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Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
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EPA R.E.D. FACTS

Silver

Pesticide Reregistration

All pesticides sold or used 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for silver.

Use Profile

Silver, a naturally-occurring element, is registered for use in water filters to inhibit the growth of bacteria within the filter unit of water filter systems designed to remove objectionable taste, odors, and color from municipally treated tap water; these bacteriostatic water filters account for over 90% of its pesticidal use. Silver also is used to control several types of algae in swimming pool water systems; this algicide use accounts for only about 3% of silver's use as a pesticide.

Silver manufacturing use products are granular formulations, the bacteriostatic water filters are impregnated with silver, and the swimming pool algicides are formulated as soluble liquid concentrates.

Silver also has many other non-pesticidal, industrial uses including use in photo processing, mirror production, dental alloys, coinage, tableware and jewelry production, solder, electroplating, the manufacture of inks and dyes, the processing of food and beverages, and the etching of ivory. Silver salts and nitrate also are used as therapeutic agents in treating warts, burns, and eye infections.

Regulatory History

Silver was first registered as a pesticide in the United States in 1954, for use in disinfectants, sanitizers and fungicides. Currently, about 80 pesticide products are registered which contain silver as an active ingredient.

Many regulations pertaining to silver have been promulgated through the years, particularly by EPA's Office of Water (OW). The most recent of these was a secondary maximum contaminant level (SMCL) issued in 1991, based on silver's ability to cause argyria, an undesirable cosmetic condition.

OW classified silver as a Group D carcinogen (one that is not classifiable as to carcinogenicity in humans) in 1988. EPA established an oral Reference Dose (RfD), or daily intake limit, of 0.005 mg/kg/day for silver in 1991.

The Office of Pesticide Programs (OPP) issued a Data Call-In (DCI) for silver in 1992, requiring additional product chemistry and toxicity data. The silver RED reflects EPA's reassessment of all data submitted in response to the DCI.

Human Health Assessment

Toxicity

Most usually-required toxicity and exposure studies have been waived for silver since adequate published information is available.

Human Toxicology

Silver can be absorbed from the lungs and the gastrointestinal tract. When an excessive amount of silver is absorbed, tissues become impregnated with silver sulfite, which forms a complex in elastic fibers. Large amounts of this complex under the skin will give it bluish, grey-blue, or in extreme cases a black color. This condition is called argyria. Although it is not a toxic effect, argyria is undesirable and usually permanent.

Excessive exposure to silver also can cause lung and kidney lesions; exposure to dusts can cause breathing problems, lung and throat infections and abdominal pain; and skin contact can cause mild allergic reactions such as rashes, swelling, and inflammation.

Animal Toxicology

The acute toxicity of silver is relatively low by the oral route (it has been placed in Toxicity Category III for this effect). Silver also is of low acute dermal toxicity (Toxicity Category III), is not an eye or skin irritant (Toxicity Category IV), and is not a skin sensitizer.

Silver is not known to have human carcinogenic potential, and does not appear to be a mutagen. Although long term ingestion of silver may cause argyria in humans and animals, this effect is cosmetic only and is not harmful to health.

Dietary Exposure

Silver is not registered for application to food or feed crops nor for use on processed commodities. Silver is a natural element and trace amounts are normally present in the human diet. Minimal dietary exposure may result from the use of silver in human drinking water systems. EPA does not anticipate that dietary exposure to these low levels of silver will be associated with any significant degree of risk.

Occupational and Residential Exposure

Occupational exposure can be expected for individuals handling silver algaecide solutions or silver-impregnated filter materials. When the soluble liquid concentrates used for water treatment in swimming pools are applied through a pool skimmer basket, splashes to the eye or on the skin may occur. People handling silver-impregnated filters may be exposed to minute quantities of silver-containing charcoal. Thus, the potential exists among mixers, loaders and applicators for eye, inhalation and dermal exposure to concentrated solutions or dusts.

Residential exposure to very low levels of silver may be expected through consumption of drinking water filtered through bacteriostatic filters, and by swimming in treated pools.

Human Risk Assessment

Applicator Exposure

Residential consumption of water filtered through filtering systems containing silver is not expected to result in build-up of silver in the body to an argyria-comparable level. The use of silver as a water treatment for pools is minor, and of little concern from a toxicity perspective. Thus, the residential uses of silver are not expected to constitute an unreasonable risk or hazard.

Occupational exposure to silver may occur; however, this exposure generally would be of such a low level, and silver is of sufficiently low toxicity, that it is not expected to present unreasonable risks or hazards.

Environmental Assessment

Environmental Fate

Because a large data base is available for silver, most environmental fate testing was waived. However, registrants must clarify the nature of the concentrate used in swimming pools, due to concern about the potential formation of water soluble or colloidal species that swimmers may ingest.

Products containing silver are not to be applied in marine/estuarine environments or oil fields. Discharge of effluent into lakes, streams and ponds or public water is subject to NPDES license restrictions. Water treated with silver as a pesticide cannot be discharged into sewage systems without notifying the sewage plant authority.

Ecological Effects

The available acute toxicity data indicate that silver is highly toxic to fish, aquatic invertebrates and estuarine organisms. Avian toxicity data were required in the 1992 Data Call-In and these studies are underway. The risk to birds will be assessed after the data are submitted and reviewed. However, exposure to birds should be low from the pesticidal uses of silver.

Ecological Effects Risk Assessment

Silver exposure from products used for swimming pool and human drinking water systems will be discharged to municipal water systems, and treated in municipal water treatment plants and is regulated under NPDES permits. The Agency does not expect unreasonable adverse effects to the environment from these uses.

Additional Data Required

EPA is requiring a new confidential statement of formula (CSF) detailing the nature of the soluble liquid concentrate. EPA also is requiring product-specific data and revised labeling for reregistration of pesticide products containing silver.

Product Labeling Changes Required

The labels of all registered pesticide products containing silver must comply with EPA's current pesticide labeling requirements. EPA has determined that the current end-use label precautions are still appropriate and are required for product reregistration. It is the Agency's position that these precautions must continue to include a statement indicating that:

a. This pesticide [silver] is toxic to fish and aquatic invertebrates.

b. "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other 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 E.P.A."

c. That the drinking water filters are for use on cold water only.

Regulatory Conclusion

The use of currently registered pesticide products containing silver in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of products containing silver registered as of June 23, 1993 are eligible for reregistration.

These silver products will be reregistered once the required confirmatory, product-specific data and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for silver 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 or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the silver RED 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 silver or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual products containing silver, please contact Joanne I. Miller, Product Manager, Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-7830.

REREGISTRATION ELIGIBILITY DOCUMENT

SILVER

LIST D

CASE 4082

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

SILVER REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Rafael Prieto	Biological Analysis Branch
Martin Lewis	Planning & Evaluation

Environmental Fate and Effects Division

Kay Valente	Ecological Effects Branch
Norm Cook	Ecological Effects Branch
Silvia Termes	Environmental Fate and Groundwater Branch
Mary Frankenberry	Science Analysis and Coordination Staff

Health Effects Division

Nguyen Bich Thoa	Chemical Coordination Branch
San Yvette Williams	Toxicology Branch II
Judy Smith	Occupational and Residential Exposure Branch
Christina Swartz	Chemistry Branch Reregistration Support

Registration Division

Karen Leavy	Antimicrobial Program Branch
Marshall Swindell	Antimicrobial Program Branch
Van M. Seabaugh	Registration Support Branch

Special Review and Reregistration Division

Margarita Collantes	Accelerated Reregistration Branch
Kathryn Davis	Accelerated Reregistration Branch
Kathleen Depukat	Accelerated Reregistration Branch
Bruce Sidwell	Accelerated Reregistration Branch

Policy and Special Projects Staff

Jean Frane	Food Safety & Regulatory Tracking Section

SILVER REREGISTRATION ELIGIBILITY TEAM (cont.)

Office of General Counsel

Phil Ross

Office of Compliance Monitoring

Shruti Sanghavi	FIFRA Policy & Analysis Branch Policy and Grants Division

Office of Research and Development

Mike Troyer

Office for Policy, Planning and Evaluation

Ronald N. Dexter	Pesticides Policy Branch

Office of Water

Julie Du

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CRAVE	Carcinogenic Risk Assessment Verification Endeavor
CSF	Confidential Statement of Formula
DCI	Data Call-In
DHHS	U.S. Department of Health and Human Services
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	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
i.v.	Intravenous
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 or feed, e.g., mg/l or ppm.)
LD_{50}	Median Lethal Dose (A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal). 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.)

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
IRIS	Integrated Risk Information System
MCL	Maximum Contaminant Level
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
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OW	Office of Water
OPP	Office of Pesticide Programs
OWRS	Office of Water Regulations and Standards
PADI	Provisional Acceptable Daily Intake
ppb	Parts Per Billion
ppm	Parts Per Million
RfD	Reference Dose
RS	Registration Standard
SMCL	Secondary Maximum Contaminant Level (A non-enforceable limit for a contaminant which may affect the aesthetic qualities of drinking water.)

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

TD	Toxic Dose (The dose at which a substance produces a toxic effect.)
TC	Toxic Concentration (The dose at which a substance produces a toxic effect.)
TMRC	Theoretical Maximum Residue Contribution.

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Attachment B - Generic DCI Response Forms (Form A) plus Instructions
Attachment C - Requirements Status and Registrants' Response Forms (Form B) plus Instructions
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Attachment F -	List of all Registrant(s) sent this DCI
Attachment G -	Cost Share/Data Compensation Forms

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (hereafter referred to as "the Agency"), has conducted a review of the published scientific literature and other relevant information supporting the reregistration of the pesticide active ingredient silver. The conduct and submission of commonly required generic toxicology and human exposure studies have been waived by the Agency due to the availability of adequate published information.

This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of products containing silver for currently registered uses. Pesticide products containing silver are used as an algicide in swimming pool water systems and to inhibit the growth of bacteria within the filter unit of water filter systems designed to remove objectionable taste, odor and color from municipally treated tap water. The Agency has determined that the use of silver as currently registered will not cause unreasonable risk to humans or the environment. The Agency is requiring a special ecological effects study as confirmatory data and for purposes of labeling to complete the generic data base.

Accordingly, the Agency has determined that all products containing elemental silver as the active ingredient are eligible for reregistration and will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, the Agency is requiring that product specific data be submitted by the registrants within eight months of the issuance of this document. Additionally, in order to remain in compliance with FIFRA, it is the Agency's position that revised labeling must be submitted by the registrants within that same time period. After reviewing these data, including the ecological effects data and the revised labels, the Agency will determine whether the conditions and requirements of FIFRA 3(c)(5) have been met for the reregistration of these products.

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 these 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 ingredients are eligible for registration" 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 silver as of June 23, 1993. The document consists of eight sections. Section I is the Executive Summary. Section II is the introduction. Section III describes silver, its uses, data requirements and regulatory history. Section IV discusses the physical chemistry, human health and environmental assessment based on the data available to the Agency. Section V presents the reregistration decision for silver. Section VI discusses the eligibility decision for silver. Section VII discusses the reregistration requirements for silver. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Silver
- **Chemical Name:** Silver
- **CAS Registry Number:** 7440-22-4
- **OPP Chemical Code:** 072501
- **Empirical Formula:** Ag

B. Use Profile

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

For Silver:

Type of Pesticide: Bacteriostatic water filter, algicide (swimming pool water systems)

Use Sites: AQUATIC NON-FOOD RESIDENTIAL:
Swimming Pool Water Systems

INDOOR FOOD:
Human Drinking Water Systems

Target Pests: Black and mustard algae; slime-forming algae (swimming pool water systems); potable water bacteria (human drinking water systems)

Formulation Types Registered:

TYPE: End use, Manufacturing use
FORM: Impregnated material, Granular, Soluble liquid concentrate (swimming pool water systems)

Method and Rates of Application:

Types of Treatment -

Bacteriostatic filter treatment, Water treatment (swimming pool water systems)

Equipment - Bacteriostatic filter unit, Bacteriostatic filter media, Bacteriostatic filter cartridge, Skimmer basket (swimming pool water systems)

Timing - Initial, Subsequent/maintenance, Winterizing, When needed (human drinking water systems)

Rate of Application -

Human Drinking Water Systems:
From 160 up to 17,100 ppm active ingredient by weight

Swimming Pool Water Systems:
0.1 ppm active ingredient by weight

Use Practices Limitations:

Generally for use with cold water only (human drinking water systems)

C. Estimated Usage Of Pesticide

Industrially, silver is used in photographic processing, mirror production, dental alloys, coinage, the manufacture of tableware and jewelry, electroplating, the manufacture of inks and dyes, solder, brazing alloys, and high capacity silver-zinc and silver-cadmium batteries, the processing of food and beverages, and the etching of ivory. As therapeutic agents, silver salts are used for their local actions: the nitrate in the treatment of warts (caustic effect), and the nitrate and insoluble silver compounds (e.g., silver sulfadiazine) for prevention of infection associated with extensive burns. Silver nitrate 1% opthalmic solution is still used for prophylaxis against ophthalmia neonatorum. Colloidal silver preparations have been used in the past to treat syphilis, but this use has been totally supplanted by antibiotics. Silver acetate is used in anti-smoking remedies.

As a pesticide, silver is registered for use as a microbiocide (algicide) primarily used with respect to two use groups (sites): Aquatic Non-Food Residential (swimming pool systems) and Indoor Food (human drinking water systems).

D. Regulatory History

Silver was first registered as a pesticide in the United States in December of 1954 for use in disinfectants, sanitizers, and fungicides. Many regulations and guidelines have been issued over the following years on silver. In 1980 the Agency's Office of Water Regulations and Standards (OWRS) established a guideline for silver of 0.05 mg/L for ambient water quality criteria to protect human health ingesting water and organisms (45 Fed. Reg. 79318, November 28, 1980). These criterion were promulgated for several states under the National Toxics Rule in December of 1992 (57 Fed. Reg. 60848, December 22, 1992). In 1985 the Agency's Office of Water (OW) established a guideline recommending drinking water limits for silver at 0.05 mg/L. In 1987 Agency OW established a maximum contaminant level (MCL) for silver in drinking water of 0.05 mg/L (40 CFR 141) and a proposed drinking water secondary maximum contaminant level (SMCL) of 0.09 mg/L in 1989. The Agency announced the deletion of the 50 μg/L MCL for silver on January 30, 1991 (56 Fed. Reg. 3573) and replaced the MCL with a secondary maximum contaminant level of 100 μg/L, based on the fact that silver causes argyria (a cosmetic effect resulting from the formation of silver complexes in the subepithelial portions of the skin resulting in a characteristic bluish pigmentation) (56 Fed. Reg. 3526, January 30, 1991). A SMCL is non-enforceable but is a limit for a contaminant which may affect the aesthetic qualitites (e.g., taste and color) of drinking water. In 1988, the U.S. Food and Drug Administration established a regulation establishing the permissible levels of silver in bottled water at 0.05 mg/L (21 CFR 103.35).

In 1988 the Agency (OW) classified silver as a Group D carcinogen - not classifiable as to human carcinogenicity, based on inadequate evidence of carcinogenicity in animal studies and the lack of carcinogenic evidence in humans. The classification was verified by the Agency's Carcinogenic Risk Assessment Verification Endeavor (CRAVE) work group (09/22/88). An oral RfD was established for silver at 0.005 mg/kg/day. The RfD was verified by the Agency RfD Work Group (07/18/91).

Under Phase 4 of the reregistration program, a comprehensive Data Call-In (DCI) was issued in September of 1992 for Silver requiring additional product chemistry and toxicity data.

Currently, there are approximately 80 pesticide products registered for uses of silver. Approximately 90% of the registered products are for bacteriostatic water filters that contain silver. A small percentage (7%) of the registered products are media which contain silver for actual filter housing and 3% of the products are used as algicides.

This Reregistration Eligibility Document reflects a reassessment of all available technical data.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Product Chemistry

Silver is a naturally occurring element which can be found as the native metal or combined with other elements in distinct mineral phases. Its physical chemistry properties are widely reported in the published scientific literature. The physical and chemical characteristics of silver are detailed below:

Chemical Name:	Silver
Chemical Formula:	Ag
Molecular Weight:	107.868
Color:	Metallic
Physical State:	Solid
Odor:	None
Melting Point:	960.5° C
Boiling Point:	2000° C
Density:	10.49 g/mL at 15° C
Solubility:	Not soluble in water
Vapor Pressure:	N/A
Dissociation Constant:	N/A
Oct/Water Part. Coeff:	N/A
pH:	N/A
Stability:	Stable to sunlight and metal/metal ions

The Agency has determined through the review of available data that elemental silver per se is not isolated during the manufacturing process, nor is it used during the manufacturing process, and that the appropriate data submitted to support the manufactured products (MP) and end use products (EP) will satisfy the generic product chemistry data requirements.

2. Residue Chemistry

The nature of the residue in plants and animals is not applicable, since treated water is used solely for human consumption, and is not directly applied to plants or consumed by livestock. Adequate analytical methodology is available for the determination of silver ions in water; the most common approach is the use of atomic absorption methods. Storage stability is not an issue for silver ions in water, since analytical methods determine total silver residues.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on silver is adequate and will support reregistration eligibility.

a. Human Toxicology

Silver can be absorbed from the lungs and the gastrointestinal tract. The major route of excretion is via the gastrointestinal tract. Urinary excretion has not been reported to occur, even after an intravenous (i.v.) injection (Goyer, 1991).

The major effect of excessive absorption of silver is local or generalized impregnation of tissues where the metal remains as silver sulfite and forms an insoluble complex in elastic fibers. Large amounts of this complex in the subepithelial portions of the skin will impart a characteristic bluish pigmentation, a condition called argyria. Although not a toxic effect, argyria is an undesirable cosmetic condition which is usually permanent. Argyria has been known to occur during treatment of syphilis with silver arsphenamine. The local form of argyria is characterized by gray-blue patches of skin and/or conjunctival pigmentation and the generalized form by widespread pigmentation of the skin. In severe cases, the skin looks black, with a metallic luster, the eyes may be so affected that vision may be impaired, and the respiratory tract may also be affected (Goyer, 1991). In a human study of argyria associated with the therapeutic use of silver arsphenamine, ten males (23-64 years old) and two females (23 and 49 years old) who were administered 31-100 intravenous injections of the silver salt (4-20 g) over a 2-9.75 year period were shown to develop generalized argyria. Although one patient showed the condition after only a total dose of 1 g, the results of the study suggest that argyria may become clinically apparent when the total accumulated intravenous dose has reached approximately 8 g (Gaul and Staud, 1935). A LOEL was established at 1 g total intravenous dose, corresponding to an oral dose of 0.014 mg/kg/day, based on the incidence of argyria in one patient. Industrial argyria is a known occupational condition for workers in primary metal industries and industries using electrical machinery, equipment, and supplies (U.S. DHHS # TP-90-24, 1990).

Excessive industrial and/or medicinal exposures to silver have been associated with arteriosclerosis and lesions of the lungs and kidneys (Goyer, 1991). Exposure to industrial dusts containing high levels of silver nitrate and/or silver oxide may cause breathing problems, lung and throat infections, and abdominal pain. Skin contact with certain silver

compounds may cause mild allergic reactions such as a rash, swelling, and inflammation in sensitive people (U.S. DHHS # TP-90-24, 1990).

b. Animal Toxicology

(1) Acute Toxicity

A single oral dose of 420 mg/kg of colloidal silver did not cause any mortality in rats (Dequidt et al., 1974). This would place silver in acute oral toxicity category III. A single application of silver nitrate (3 drops of a 0.66% solution; 42 ppm silver) into the right eye of male Wistar rats resulted in silver deposits in the cornea and conjunctiva. In addition, silver deposits were scattered in the cells of the outermost part of the anterior corneal epithelium, and heavy deposits were found in Bowman's layer, reticular fibers of the corneal stroma, Descemet's membrane, and the posterior corneal epithelium. These effects were observed 45 days after treatment and were not accompanied by any other adverse effects (Rungby, 1986). The following toxicological data were obtained from acute toxicological studies with Sildate, an end-use product containing 7.5 g powdered Sildate dispersed in 250 ml distilled water.

ACUTE TOXICITY DATA WITH SILDATE

TEST	RESULT	CATEGORY
Oral LD50	LD50 > 5000 mg/kg	IV
Inhalation LC50	N/A	N/A
Dermal LD50	LD50 > 2000 mg/kg	III
Primary Eye irritation	non-irritant	IV
Primary dermal irritation	non-irritant	IV
Dermal Sensitization	Not a sensitizer	N/A

(2) Subchronic Toxicity

The influence of vitamin E and selenium on the toxicity of silver was investigated in a series of two studies in young rats (21-day old) of the Holtzman strain. In the first study, silver acetate was added to the drinking water for 52 days at concentrations of 0, 76, or 751 mg/L. Silver was markedly toxic in rats (10/group) when their diet contained no vitamin E and only 0.02 ppm selenium. Growth depression occurred at 76 mg/L and severe growth depression and death (4/10) at 751 mg/L. Hepatic glutathione peroxidase activity was undetectable, but there was no evidence of liver necrosis at necropsy. The toxicity of silver was reduced when 0.5 ppm selenium was added to the above diet. No growth depression was observed at 76 mg/L, and survival was improved at 751 mg/L. Hepatic glutathione activity was, however, still reduced to 5% of controls at 751 mg/L. In the second study, silver acetate (751 mg/L; corresponding to 114.2 mg silver/kg/day) was added to the drinking water for 15 weeks and the diet contained both vitamin E (100 IU/kg) and selenium (0.5 ppm). The toxicity of silver was further alleviated. Body weight was only decreased by 15%, but glutathione peroxidase activity was still decreased in the liver to 5% of control levels. A LOEL for the 15 week study was suggested at 114.2 mg silver/kg/day (Wagner, 1975).

In a study in swine, four weanling swine were fed a diet containing adequate selenium and vitamin E and 0.5% silver acetate (3,250 ppm silver, corresponding to 130 mg/kg/day) for 4 weeks. All experienced anorexia, diarrhea, and growth depression. Three of the four pigs died. Hepatic lesions in all four pigs were consistent with hepatosis dietetica. No lesions were observed when pigs (number unreported) were fed 0.2% silver acetate (1,300 ppm silver, corresponding to 52 mg/kg/day). Vitamin E (100 IU/kg diet) but not selenium (1 ppm) supplementation in the diet (2 pigs/group) prevented development of lesions and mortality. A NOEL was established at 52 mg/kg/day and a LOEL at 130 mg/kg/day based on the signs/symptoms of toxicity observed (Van Vleet, 1976).

In a mice study (strain and number unreported), silver nitrate was added to the drinking water at a concentration equivalent to 65 mg/kg/day for 12 days to 14 weeks. No toxicity was observed but silver deposits were observed in the basement membrane of the kidneys at necropsy. A NOEL was established

at 65 mg/kg/day (Day et al., 1976).

(3) Chronic toxicity

In a rat study, Sprague Dawley rats (number unreported) were given silver nitrate in their drinking water at concentrations of 6 mM (648 mg/L; equivalent to 65 mg/kg/day assuming a 200 g rat drinks 20 ml water/day) for only 12 weeks or 12 mM (1,296 mg/L; 130 mg/kg/day) for 4, 6, 8, 10, 12, 16, 25, or 60 weeks. A NOEL was not established (although no toxicity was observed at 65 mg/kg/day, this dose was administered for only 12 weeks). The LOEL was established at 130 mg/kg/day, based on clinical signs of poor grooming and listlessness and histology findings of silver deposits within the glomerular basement membrane of the kidneys (Walker, 1971).

The following are three related rat studies, conducted by the same investigator:

In the first study, rats were given silver nitrate in their drinking water at a concentration equivalent to 63.5 mg/kg/day for 218 days (Olcott, 1948). No toxic effects were observed, but intense silver pigmentation of many tissues was observed at necropsy, including the basement membrane of the kidneys' tubules, the portal vein and other parts of the liver, the choroid plexus of the brain, the choroid layer of the eyes, and the thyroid gland. A NOEL was established at 63.5 mg/kg/day (silver deposition in tissues was apparently not considered an adverse effect).

In the second study, 139 albino rats were given silver nitrate in their drinking water at a concentration equivalent to 63.5 mg/kg/day for up to 553 days (Olcott, 1947). Examination of their eyes at various time points showed the color changing from normal to slightly gray after 218 days (stage 1), to more gray than pink (stage 2) after 373 days, to dark/translucent (stage 3) after 447 days, and to opaque (stage 4) after 553 days. The total cumulative amount of silver consumed at these respective stages were 3.2 g, 5.7 g, 6.8 g, and 9.4 g. Histological observation of the membrane of Bruch showed a few silver granules after 218 days and complete blackening by silver deposits after 553 days. The study did not state whether silver deposition in the eye was accompanied by any vision impairment. A NOEL was nonetheless identified at 63.5 mg/kg/day.

In the third study, older rats (> 9-months old) were given

silver nitrate in their drinking water at a concentration equivalent to 63.5 mg/kg/day for an unstated duration (Olcott, 1950). The treated rats showed an increase in the relative (to body) weight of the left ventricle (left ventricular hypertrophy rate = 29% in treated rats and 12% in control rats). The total number of rats autopsied was 233. Although blood pressure was not measured, it was postulated that the cardiac effect observed was caused by hypertension, which was brought about by a thickening of the basement membrane of the kidney glomeruli caused by deposits of silver. Neither a NOEL or a LOEL were identified because the duration of exposure was unspecified.

(4) Carcinogenicity

Although local sarcomas were shown to occur in animals after implantation of foils and discs of silver, these findings were considered as questionable carcinogenicity evidence (i.e., they may only reflect a phenomenon known as solid-state carcinogenesis, whereby local fibrosarcomas could be induced even by insoluble solids such as plastics) (Furst 1979, 1981). In a rat carcinogenicity study designed to avoid solid-state carcinogenesis, a suspension of silver powder in trioctanion was given once a month by intramuscular (i.m.) injection to Fischer 344 rats (50/sex/group). The dose given was 5 mg each for 5 treatments and 10 mg each for 5 more treatments, for a total of 75 mg of silver. An inert material was used as the vehicle control, and cadmium was used as a positive control. No fibrosarcomas (0/50) appeared at the injection site in silver-treated animals. Injection site sarcomas were found only in the vehicle-control (1/50) and cadmium-treated (30/50) rats. The latent period in the vehicle-control group was 19 months, and the latent period in the cadmium-treated group was as short as 4 months. The authors concluded that finely divided silver powder injected i.m. did not induce cancer (Furst and Schlauder, 1977).

In another carcinogenicity study in rats, colloidal silver (dose unspecified) injected subcutaneously resulted in tumors in 8 of 26 rats surviving more than 14 months. In 6/8 rats, the tumor was at the subcutaneous injection site. In 700 untreated rats, the rate of spontaneous tumor formation was 1 to 3%; no vehicle control was reported (Schmaehl and Steinhoff, 1960).

The Agency has classified silver as a Group D carcinogen - not classifiable as to human carcinogenicity, based on inadequate carcinogenic evidence in animal studies and the lack of carcinogenic evidence in humans (IRIS, 9/1/92).

(5) Developmental Toxicity

In a post-natal study in rats, Wistar rat pups from two litters were given subcutaneous injections of silver lactate monohydrate: two pups from each litter received daily injections of 0.10, 0.20, or 0.35 mg during post-natal weeks 1, 2, or 3 to 4, respectively. The only effect reported was that hippocampal tissues from the treated pups contained significantly ($p < 0.05$) smaller pyramidal cells. The authors speculated that the findings suggest toxicity and that the hippocampus is a selective site for silver neurotoxicity (Rungby et al. , 1987).

(6) Mutagenicity

Silver was not mutagenic in several bacterial systems. Concentrations of silver nitrate from 5×10^{-6} to 1×10^{-5}% were not mutagenic in E. coli in the absence of metabolic activation (Demerec et al., 1951). The end-point was a reversion to streptomycin independence. Silver nitrate, at 0.1 μM, was not directly mutagenic in E. coli WP2 and did not influence the mutagenic effect of ultraviolt irradiation on E. coli WP2 (Rossman and Molina, 1986). Silver chloride, at 0.05 M, was not mutagenic to B. subtilis in the absence of metabolic activation (Nishioka, 1975).

(7) Metabolism

Very little absorption occurred in rats administered carrier-free radioactive silver (<1 μg; 1 μCi) by stomach tube. Approximately 99% and 0.18% of the original dose were eliminated in the feces and urine, respectively, within 4 days after dosing. Total tissue distribution amounted to 0.835% of the administered dose (Scott and Hamilton, 1950).

Radiolabeled silver nitrate was administered by oral and i.v. routes to female RF mice (0.25 μCi, oral; 0.25 to 0.26 μCi, i.v.), male Sprague-Dawley rats (0.5 μCi via either route), beagle dogs (0.6 μCi oral, 0.4 μCi, i.v.), and Macacca mulatta monkeys (0.6 μCi via either route). In all species, cumulative excretion ranged between 90 and 99% within 2 days of oral ingestion. The extent of absorption was found to be directly proportional to the transit time through the gut in these species (Furchner et al., 1966 and 1968). About 90 to 99% of the silver administered orally as (silver nitrate) to male Sprague-Dawley rats, female beagle dogs, and Macacca mulatta monkeys was eliminated in the feces; small amounts were eliminated in the urine (Furchner et al., 1968). A

similar elimination pattern was detected in rats after i.v. administration of silver (Gregus and Klaassen, 1986; Scott and Hamilton, 1950). Most of the radioactivity found in the feces was eliminated via the bile (Tichy et al., 1986; Gregus and Klaassen, 1986; Klaassen, 1979). A marked variation in biliary excretion was observed in different species administered silver as silver nitrate in a single i.v. injection at 0.1 mg/kg of silver over a 2-hour period (Klaassen, 1979). Thirty minutes after treatment, male Sprague-Dawley rats excreted silver into the bile at a rate of 0.25 μg/min/kg, New Zealand White male rabbits excreted 0.05 μg/min/kg, and mongrel male dogs excreted 0.005 μg/min/kg. The concentration of silver in the plasma was markedly lower in the dog than in the rat or rabbit, indicating a larger volume of distribution in the dog. This variation appears to be attributable to differences in the transfer of silver from liver to bile. The species with the lowest biliary excretion rate (dog) had the highest liver concentration of silver (rat = 1.24, rabbit = 2.13 and dog = 2.9 μg silver/g liver). In all species, the concentration of silver in the bile was greater than that in plasma with no observable dose gradient, thereby indicating an active transport process and a saturable mechanism.

(8) Secondary Maximum Contaminant Level (SMCL)

The Agency initially regulated silver with a Maximum Contaminant Level (MCL) of 50 μg/L drinking water. In 1991, the Agency replaced the MCL with a Secondary Maximum Contaminant Level (SMCL) of 100 μg/L, based on the fact that silver causes argyria, only a cosmetic effect (FR Notice dated 01/30/91). SMCL are non-enforceable and establish limits for contaminants which may affect the aesthetic qualities (e.g. taste and color) of drinking water (IRIS, 09/01/92). It is recommended that systems monitor for these contaminants every three years (IRIS, 09/01/92).

(9) Reference Dose (RfD)

An oral RfD was established for silver at 0.005 mg/kg/day (IRIS, 09/01/92). The RfD was based on the Gaul and Staud 2-9 year human i.v. 1935 study, with an oral LOEL of 0.014 mg/kg/day, and an uncertainty factor of 3 to account for minimal effects in a subpopulation which exhibited an increased propensity for development of argyria. A conversion factor was used to convert i.v. to oral doses (each i.v. dose of 1 g is divided by 0.04, an assumed oral retention factor). No uncertainty factor for less-than-chronic to chronic duration was needed since the dose has

been apportioned over a lifetime of 70 years. The RfD has been verified (07/18/91) by the Agency (IRIS, 09/01/92).

2. Exposure Assessment

a. Dietary Exposure

Currently, silver is neither registered for application to food or feed crops nor is it registered for use on processed commodities. The only current dietary exposure is from the use of silver as a bacteriocide for use in human drinking water systems. The swimming pool uses of silver would not be expected to be associated with any significant dietary exposure; the SMCL of 0.1 mg/L drinking water established by the Agency's Office of Water is not expected to be exceeded following typical use of filters containing silver.

b. Occupational and Residential

Occupational exposure can be expected based on the currently registered uses of this chemical. Silver, formulated as a granular, impregnated material or soluble liquid concentrate, is used as an algicide or as part of a bacteriostatic water filter in swimming pool wataer systems and human drinking watear systems. The potential for mixer/loader/applicator exposure exists for individuals handling silver solutions or silver-impregnated filter materials. Based on the application methods (specified and implied) and the formulation types, the potential for eye, inhalation, and dermal exposure to concentrated solutions or dusts for mixers, loaders and applicators exists.

Filtering media are impregnated with concentrations ranging from 0.026% a.i. to 1.05% a.i. Soluble liquid concentrates are used for treatment in swimming pools. Typical application rates are 8 fluid ounces per 10 minute interval with a maximum of 48 fluid ounces being utilized for winterizing pools. These treatments are applied through the pool skimmer basket. With ready-to-use solutions, the potential for exposusre exists for inadvertent splashes to the eye; however, silver is not readily transported across the skin. Handling of silver-impregnated filters may frsult in short-term exposure to minute quantities of silver-containing charcoal. In general, filters containing 1.05% a.i. or less are replaced one or two times per year depending upon the use rate and rated filter capacity.

Silver concentrations in water depend upon pH and chloride concentration. Maximum silver concentrations in water are expected to be less than 10 mg/L (10 ppm). Water treatments would result in less than 0.6 ppm (0.6 mg/L) silver present in pool water (0.8% a.i. used).

Presence of silver in potable water is not uncommon; median concentrations of silver present in public water supplies of 100 U.S. cities was reported to average 2.68 μg/L (2.68 ppb). The Agency's Office of Water estimates that a concentration of silver in water of 100 μg/L or 0.1 mg/L will not produce darkening of the skin and other cosmetic effects associated with argyria.

The overall exposure from silver from human drinking water systems and swimming pool systems is not expected to result in adverse effects.

3. Risk Assessment

a. Dietary

Silver is a naturally occurring element and trace amounts are expected to be present in the human diet. It is not anticipated that low levels of exposure to silver such as those normally consumed from water filtered with filtering systems containing silver would be associated with any significant degree of risk or result in the build-up of silver in the body to an argyria compatible level.

The data available on the toxicological effects of silver in humans and laboratory animals are sufficient for assessing human risks. The acute toxicity of silver is relatively low by the oral route (Toxicity Category III). The end-product Sildate has low acute oral and dermal toxicity (Toxicity Categories IV and III), is not inhalable, not a eye or dermal irritant (Toxicity Category IV), and not a dermal sensitizer. Silver is not known to have human carcinogenic potential and does not appear to be a mutagen. Although long term ingestion of silver may be associated with argyria in humans and animals, this effect is considered cosmetic, not adverse.

b. Occupational and Residential

The overall human and animal toxicology data on silver indicate that this pesticide does not meet any Agency toxicity criteria that would trigger the requirements for occupational or residential exposure data. Based upon the available use data, the use of the chemical as a water treatment for pools is of little concern from a toxicity perspective. For the above reasons, it is not expected that use consistent with the product label of silver-impregnated filters or the treatment of pool water with silver-containing compound would constitute an unreasonable risk.

C. Environmental Assessment

1. Environmental Fate

Because of the available data base on silver chemistry, most standard environmental fate data requirements were waived. The environmental chemistry section presented here is based on numerous literature sources that are cited below.

a. Environmental Chemistry - Fate and Transport

Although silver occurs as native metal, it also occurs as distinct mineral phases (mostly as sulfide minerals in complex ores) from where it is mined, processed (primarily by froth flotation) and then refined (Reese, 1985). The relative abundance of silver in the earth's crust is about 0.08 ppm (Greenwood and Earnshaw, 1984).

Silver is the metal with the highest thermal and electrical conductivity (Cotton and Wilkinson, 1988; Greenwood and Earnshaw, 1984). Although silver is, in general, not prone to ordinary oxidation and is resistant to corrosion by weak acids, the presence of sulfur-containing gases in the atmosphere and of sulfide ions in waters can tarnish the surface of silver (Murr, 1975; Pourbaix, 1974; Shumilova and Zhutaeva, 1978; Zhutaeva and Shumilova, 1985). Strong, concentrated oxidizing acid solutions can dissolve silver, producing silver(I) species in solution; in alkaline solutions, silver is generally stable (Pourbaix, 1974). Silver(I) forms soluble complexes with halide anions and with cyanide (Cotton and Wilkinson, 1988; Greenwood and Earnshaw, 1984; Irgolic and Martell, 1985). Chloride and bromide ions can react with surface silver oxides to form complexes that are more soluble than the oxides (Buffle, 1990; Pourbaix, 1974).

The oxidation states of I, II and III have been identified in silver compounds, but in aqueous media the only oxidation state is silver(I) (Cotton and Wilkinson, 1988; Shumilova and Zhutaeva, 1978). The extent of oxidation (corrosion) of silver metal in aqueous environments is thus determined by the pH, the redox potential and the temperature of the media (Morel, 1983; Murr, 1975; Pourbaix, 1974; Stumm, 1992). The type and concentration of soluble silver(I) that can form in aqueous media are determined by the nature and concentration of complexing anions present in the media; formation of insoluble phases (such as silver sulfides) are also determined by the chemical characteristics of the aqueous media (Buffle, 1990; Irgolic and Martell, 1985; Morel, 1983; Stumm, 1992).

Silver(I) can readily react with sulfide ions and organic materials

bearing thiol groups. Silver sulfides are insoluble and in sulfide-rich natural waters the formation of insoluble sulfides serves to immobilize silver (Morel, 1983). Thiol groups in aquatic sediments also contribute to the removal of silver(I) from the aqueous phase (Morel, 1983). However, in recent years it has been speculated that the transport and re-deposition of silver in the environment may involve formation of polysulfido silver species (Morel, 1983; Muller and Krebs, 1984).

The germicidal properties of silver metal and silver compounds (such as oxides and salts) have long been recognized. The lethal effect of silver towards bacteria and lower life forms, the so-called "oligodynamic effect" is high and second to that of copper. The term "oligodynamic activity" is restricted to solutions in which the metal ion concentration is many orders of magnitude below what would be lethal to higher order organisms (Thompson, 1973). Silver-resistant bacteria have been found in urban and industrial polluted sites (Irgolic and Martell, 1985; Silver, 1983; Silver, et al., 1982). It is believed that the resistance to silver is determined by genes in plasmids. The lowered affinity of the cells for silver(I) is related to the tendency of silver(I) to be more effectively complexed with extracellular halides, thiols, or organic compounds (Silver, 1983; Silver et al., 1982).

b. Environmental Fate Assessment

Silver from products used for swimming pool and human drinking water systems is discharged into the municipal wastewater effluent and treated in municipal water treatment plants. In these sewage treatment plants, microorganisms convert silver(I) salts to insoluble silver sulfides and some metallic silver which are removed in the settling step.

Products containing silver are not to be applied in marine/estuarine environments or oil fields. Discharge of silver-containing effluents into lakes, streams, ponds estuaries, oceans or other waters are subject to National Pollutant Discharge Elimination System (NPDES) permit restrictions. In addition, waters treated with silver as a pesticide cannot be discharged into sewage systems without notifying the sewage plant authority. (See Sections IV.B.2., V.B.2. on Labeling.)

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

There are no avian toxicity data available. In the reregistration DCI of September 1992, avian studies on one species

of upland gamebird and/or waterfowl were required using the formulated product (due to variations in complexes formed by pure silver as the technical grade active ingredient). The risk to birds will be assessed after the data are submitted and reviewed. However, exposure to birds is expected to be low from the pesticidal uses of silver. These studies were required for labeling statements only.

(2) Aquatic Data - Freshwater Fish, Freshwater Invertebrates & Estuarine Organisms

The acute LC_{50} for freshwater fish ranges from 3.9 to 280 μg/L (ppb). The average toxicity values were 51.4 μg/L for Rainbow trout (Oncorhynchus mykiss), 36.25 μg/L for Fathead minnow (Pimphales promelas) and 44.0 μg/L overall.

The acute EC_{50} range for freshwater invertebrates ranges from 0.25 to 4500 μg/L (ppb). The average toxicity value for Daphnia magna was 9.21 μg/L.

The acute toxicity values for marine/estuarine fish ranged from 4.7 for Summer flounder (Paralicthys dentatus) to 1400 μg/L for the Sheepshead minnow (Cyprinodon variegatus) with an average of 494.12 μg/L.

The values for marine/estuarine invertebrates ranged from 5.8 for the Eastern oyster (Crassostrea virginica) to 250 μg/L for the Mysid shrimp (Mysidopsis bahia) with an average of 54.6 μg/L.

These results presented above are sufficient to indicate that silver is very highly toxic to highly toxic to fish and invertebrates. No further studies with freshwater fish, freshwater invertebrates, or estuarine organisms are required for the currently proposed uses of silver. Neither chronic nor degradate testing is required for the currently proposed uses of silver.

b. Ecological Effects Risk Assessment

Based on the available acute toxicity data, silver is highly toxic to fish and aquatic invertebrates. However, silver from products used for swimming pool and human drinking water systems is discharged into the municipal wastewater effluent and treated in municipal water treatment plants and is, therefore, regulated under NPDES permits. Little exposure to fish and aquatic invertebrates is expected from these uses. The Agency does not expect unreasonable adverse effects from these uses.

A risk assessment for birds will be conducted after the required avian studies are submitted and reviewed. The Agency will use the data to provide avian labeling statements.

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 ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing silver. 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 silver. Appendix B identifies the generic data requirements that the Agency considered in its determination of reregistration eligibility of silver, and lists the submitted studies that the Agency found acceptable for these requirements.

The data identified in Appendix B are sufficient to allow the Agency to assess the registered uses of silver and to determine that silver can be used as currently registered without resulting in unreasonable adverse effects to man and the environment. The Agency therefore finds that all products containing silver registered as of June 23, 1993 as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency makes its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency finds that all uses of silver registered as of June 23, 1993 are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the further submission of additional data to support the registration of products containing silver, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on a sufficiently complete database for silver and a determination that unreasonable adverse effects are unlikely from the uses of the current products, the Agency concludes that products containing silver for all uses registered as of June 23, 1993 are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of products registered as of June 23, 1993 of silver are eligible for reregistration, subject to the label and use specifications of this document.

B. Regulatory Position

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

1. Tolerance Reassessment

There are no proposed or established U.S. EPA, CODEX (international), Canadian or Mexican tolerances for silver nor exemptions from the requirements of a tolerance. Therefore, there are no harmonization issues to be resolved.

The Agency announced the deletion of the 50 μg/L MCL (maximum contaminant level) for silver on January 30, 1991 (56 Fed. Reg. 3573). Instead, a SMCL (secondary maximum contaminant level) of 100 ppb (0.1 mg/l) was established by the Agency (OW) in the same Federal Register notice, based on the skin cosmetic effect called argyria.

2. Labeling Rationale

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of all registered pesticide products containing silver must comply with the Agency's current pesticide labeling requirements. The Agency has determined that the current end-use label precautions are still appropriate and are required for product reregistration. Because the swimming pool water systeam pesticide uses of silver are regulated by an NPDES permit, it is the Agency's position that label precautions must continue to include the NPDES permit required language.

Based on the submitted data, it is the Agency's position that a label statement indicating that silver is "toxic to fish and aquatic invertebrates" must be included on all registered products containing silver in order to remain in compliance with FIFRA.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of silver for the above eligible uses has been reviewed and determined to be substantially complete. No additional data are required on these products at this time.

2. Labeling Specifications for Manufacturing-Use Products

In order to remain in compliance with FIFRA, it is the Agency's position that the following statement must be included on all products whose use requires an NPDES permit:

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permittting 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 statement must appear in the Environmental Hazards section of the label and be in addition to any other required statements.

Registrants should make the changes specified above and submit revised labels to the Agency via notification in accordance with PR Notice 88-6 or refer to 40 CFR § 152.46(a)(1). In order to be in compliance with FIFRA, all products distributed or sold by registrants and distributors (supplemental registrants) after July 1, 1995 must bear labeling which is consistent with this notice. All products distributed or sold by persons other than registrants or supplemental registrants after July 1, 1997 must bear labeling which is consistent with these notices. After these dates, the Agency may either issue a Notice of Intent to Cancel a product or bring enforcement action against products bearing false or misleading claims covered by this notice.

In order to remain in compliance with FIFRA, the following label statement must appear in the Environmental Hazards section of the label on all manufacturing-use products.

> "This pesticide is toxic to fish and aquatic invertebrates."

In order to remain in compliance with FIFRA, the following label statement must appear on the label on all manufacturing-use products intended for use for human drinking water systems:

> "Use with cold water only."

In order to remain in compliance with FIFRA, the labels and labeling of

all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. All label amendments must be submitted to the Agency within 8 months from issuance of the product specific data call-in. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

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 G, the Product Specific Data Call-In Notice.

The registrants must clarify the nature of the "soluble liquid/concentrate" used in swimming pools, due to concerns over the potential formation of water soluble or colloidal species that may be ingested by swimmers. A new Confidential Statement of Formula (CSF) must be submitted detailing the nature of the "soluble liquid/concentrate".

Ecological effects studies on one species of upland gamebird and/or water fowl as required in the September 1992 DCI are due to the Agency shortly. Both tests are being conducted using the formulated product (due to variations in complexes formed by pure silver as the technical grade active ingredient). The risk to birds will be assessed after the data are submitted and reviewed. However, exposure to birds from the pesticide uses of silver is expected to be low. These data were required for labeling statements only.

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

2. Labeling Specifications for End-Use Products

In order to remain in compliance with FIFRA, it is the Agency's position that the following statement must be included on all products whose use requires an NPDES permit:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permittting 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 statement must appear in the Environmental Hazards section of the label and be in addition to any other required statements.

Registrants should make the changes specified above and submit revised labels to the Agency via notification in accordance with PR Notice 88-6 or refer to 40 CFR § 152.46(a)(1). In order to be in compliance with FIFRA, all products distributed or sold by registrants and distributors (supplemental registrants) after July 1, 1995 must bear labeling which is consistent with this notice. All products distributed or sold by persons other than registrants or supplemental registrants after July 1, 1997 must bear labeling which is consistent with these notices. After these dates, the Agency may either issue a Notice of Intent to Cancel a product or bring enforcement action against products bearing false or misleading claims covered by this notice.

In order to remain in compliance with FIFRA, the following label statement must appear in the Environmental Hazards section of the label on all end-use products intended for use in swimming pool water systems:

"This pesticide is toxic to fish and aquatic invertebrates."

In order to remain in compliance with FIFRA, the following label statement must appear in the directions for use section of the label on all end-use products intended for use for human drinking water systems:

"Use with cold water only."

1. "This product inhibits the growth of bacteria in the filter to prolong the life of the filter."

2. "This product is designed to remove objectional tastes, odors, and color from municipally treated tap water."

In order to remain in compliance with FIFRA, the labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. All label amendments must be submitted to the Agency within 8 months from issuance of the product specific data call-in. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

VI. APPENDICES

APPENDIX A - Case 4082, [Silver, and Compounds] Chemical 072501 [Silver]

	Application Type	Application Timing	Application Equipment	Surface Type	Form	Minimum Application Rate (ppm a.i.)	Maximum Application Rate (ppm a.i.)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations
example	**USES ELIGIBLE FOR REREGISTRATION**													
	FOOD/FEED USES													
	Site: Human Drinking Water Systems (Use Group: INDOOR FOOD)													
64625-1 3625-4	bacteriostatic filter treatment, when needed, bacteriostatic filter unit, NA				Impr	160 W	17,100 W	NS	NS	NA	NA	NA	NA	NA
64625-2 3625-5	bacteriostatic filter treatment, when needed, bacteriostatic filter cartridge, NA				Impr	160 W	17,100 W	NS	NS	NA	NA	NA	NA	NA
64646-2 65172-1	bacteriostatic filter treatment, when needed, bacteriostatic filter media, NA				Impr	260 W	2,000 W	NS	NS	NA	NA	NA	NA	NA
64606-2	water purifier treatment, when needed, water purifier filter, NA				Impr	260 W	260 W	NS	NS	NA	NA	NA	NA	NA
	NON-FOOD/NON-FEED USES													
	Site: Swimming Pool Water Systems (Use Group: AQUATIC NON-FOOD RESIDENTIAL)													
4855-2 10324-18	water treatment, initial, skimmer basket, NA				SC/L	0.1 W	0.1 W	NS	NS	NA	NA	NA	NA	Preclean claim. Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
4855-2 10324-18	water treatment, subsequent/maintenance, skimmer basket, NA				SC/L	0.1 W	0.1 W	NS	NS	NA	NA	NA	NA	Preclean claim. Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

	APPENDIX A - Case 4082, [Silver, and Compounds] Chemical 072501 [Silver]													
	Application Type	Application Timing	Application Equipment	Surface Type	Form	Minimum Application Rate (ppm a.i.)	Maximum Application Rate (ppm a.i.)	Max. # Appe.	Max. # Appe. @ Max. Rate	Min. Interval Between Appe. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations		Use Limitations
												Allowed	Disallowed	
example	USES ELIGIBLE FOR REREGISTRATION													
4865-2 10324-18	water treatment, winterizing, skimmer basket, NA				SC/L	0.1 W	0.1 W	NS	NS	NA	NA	NA	NA	Preclean claim. Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

Abbreviations used

Header: ppm a.i. = parts per million of active ingredient; Max. # Appe. = maximum number of applications
Max. # Appe. @ Max. Rate = maximum number of applications at maximum rate
Min. Interval Between Appe. @ Max. Rate (Days) = minimum interval between applications at maximum rate (in days)

Form: SC/L = Soluble Concentrate/Liquid; Impr = Impregnated Material

Rate: W = calculated by weight

In general: NOL = not on the label; NA = not applicable; NS = not specified

APPENDIX B

Table of The Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the silver covered by this Reregistration Eligibility document. It contains generic data requirements that apply to silver 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.

SILVER

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	WAIVED
61-2(a)	Beginning Materials and Manufacturing Process	All	WAIVED
61-2(b)	Formulation of Impurities	All	WAIVED
62-1	Preliminary Analysis	All	WAIVED
62-2	Certification of Limits	All	WAIVED
62-3	Analytical Methods	All	WAIVED
63-2	Color	All	WAIVED
63-3	Physical State	All	WAIVED
63-4	Odor	All	WAIVED
63-5	Melting Point	All	WAIVED
63-6	Boiling Point	All	WAIVED
63-7	Density	All	WAIVED
63-8	Solubility	All	WAIVED
63-10	Dissociation Constant	All	WAIVED
63-12	pH	All	WAIVED
63-13	Storage Stability	All	WAIVED

SILVER

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.130 Environmental Fate			
All environmental fate data requirements have been waived.			
§158.135 Toxicology			
81-1	Acute Oral Toxicity - Rat	All	WAIVED
81-2	Acute Dermal Toxicity - Rabbit	All	WAIVED
81-3	Acute Inhalation Toxicity - Rat	All	WAIVED
81-4	Primary Eye Irritation - Rabbit	All	WAIVED
81-5	Primary Dermal Irritation	All	WAIVED
81-6	Dermal Sensitization - Guinea Pig	All	WAIVED
§158.145 Ecological Effects			
71-1(a)	Acute Avian Oral Toxicity - Quail/Duck	All	REQUIRED
71-2(a)	Avian Dietary Toxicity - Quail/Duck	All	REQUIRED
71-2(b)	Acute Avian Dietary - Duck	All	WAIVED
72-1(a)	Freshwater Fish Toxicity - Bluegill	All	WAIVED
72-1(c)	Fish Toxicity - Rainbow Trout	All	42650501
72-2(a)	Freshwater Invertebrate Toxicity	All	42650501

APPENDIX C
SILVER BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting the Reregistration of Silver

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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APPENDIX E

Pesticide Reregistration Handbook, PR Notice 91-2 and PR Notice 86-5

PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

PESTICIDE REGISTRATION HANDBOOK

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

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****

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

+Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

+Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
12	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter _____

Sponsor _____

Study Director _____

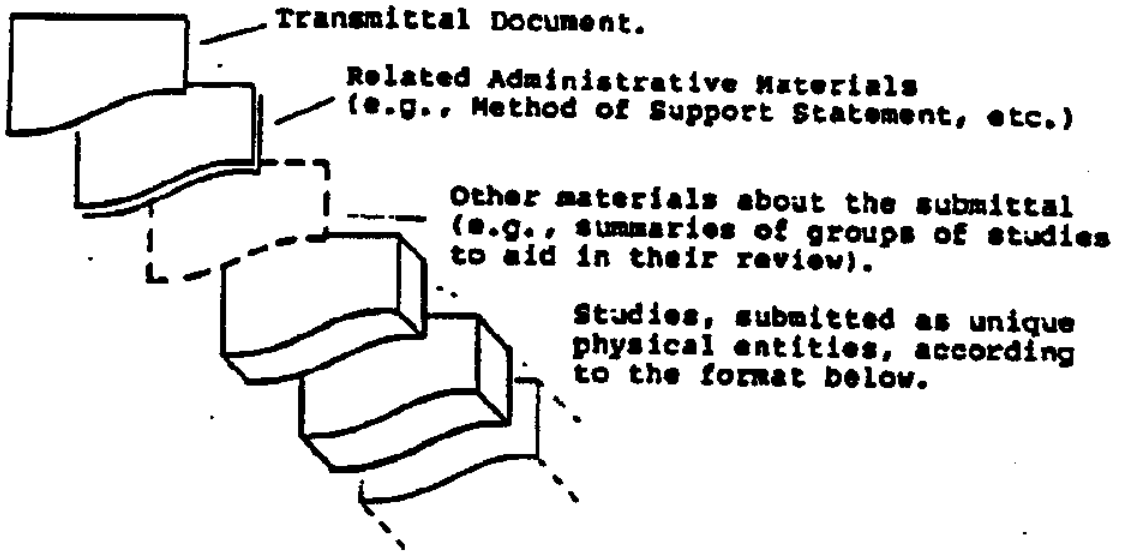
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

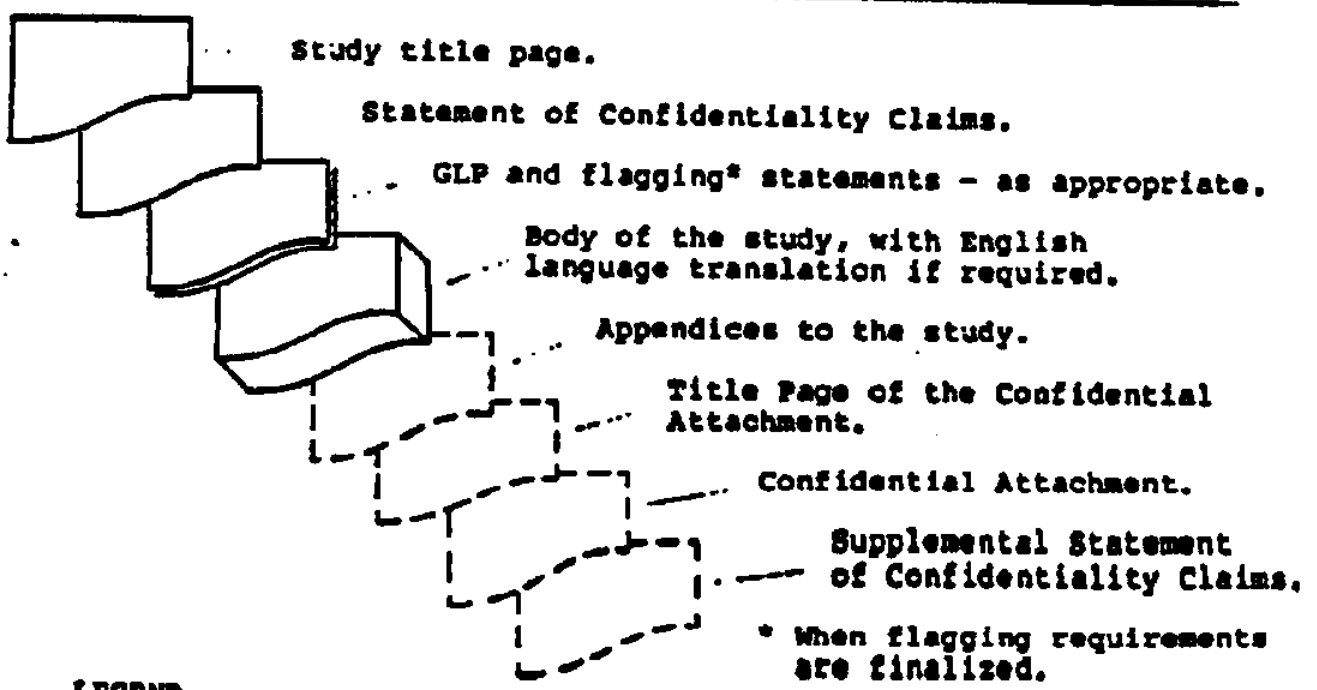
Submitter _____

ATTACHMENT 7.

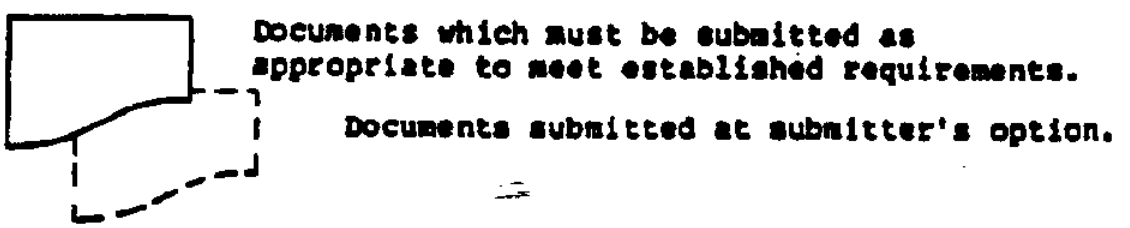
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



APPENDIX F

Generic Data Call-In

For Case 4082, Silver, no Generic Data Call-In will be issued.

APPENDIX G

Product Specific Data Call-In

ATTACHMENT A

CHEMICAL STATUS SHEET

SILVER: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 silver. 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 B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this Silver Product Specific Data Call-In (Attachment G). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of silver, please contact Kathleen Depukat at (703) 308-8587.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Joanne I. Miller at (703) 305-7830.

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

Joanne I. Miller, Product Manager Team 23
Herbicide/Fungicide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: SILVER

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS

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</u> <u>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.

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.

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.

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.

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.

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. If I cite another registrant's data, I will submit a completed **"Certification with Respect To Data Compensation Requirements" form.**

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.

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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING DATA REQUREMENTS FOR REREGISTRATION

EPA'S DECISION TO BATCH END-USE PRODUCTS CONTAINING SILVER 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 silver, the Agency has batched products which can be considered similar 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.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above. Frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively gener- ate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so 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 registrants are must clearly identify the material tested by its EPA registration number.

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 who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study

(Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

End-Use Products Containing Silver

The following table (Table I) lists 5 batches containing 62 products containing silver.

Table I.

Batch No.	EPA Registration Number	% Silver	Formulation Type
1	35900-3	0.07	Impregnated Materials
	35900-6	0.50	Impregnated Materials
	35900-7	0.20	Impregnated Materials
	35900-13	0.47	Impregnated Materials
	35900-16	0.026	Impregnated Materials
	35900-18	0.35	Impregnated Materials
	35920-11	0.20	Impregnated Materials
	35966-2	0.20	Impregnated Materials
	36430-1	1.05	Impregnated Materials
	37589-2	0.20	Impregnated Materials
	37589-4	1.05	Impregnated Materials
	37589-5	0.75	Impregnated Materials
	39104-1	1.05	Impregnated Materials
	39446-3	1.05	Impregnated Materials
	39446-4	1.05	Impregnated Materials
	39446-5	1.05	Impregnated Materials
	39446-6	1.05	Impregnated Materials
	39446-7	1.05	Impregnated Materials
	40184-1	1.05	Impregnated Materials
	40184-8	1.05	Impregnated Materials
	44751-1	0.105	Impregnated Materials
	44751-2	0.087	Impregnated Materials
	44751-3	0.10	Impregnated Materials
	44751-4	0.08	Impregnated Materials
	44751-5	0.624	Impregnated Materials

Batch No.	EPA Registration Number	% Silver	Formulation Type
1 (con't.)	44751-7	0.624	Impregnated Materials
	44751-9	0.624	Impregnated Materials
	44751-10	0.624	Impregnated Materials
	44751-11	0.624	Impregnated Materials
	44919-2	0.026	Impregnated Materials
	44919-5	0.026	Impregnated Materials
	44919-6	0.026	Impregnated Materials
	46379-5	1.05	Impregnated Materials
	51160-1	1.05	Impregnated Materials
	51160-2	1.05	Impregnated Materials
	51160-3	1.05	Impregnated Materials
	54159-1	1.05	Impregnated Materials
	54646-2	0.026	Impregnated Materials
	55228-1	1.05	Impregnated Materials
	57700-1	0.10	Impregnated Materials
	58295-1	0.026	Impregnated Materials
	58295-2	1.05	Impregnated Materials
	58295-3	0.50	Impregnated Materials
	59243-2	0.20	Impregnated Materials
	61388-1	0.20	Impregnated Materials
	61944-1	0.026	Impregnated Materials
	62275-1	0.07	Impregnated Materials
	63949-1	1.05	Impregnated Materials
	63949-2	0.50	Impregnated Materials
	64906-1	0.026	Impregnated Materials
	64906-2	0.026	Impregnated Materials
	64938-1	0.20	Impregnated Materials
	65172-1	0.20	Impregnated Materials

Batch No.	EPA Registration Number	% Silver	Formulation Type
2	54625-1	0.016	Impregnated Materials
	54625-2	0.016	Impregnated Materials
3	2623-4	1.71	Impregnated Materials
	2623-5	0.171	Impregnated Materials
4	4855-2	0.8	Ready To Use Solutions
	10324-18	0.8	Ready To Use Solutions
5	35900-2	1.05	Impregnated Materials
	35900-9	0.07	Impregnated Materials
	35900-12	0.07	Impregnated Materials

One product (Table II) was considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and not placed in any batch. The registrant is responsible for meeting the acute toxicity data requirements for the product.

Table II.

EPA Registration Number	% Silver	Formulation Type
37589-6	0.80	Impregnated Materials

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered; for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____ Description of manufacturing process:
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor

____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA (cont.)

63-10 Dissociation Constant

____ Experimental method described

____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C

____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)

____ Data supporting reported value provided

63-12 pH

____ Measured at about 20-25° C

____ Measured following dilution or dispersion in distilled water

63-13 Stability

____ Sensitivity to metal ions and metal determined

____ Stability at normal and elevated temperatures

____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 μm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm$2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
   _____ Freund's complete adjuvant test
   _____ Guinea pig maximization test
   _____ Split adjuvant technique
   _____ Buehler test
   _____ Open epicutaneous test
   _____ Mauer optimization test
   _____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

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
Approval Expires 12-31-92

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
Chemical Name	EPA Chemical Number

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)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
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:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	