such as disconnecting hoses and inserting measuring devices than pouring operations. Further, in a small machine shop one person is likely to perform all of the activities in pumping applications.

Post-Application Exposure

The Agency has determined that industrial and manufacturing workers may be exposed to sodium omadine through dermal and inhalation routes after use of sodium omadine containing fluids. However, based on the use patterns and the chemical properties of sodium omadine (low vapor pressure, and stable at 100° C for 120 hours, etc.), inhalation exposure to industrial/manufacturing workers immediately after sodium omadine use is likely to be minimal (during and after application process). Also since the amount of diluted sodium omadine for all registered uses are negligible, the toxic effects are expected to be minimal from dermal and inhalation exposure when substances containing sodium omadine are used. Post application exposure criteria are not met for requiring post application exposure data.

3. Risk Assessment

a. Dietary

Sodium omadine is not registered for food use. Therefore, a dietary risk characterization is not required.

b. Occupational and Residential

Based on available toxicity data and use patterns information, the Agency has determined that estimation of risk for handlers exposed to sodium omadine during pouring and pumping applications is required. Based on the margins of exposure (MOEs) presented in the tables in Section III, B, 2, b, the potential for occupational handler health risk is expected to be minimal for workers exposed to sodium omadine during pumping and pouring operations.

Sodium omadine is not registered for homeowner uses; therefore, risk characterization of residential exposure is not required. The Agency, however, believes that the amount of sodium omadine in products that may enter the home or occupational setting such as laundry rinse additives, detergents, carpet cleaners, emulsions and jet printer inks would be very low due to dilution. For this reason, health risks from exposure to consumers products containing sodium omadine are also expected to be very low.

C. Environmental Assessment

1. Ecological Toxicity Data

All data requirements for assessing the ecological risk of sodium omadine have been satisfied. Ecological effects data required to support sodium omadine reregistration are avian acute oral, avian subacute dietary, fish acute toxicity and acute aquatic invertebrate studies.

a. Toxicity to Terrestrial Animals

Avian Acute Toxicity

Avian Acute Oral Toxicity Findings			
Species	% Test Material	LC_{50} or LD_{50}	Conclusions
Bobwhite Quail	41.9%	185 mg ai/kg*	Moderately toxic

* Converted to TGAI per kg based on end-use concentrations.

An acute oral toxicity study shows that sodium omadine is moderately toxic to bobwhite quail. (MRID 40363401)

Avian Subacute Dietary Toxicity

Avian Subacute Dietary Toxicity Findings			
Species	% Test Material	LC_{50}	Conclusions
Mallard Duck	40 %	3650 mg ai/l*	Slightly toxic
Bobwhite Quail	40 %	1300 mg ai/l*	Slightly toxic

* Converted to mg/l TGAI based on end-use concentrations.

On a subacute dietary basis, sodium omadine has been characterized as slightly toxic to mallard duck and bobwhite quail. (MRID 00073656 and 00073657)

b. Toxicity to Aquatic Animals

Freshwater Fish Acute Toxicity

Freshwater Fish Acute Toxicity			
Species	% Test Material	LC_{50}	Conclusions
Rainbow Trout	41.9 %	< 7.3 µ ai/l	Very highly toxic
Bluegill Sunfish	41.9 %	8100 µ ai/l	Very highly toxic

Sodium omadine was found to be very highly toxic to rainbow trout and bluegill sunfish. The requirement of a fish acute toxicity study is satisfied by the bluegill sunfish study (MRID 40358501) and supplemental information from a rainbow trout study (MRID 4094501). The trout study was found to be supplemental but provided useful information indicating that the LC_{50} should be regarded as an upper bound for the true LC_{50} value. A repeat rainbow trout study will not be required.

Freshwater Invertebrates

Freshwater Invertebrates			
Species	% Test Material	LC_{50}	Conclusions
Daphnia magna	40 %	9.2 µ ai/l	Very highly toxic

Sodium omadine has been found to be very highly toxic to freshwater invertebrates. (MRID 00103228)

2. Environmental Fate

The environmental fate database for sodium omadine is adequate for reregistration purposes. The only environmental fate data required to support the reregistration of sodium omadine is a hydrolysis study. A hydrolysis study was submitted but was found to be only partially acceptable. However, a repeat of this study is not considered necessary to support the biocide uses covered in this document. No additional studies are required at this time.

a. Environmental Fate Assessment

In the hydrolysis study, measurements at each combination of concentration (10 mg/l or 100 mg/l), temperature (5°C or 40°C), and pH (4, 7, or 10), indicate that a half-life of 23 days was obtained at 40°C, pH 10, and 10 mg/l concentration. At other levels of concentration, temperature, and pH, sodium omadine hydrolyzed more slowly, or was stable to hydrolysis.

Hydrolytic products were more readily formed at an alkaline pH than at neutral and acidic pH. It has been hypothesized that omadine disulfide is formed by oxidation at all pH's, and at alkaline conditions omadine disulfide reacts with hydroxide ions to form omadine sulfinic acid.

Photolysis is probably a more important route of dissipation than hydrolysis. Photolytic half-lives of 40-126 minutes have been reported at a concentration of 100 mg/l, with irradiation by natural sunlight. Raw data have been provided to the Agency by Olin Corporation, but the methodology was not documented in sufficient detail, and decline of specific degradates was not addressed.

b. Environmental Fate and Transport

As discussed above, a hydrolysis study has been submitted to the Agency. Although this study does not conform to Agency guidelines, no further hydrolysis data will be required by the Agency. Sodium omadine was incubated in sterile, aqueous buffer solutions at each combination of concentration (10 mg/l or 100 mg/l), temperature (5°C or 40°C), and pH (4, 7, or 10). A half-life of 23 days was obtained at 40°C, pH 10, and 10 mg/l concentration. At other levels of concentration, temperature, and pH, sodium omadine hydrolyzed more slowly, or was stable to hydrolysis. The Agency assumes that at normal environmental temperatures the hydrolytic half-life of sodium omadine will be 23 days or longer.

No further characterization of degradation or transport can be made from the required data.

3. Exposure and Risk Characterization

While the hazard to aquatic organisms from exposure to sodium omadine has been characterized, a quantitative risk assessment has not been conducted. The Office of Pesticide Programs has established a policy that risks to aquatic environments from sodium omadine use as a biocide are best characterized and regulated under the NPDES permitting program of the Office of Water. All sodium omadine products are required to state on their labels that discharges to aquatic environments must comply with an NPDES permit. Refer to Section IV for further details.

4. Endangered Species

The Agency expects little exposure to endangered fish and wildlife.

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 sodium omadine 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 sodium omadine. Appendix B identifies the generic data requirements that the Agency reviewed as part of

its determination of reregistration eligibility of sodium omadine, 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 sodium omadine and to determine that sodium omadine can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing sodium omadine 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. The Agency has found that all uses of sodium omadine registered prior to March 23, 1995 and listed in Appendix A 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 sodium omadine, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients sodium omadine, the Agency has sufficient information on the health effects of sodium omadine and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that sodium omadine products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Uses registered after March 23, 1995 are not included in this document. Therefore, the Agency concludes that products containing sodium omadine for all uses registered prior to March 23, 1995 are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of sodium omadine registered prior to March 23, 1995 are eligible for reregistration.

B. Regulatory Position

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

1. Effluent Discharge/Aquatic Risk Rationale

By their nature, industrial biocides are often toxic to aquatic organisms. This is evident from the ecotoxicity data presented in the Science Assessment presented above. The effect to the environment of discharges containing biocides depends heavily upon the volume, concentration, and other constituents of a particular discharge, as well as such features as the size, nature, and flow rate of waters receiving the discharge.

FIFRA permits EPA to require the generation of data on the effects of biocides and to set general limits and conditions of use of a biocide through statements on its labeling. However, these mechanisms do not readily provide for adaptation to varied and changing local conditions. Consequently, generalized regulation of a pesticide under FIFRA could inadequately restrict pesticide use under some local conditions. The NPDES process is designed to take local conditions into account through the issuance of permits for the discharge of pollutants to bodies of water. However, historically, specific information about the toxicological and environmental properties of biocides in effluent streams was not always readily available or considered in writing permits.

EPA's Office of Pesticide Programs and Office of Water intend to cooperate in the oversight of biocide uses to better employ the advantages offered by each program while avoiding unnecessary overlap in regulation. Under FIFRA, OPP will require the generation and submission to the Agency of information that will be used by OPP to identify extraordinary hazards that could affect national registration of biocide products use. Current information and that gathered in the future will be shared with the Office of Water where it can be made available to NPDES permit writers in addressing local aquatic effects of biocide use. In addition, OW will alert OPP to any additional information that becomes available concerning unanticipated aquatic effects of the use of this biocide for OPP's use in national registration decisions for these products. This approach should provide sufficient environmental safeguards while avoiding redundant effort since it allows OPP to control the general approval of the biocide as required by FIFRA, but includes a mechanism for recognizing and dealing with potential unacceptable effects on a local level through the NPDES program. Improved limitations on use under FIFRA and more accurate NPDES permitting decisions and accompanying permit limits for industrial biocides may be developed in the future as the information gathering and exchange program between the Offices progresses.

The Agency believes that the above process adequately addresses the test for reregistration of a pesticide under FIFRA -- "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

Therefore, despite some concerns about potential effects to aquatic organisms exposed to the effluent resulting from its use, the Agency has concluded that unreasonable adverse effects from the uses of sodium omadine involving discharge to water are generally unlikely provided any such discharge is subject to the NPDES permit process.

2. Reference Dose

A reference dose of 0.005 mg/kg/day has been established based on a NOEL of 0.5 mg/kg/day in a chronic rat study and an uncertainty factor of 100.

3. Cancer Classification

The Agency has classified sodium omadine as a Group D chemical (indicating insufficient weight of evidence of carcinogenicity for humans). Sodium omadine was assigned this classification because the dermal carcinogenicity study in mice was found to be unacceptable due to inadequate dose selection. The Agency has concluded that a repeat study is not required as long as the use patterns do not dramatically change and the potential for human exposure remains low.

4. Environmental Hazard Statements

Certain environmental hazard statements are required for sodium omadine products because of toxicity to aquatic organisms. Specific language is found in Section V of this document.

5. Endangered Species Statement

No endangered species labeling is required at this time.

6. Occupational Labeling Rationale

The following is a summary of the regulatory positions and rationales for the sodium omadine. Where labeling revisions are imposed, specific language is set forth for this document. (Refer to Section V).

Occupational and Residential Labeling Rationale/Risk Mitigation

Personal Protective Equipment/Engineering Controls for Handlers

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

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

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

- In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most 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 the 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.

The Agency is establishing active-ingredient-based minimum PPE requirements for occupational handlers. Since gloves were worn by the handlers in the CMA studies that were used to estimate exposures, chemical-resistant gloves are required for occupational handlers of sodium omadine.

Post-Application/Entry Restrictions

Occupational-Use Products

The Agency is not establishing entry restrictions at this time for occupational uses of sodium omadine end-use products because the potential

exposures to sodium omadine are expected to be minimal due to the dilution factor, industrial process, and the stability of products.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing sodium omadine. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of sodium omadine products.

A. Manufacturing-Use Products

There are no manufacturing use products registered for sodium omadine at this time. According to PR Notice 93-10 almost all products, including manufacturing-use products must contain the effluent discharge statement listed below (Section V, B, 2). (Exceptions for small, end-use containers are outlined in PR Notice 95-1). Any new manufacturing-use products must contain this label language.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of sodium omadine for the above eligible uses has been reviewed and determined to be complete. No additional studies are required at this time.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Effluent Discharge and Aquatic Hazard Labeling Statements:

The following labeling statements are required on all end-use products.

> "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

> "This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine."

Worker Protection Labeling Statements

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain sodium omadine, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain sodium omadine, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

Minimum (Baseline) PPE/Engineering Control Requirements

The Agency is establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for sodium omadine end-use products that are intended primarily for occupational use. The

minimum (baseline) PPE for such occupational uses of sodium omadine end-use products is chemical-resistant gloves. (For the glove statement, use the statement established for sodium omadine through the instructions in Supplement Three of PR Notice 93-7). Please note: All end-use product labels must also require, at a minimum, that applicators and other mixer/loader handlers wear long-sleeve shirt, long pants and socks plus shoes. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required. (Note: eye irritation data will be required in the product specific Data Call-In notice).

Entry Restrictions

No entry restrictions are required for sodium omadine.

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing sodium omadine that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons."

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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 inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing."

Application Method Timing and Equipment

All labeling must contain instructions stating when (i.e., as needed, during manufacture, etc.) and how (i.e., pour from container, applied through a closed delivery system, etc.) the preservative is added.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this 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 sodium omadine 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 unless noted Max. /crop cycle	Max. Dose [(AI otherwise)/A] /crop cycle	Max. Dose [(AI otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED												
ADHESIVES, INDUSTRIAL			Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 400	W 400	*	NS	NS	NS	NS	NS	NS		C23
EMULSIONS, RESIN/LATEX/POLYMER			Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 46	W 46	*	NS	NS	NS	NS	NS	NS		C23
	SC/L	W 400	W 400	*	NS	NS	NS	NS	NS	NS		C23
METALWORKING CUTTING FLUIDS			Use Group: INDOOR NON-FOOD									
Preservative treatment., Initial., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 27	V 40	*	NS	NS	NS	NS	NS	NS		
	SC/L	W 498	W 498	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	W 499	W 499	*	NS	NS	NS	NS	NS	NS		A08, C23
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 72	V 72	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	V 128	V 128	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	V 2560	V 2560	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	W 1440	W 1440	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	W 2000	W 10000	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	W 10000	W 10000	*	NS	NS	NS	NS	NS	NS		A08, C23
Preservative treatment., Subsequent/maintenance., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 27	V 40	*	NS	NS	NS	NS	NS	NS		
	SC/L	W 498	W 498	*	NS	NS	NS	NS	NS	NS		A08, C23
	SC/L	W 499	W 499	*	NS	NS	NS	NS	NS	NS		A08, C23

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 /crop cycle	Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
SPECIALITY INDUSTRIAL PRODUCTS				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	U 320	U 320	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	V 64	V 64	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 520	W 5000	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 639	W 639	*	NS	NS	NS	NS	NS	NS			C23
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 64	V 64	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 125	W 125	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 499	W 499	*	NS	NS	NS	NS	NS	NS			C23

LEGEND

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)

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

SC/L : SOLUBLE CONCENTRATE/LIQUID

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, --

LEGEND

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
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
A08 : Preclean claim.
C23 : NPDES license restriction.
* 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 sodium omadine covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to sodium omadine 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 D

Data Supporting Guideline Requirements for the Reregistration of Sodium Omadine

REQUIREMENT		USE PATTERN	CITATIONS
PRODUCT CHEMISTRY			
61-2A	Start. Mat. & Mnfg. Process	ALL	00159036, 00159037
61-2B	Formation of Impurities	ALL	00159036
62-1	Preliminary Analysis	ALL	40170101, 41189901
62-2	Certification of limits	ALL	00159036, 40170101
62-3	Analytical Method	ALL	00159038, 00159039, 40170101
63-2	Color		Waived
63-3	Physical State		N/A
63-4	Odor	ALL	Waived
63-5	Melting Point	ALL	5/12/95 Correspondence from registrant, No MRID
63-6	Boiling Point		N/A
63-7	Density		N/A
63-8	Solubility	ALL	40974101
63-9	Vapor Pressure		N/A
63-10	Dissociation Constant	ALL	40974101
63-11	Octanol/Water Partition		N/A
63-12	pH		5/12/95 Correspondence from registrant, No MRID
63-13	Stability		N/A

Data Supporting Guideline Requirements for the Reregistration of Sodium Omadine

REQUIREMENT		USE PATTERN	CITATIONS
63-14	Oxidizing/Reducing Action	ALL	40974101
63-15	Flammability		N/A
63-16	Explodability	ALL	40974101
63-17	Storage stability	ALL	40974101
63-18	Viscosity	ALL	40974101
63-19	Miscibility		N/A
63-20	Corrosion characteristics	ALL	40974101
ECOLOGICAL EFFECTS			
71-1B	Acute Avian Oral - Quail/Duck TEP	F, M	40363401
71-2A	Avian Dietary - Quail	F, M	00073656
71-2B	Avian Dietary - Duck	F, M	00073657
72-1B	Fish Toxicity Bluegill - TEP	F, M	40358501
72-1D	Fish Toxicity Rainbow Trout- TEP	F, M	40494501
72-2B	Invertebrate Toxicity - TEP	F, M	00103228
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	F, M	40247801
81-2	Acute Dermal Toxicity - Rabbit/Rat	F, M	40247802
81-3	Acute Inhalation Toxicity - Rat	F, M	40339001
81-4	Primary Eye Irritation - Rabbit	F, M	Food & Drug Research Laboratory (88496 c and d), DATA GAP

REQUIREMENT		USE PATTERN	CITATIONS
81-5	Primary Dermal Irritation - Rabbit	F, M	40247803
81-6	Dermal Sensitization - Guinea Pig	F, M	40247804, 40387401
82-1A	90-Day Feeding - Rodent	F, M	40756901
82-3	90-Day Dermal - Rodent	F, M	40936201
82-4	90-Day Inhalation - Rat	F, M	41178201
82-5B	90-Day Neurotoxicity - Mammal	F, M	40756901
83-1A	Chronic Feeding Toxicity - non-rodent (monkey)	F, M	41178101
83-5	Oncogenicity - Rat	F, M	42100901
83-2B	Oncogenicity - Mouse	F, M	42100801
83-3B	Developmental Toxicity - Rabbit	F, M	40487201
83-4	2-Generation Reproduction - Rat	F, M	41097201
84-2A	Gene Mutation (Ames Test)	F, M	40411501
84-2B	Structural Chromosomal Aberration	F, M	40343701
84-4	Other Genotoxic Effects	F, M	40387501
85-1	General Metabolism	F, M	41269001
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
80-A-SS	Special Human Exposure Study	F, M	Antimicrobial Exposure Assessment Study (41412201), Chronic Toxicity Studies Cited Above

Data Supporting Guideline Requirements for the Reregistration of Sodium Omadine

REQUIREMENT		USE PATTERN	CITATIONS
ENVIRONMENTAL FATE			
161-1	Hydrolysis	F, M	40383001
161-4	Photodegradation - Air		Evans, Sugden and Van Abbe, 1975. Neihoff, Bailey, Patouillet and Hannan, 1979.

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.

BIBLIOGRAPHY

MRID	CITATION
00073656	Fink, R. (1976) Final Report: Eight-Day Dietary LC50--Bobwhite Quail: Project No. 133-103. (Unpublished study received Nov 16, 1976 under 1258-842; prepared by Truslow Farms, Inc., submitted by Olin Corp., Stamford, Conn.; CDL:226871-BO)
00073657	Fink, R. (1976) Final Report: Eight Day Dietary LC50--Mallard Ducks: Project No. 133-104. (Unpublished study received Nov 16, 1976 under 1258-842; prepared by Truslow Farms, Inc., submitted by Olin Corp., Stamford, Conn.; CDL:226871-BP)
00103228	Union Carbide Corp. (1976) Acute Toxicity of Sodium Omadine, 40% Aqueous Solution to Daphnia magna. (Unpublished study received Jun 3, 1982 under 1258-842; submitted by Olin Corp., Stamford, CT; CDL:247630-A)
00159036	Olin Corp. (1986) 40% Sodium Omadine: Manufacturing Process & Discussion of Impurities: Raw Materials Specifications and Material Safety Data Sheets. Unpublished compilation. 68 p.
00159037	Olin Corp. (1983) Product Specifications and Material Safety Data Sheet: Sodium Omadine. Unpublished study. 4 p.
00159038	Olin Corp. (1986) Quality Control Methods: Sodium Omadine. Unpublished compilation. 38 p.
00159039	Putnam, E. (1985) Color, Gardner: Sodium Omadine: CL-5-763. Unpublished study prepared by Olin Corp. 2 p.
40170101	Hyde, G. (1987) Sodium Omadine: Preliminary Analysis & Certification of Limits. Unpublished study prepared by Olin Corp. 81 p.
40247801	Moreno, O. (1987) Sodium Omadine: Oral LD50 in Rats: Laboratory Project ID: MB 86-8370A. Unpublished study prepared by MB Research Laboratories, Inc. 25 p.
40247802	Moreno, O. (1987) Sodium Omadine: Acute Dermal Toxicity in Rabbits/ LD50 in Rabbits: Laboratory Project ID: MB 86-8370B. Unpublished study prepared by MB Research Laboratories, Inc. 26 p.

BIBLIOGRAPHY

MRID	CITATION
40247803	Moreno, O. (1987) Sodium Omadine: Primary Dermal Irritation in Albino Rabbits: Laboratory Project ID: MB 86-8370C. Unpublished study prepared by MB Research Laboratories, Inc. 11 p.
40247804	Moreno, O. (1987) Sodium Omadine: Guinea Pig Maximization Test (Magnusson-Kligman): Laboratory Project ID: MB 86-8370F. Unpublished study prepared by MB Research Laboratories, Inc. 11 p.
40339001	Drummond, J. (1987) Acute Inhalation Toxicity Evaluation on Na Omadine in Rats: Laboratory Project ID: 397-045. Unpublished study prepared by International Research and Development Corp. 67 p.
40343701	Sorg, R. (1987) Sodium Omadine: Micronucleus Test: Laboratory Project ID: PH 309-OL-001-87. Unpublished study prepared by Pharmakon Research International, Inc. 52 p.
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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 and Confidential Statement of Formula

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

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 Confidential Statement of Formula

SODIUM OMADINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 sodium omadine. 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) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this sodium omadine Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for sodium omadine are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on sodium omadine 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 sodium omadine products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of sodium omadine, please contact Judy Loranger at (703) 308-8056.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Bruce Kapner at (703) 308-8013.

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

Bruce Kapner
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: **Sodium Omadine**

Sodium omadine DATA CALL-IN CHEMICAL STATUS SHEET

No generic data are required for sodium omadine at this time.

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.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0209 Sodium Omadine	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

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

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

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

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

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

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To 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.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0209 Sodium Omadine EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	productn & formulatn								
	process								
61-2(b)	Discussion of formation of (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	impurities								
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-13	Study not required for product							8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0209 Sodium Omadine EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	specific reregistration.									
63-14	Oxidizing or reducing action	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability	(18)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0209 Sodium Omadine

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product;TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
17 Not required unless efficacy data are required.
18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0209 Sodium Omadine

Footnotes (cont.):

of potential eye and dermal irritation effects.

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).

4 Required unless repeated dermal exposure does not occur under conditions of use.

36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING SODIUM OMADINE FOR PURPOSES OF 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 end-use products containing the active ingredient sodium omadine, the Agency considered batching end-use products. This process involves grouping similar products for purposes 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., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.).

However, batching of end-use products containingsodium omadine was not possible after considering the available information described above. Table I lists all the end-use products containing sodium omadine. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their products. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by 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 cited, the registrant must clearly identify the material tested 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 which 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 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). Since the end-use products containing sodium omadine could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING SODIUM OMADINE FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

Table I. End-Use Products Containing sodium omadine

EPA Reg. No.	% of sodium omadine & Other Active Ingredients	Formulation Type
1258-843	40% sodium omadine	Ready-to-Use-Solution
1258-990	6.4% sodium omadine 63.6% Bioban GK Brand of hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	Ready-to-Use-Solution
1258-1205	3.6% sodium omadine 71.4% Bioban GK Brand of hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	Ready-to-Use-Solution
1258-1213	10% sodium omadine	Ready-to-Use-Solution
4808-3	4.0% sodium omadine	Ready-to-Use-Solution

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0209 Sodium Omadine

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
001258	OLIN CORPORATION		BOX 586	CHESHIRE CT	06410
004808	CINCINNATI MILACRON		BOX 9013	CINCINNATI OH	45209

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.

EPA Confidential Statement of Formula

☐ Alternate Formulation | Page of

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

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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
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CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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se fill in blanks below.

ny Name	Company Number
Name	EPA Reg. No.

y that:

or each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act A) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original ubmitter to cite that study.

hat for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the l data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the ny(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with section (F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation ement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

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

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

re	Date
nd Title (Please Type or Print)	

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

re	Date
nd Title (Please Type or Print)	

8570-31 (4-96)

The following is a list of available documents related to sodium omadine. 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 sodium omadine 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. Sodium Omadine 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

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-026 January 1996

EPA

R.E.D. FACTS

Sodium Omadine

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 209, sodium omadine.

Use Profile

Sodium omadine is a broad spectrum antimicrobial compound used as a preservative in certain manufacturing materials and as additive in process fluids which may otherwise be subject to deterioration through bacterial and/or fungal growth. Sodium omadine may be used as a biocide in: aqueous metalworking, cutting, cooling and lubricating fluids; latex emulsions used in adhesives, caulks, patching compounds, sealants, pastes and grouts; latex emulsions; aqueous fiber lubricants and inks; laundry rinse additives and detergents; carpet cleaners and analytical and diagnostic reagents. This RED did not address the use of sodium omadine as an in can preservative of water based chemical or mineral add mixtures used in concrete preparation, registered by the Agency on March 23, 1995. Currently there are 5 registered products that contain from 3.6 to 40 percent sodium omadine. All of these end-use products are formulated as liquid soluble concentrates. There are no registered food uses.

Regulatory History

Sodium omadine was first registered in the United States in 1968 for use as a biocide. The Registration Standard on sodium omadine (NTIS # PB86-173929) was issued in July 1985, and required submission of product chemistry, toxicology, ecotoxicity and environmental fate data. The 1987 Antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies.

Human Health Assessment

Toxicity

Sodium omadine caused slight erythema and edema in a dermal irritation study using rabbits. Sodium omadine was found to be moderately toxic by the dermal route (Toxicity Category II), slightly toxic by the oral and inhalation routes (Toxicity Category III) and did not cause skin sensitization in animals studies.

In a 90-day rat dermal toxicity study, there was no evidence of dose-related dermal irritation. Dose related clinical signs seen in females included emaciation, hunched posture, stiff hindlimbs, incoordination and tremors. In a subchronic oral toxicity/neurotoxicity study, high dose rats exhibited treatment related neurotoxic signs.

In a chronic toxicity study, clinical signs of toxicity noted in monkeys administered sodium omadine by gavage included prostration, decreased activity, emesis, thinness, weakness and cold extremities. Slight hematologic changes were observed and were considered of minor toxicologic importance.

In a rat oral carcinogenicity study, an increase in neoplasms was not observed at any site. In a mouse dermal carcinogenicity study, application of sodium omadine did not induce any benign or malignant neoplasms. Although this study was found to be inadequate because the chemical was not tested at a sufficiently high dose level, the Agency concluded that a new study will not be required as long as the use patterns do not dramatically change and the potential for human exposure remains low. Sodium omadine has been classified as a Group D carcinogen based on the insufficient weight of evidence regarding its cancer-causing potential.

In a developmental toxicity study in rabbits, there was no evidence of maternal or fetal toxicity at any dose. In a two-generation reproduction study, rats showed parental (skeletal muscle atrophy and decreased body weight) and reproductive effects (slightly decreased number of pups per litter, delayed development, decreased pup body weight and weight gain). Sodium omadine was negative in three mutagenicity studies. Metabolism studies indicated that it was rapidly absorbed, metabolized, and excreted at all dosing levels tested.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of sodium omadine since no food or feed uses are registered.

Occupational and Residential Exposure

Based on current use patterns, handlers may be exposed to sodium omadine through dermal or inhalation routes from pouring and pumping of sodium omadine in metal working fluids.

EPA has conducted exposure and risk assessments for workers exposed to sodium omadine during pouring and pumping operations and finds that margins of exposure (MOEs) for workers are greater than 100. Thus, minimal risks are posed to workers during the pouring and pumping of liquids that contain sodium omadine. The Agency has not evaluated occupational risk to machinists because these worker's exposure is regulated by the Occupational Safety Administration (OSHA). Available information indicates that the amount of active ingredient (0.005 to 0.5%) present in the oil used by machinists would most likely be even lower than the amount to which handlers would be exposed. Therefore, exposure to sodium omadine treated fluids would represent a lesser hazard to the machinist than to handlers involved in pumping and pouring operations.

Sodium omadine is not registered for homeowner uses; therefore, risk characterization of residential exposure is not required. The Agency, however, believes that the amount of sodium omadine in products that may enter the home or occupational setting such as laundry rinse additives, detergents, carpet cleaners, emulsions and jet printer inks would be very low due to dilution. For this reason, health risks to consumers from exposure to products containing sodium omadine are also expected to be very low.

Human Risk Assessment

Because sodium omadine is slightly to moderately acutely toxic, the Agency is establishing active-ingredient-based minimum (baseline) personal protective equipment (PPE) and engineering control requirements (chemical resistant gloves) for end-use products that are intended primarily for occupational use. All end-use product labels must also require, at a minimum, that applicators and other mixer/loader handlers a wear long-sleeve shirt, long pants and socks plus shoes. If the required eye irritation study indicates that the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

Environmental Assessment

Environmental Fate

Under normal environmental conditions, the hydrolytic half-life of sodium omadine will likely be 23 days or longer. Photolysis is probably a more important route of dissipation than hydrolysis. Photolytic half-lives of 40-126 minutes have been reported with irradiation by natural sunlight.

Ecological Effects

An acute oral toxicity study shows that sodium omadine is moderately toxic to bobwhite quail. On a subacute dietary basis, sodium omadine has been characterized as slightly toxic to mallard ducks and bobwhite quails. Sodium omadine was found to be very highly toxic to rainbow trout, bluegill sunfish and freshwater invertebrates.

Ecological Effects Risk Assessment

While the hazard to aquatic organisms from exposure to sodium omadine has been characterized, a quantitative risk assessment has not been conducted. The Office of Pesticide Programs has established a policy that risks to aquatic environments from use of biocides such as sodium omadine are best characterized and regulated under the NPDES permitting program of EPA's Office of Water. All sodium omadine products are required to state on their labels that discharges to aquatic environments must comply with an NPDES permit.

Additional Data Required

All generic data requirements have been satisfied for sodium omadine. The Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All sodium omadine end-use products must comply with EPA's current pesticide product labeling requirements, and with the additional requirements summarized below. Please see the RED document for the complete text of these labeling requirements.

Effluent Discharge and Aquatic Hazard Labeling Statements:

"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment

plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

"This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine."

Worker Protection Labeling Statements

•Minimum (Baseline) PPE/Engineering Control Requirements

For **sole-active-ingredient** end-use products that contain sodium omadine, revise the product labeling to adopt these handler PPE/engineering control requirements and remove any conflicting PPE requirements.

For **multiple-active-ingredient** end-use products, compare these handler PPE/engineering control requirements to those on current labeling and retain the more protective. To determine which requirements are considered more protective, see PR Notice 93-7.

The minimum (baseline) PPE for occupational uses of sodium omadine end-use products is chemical-resistant gloves. (For the glove statement, use the statement established for sodium omadine through the instructions in Supplement Three of PR Notice 93-7). Please note: All end-use product labels must also require, at a minimum, that applicators and other mixer/loader handlers wear a long-sleeve shirt, long pants, and socks plus shoes. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

•Other Labeling Requirements for Occupational Use Products

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons."

User Safety Requirements

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

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 inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing."

Application Method Timing and Equipment

All labeling must contain instructions stating when (i.e., as needed, during manufacture, etc.) and how (i.e., pour from container, applied through a closed delivery system, etc.) the preservative is added.

Regulatory Conclusion

The use of currently registered products containing sodium omadine in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of sodium omadine registered prior to March 23, 1995, are eligible for reregistration. (Uses registered on or after that date not included in this RED).

Sodium omadine products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for sodium omadine during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the sodium omadine RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the sodium omadine RED, or reregistration of individual products containing sodium omadine, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.