United States Environmental Protection Agency

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

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EPA R.E.D. FACTS

BROMINE

Pesticide Reregstration

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 Decision Document, or RED. This fact sheet summarizes the information in the RED for bromine.

Use Profile

Bromine is registered for use in water filters to purify drinking water aboard U.S. Naval ships and offshore oil well platforms. It also is used as a general disinfectant and sanitizer in indoor, non-food contact areas such as commercial establishments, hospitals and households, to control bacteria and fungi. Bromine pesticide products may be formulated as a solid soluble concentrate or ready-to-use liquid. They are applied using a water filter unit, drip dispenser, automated metering system, fogger, or hand held or power sprayer.

REGULATORY HISTORY

Bromine was first registered in May of 1976 for use in treating potable water through a polybrominated ion exchange resin aboard Naval surface ships. A food additive tolerance for 1.0 ppm residual bromine in potable water aboard Naval surface ships was established in April 1976 by the Environmental Protection Agency. Bromide ion levels in potable water were exempted from the requirement of a tolerance. (40 CFR § 185.425).

HUMAN HEALTH ASSESSMENT

Toxicity

In water and living organisms, bromine reacts with other compounds to form bromides. A great deal of information is available in the literature on bromides, which have long been used as human drugs (primarily as oral sedatives, diuretics and anti-epileptic treatments). Their human health effects are well known. Bromides depress the central nervous system when taken daily at a level of 1 to 2 grams per day. The effect is slowly reversed when dosing is stopped. Bromide has a half-life of about 12 days in the human body.

The levels of bromides consumed as drugs are far greater than the amounts that are ingested from the registered water purification uses. A moderate dose to treat epilepsy would be 50 milligrams per kilogram (mg/kg) per day. By comparison, ingestion of water treated with the bromine water filter unit results in consumption of no more than approximately 0.03 mg/kg/day from water containing up to 1 ppm available bromine for a 70 kg adult.

The lowest level of oral exposure known to result in bromide intoxication was 100 mg/dl (milligrams per deciliter), but signs of such effects may not occur even when blood levels are over 200 mg/dl. Most people develop signs of bromide intoxication at blood levels between 200 and 300 mg/dl.

Doses of 1.9 to 2.9 grams per day given to patients over a four month period did not induce signs of bromide intoxication. However, tremendous variation in responses among patients was noted. Acute overdoses in humans have produced vomiting or stupor, while chronic use has caused depression, loss of muscle coordination and psychoses. Two cases of human reproductive effects have been reported.

Based on acute toxicity studies using laboratory animals, sodium bromide has been placed in Toxicity Category III for acute oral and acute dermal effects, and in Toxicity Category IV (indicating the lowest level of acute toxicity) for eye and skin irritation. Sodium bromide is nonsensitizing to skin.

In subchronic feeding studies, at the highest dose level, effects on rats included lack of grooming, motor incoordination, growth retardation

and thyroid inaction. In a chronic toxicity study using dogs, at the highest dose level, signs of bromide intoxication were seen. Pregnant rats fed bromide produced offspring with reduced learning ability.

In addition to bromide, bromate may form as a by-product under some conditions. The Agency believes there is sufficient and clear evidence that chronic oral exposure to bromate causes increased renal tumors in rats.

Based on information from several studies and the incidence of renal tumors in male rats, the Agency has assigned the bromate ion a Group B2 (probable human carcinogen) classification. A low dose linearized extrapolation model was used to quantitatively characterize risk for humans. A Q_1* of 4.9×10^{-1} $(mg/kg/day)^{-1}$ for the potassium bromate was derived from the combined renal adenoma and adenocarcinoma data (Kurokowa et al., 1986a). It is expected that other soluble salts of bromate are equally carcinogenic. Adjusting for the molecular weight, the unit risk for the bromate ion is calculated to be 6.5×10^{-1} $(mg/kg/day)^{-1}$.

Dietary Exposure

People may consume small amounts of bromine residues in treated drinking water aboard Navy ships or on oil well drilling platforms. However, adequate controls are in effect to ensure that residues will not exceed 1.0 ppm, the food additive tolerance level established for bromine in potable water (please see 40 CFR 185.425). EPA has reassessed this tolerance and found that it is set at an appropriate level and provides an adequate margin of safety to protect the public health.

However, there are no data on the amount of bromate, a species of potential concern. In the absence of actual data on the magnitude of bromate ion in potable water generated via bromination, the Agency attempted to determine the likelihood of the presence of bromate ion based on theoretical considerations. Information obtained from registrants, a bromine producer, other EPA offices, the bromine test kit manufacturer, a halogen chemist, and both medical and engineering specialists within the Navy Dept. indicate that when at port, virtually all potable water is obtained from an approved water source, and bromination is not necessary as such water has already been chlorinated. Virtually all (99%) brominated potable water used on board naval vessels has been derived via desalination using distillation. The pH of distilled water is known generally to be close to 6. Also, the "total available bromine" (TAB) concentrations in the potable water are initially ≤ 2 ppm (usually much

less) but that the typical (and required) concentration is about 0.2 ppm in water after exposure to bromine for 30 min. The concentration of bromate ion in water cannot be calculated because the kinetics of bromine disproportionation have not been elucidated as they have for chlorine and iodine. However, the Agency expects that bromate ion would be nondetectable (<0.5 ppb) in water of pH 5-6.

The available information does not allow the Agency to calculate the bromate ion concentration in potable water. A concentration of approximately 0.7 ppb bromate ion in water would correspond to a risk of 1×10^{-6} assuming 1.2 liters of water consumed per day and that ship personnel would be exposed for 6 months a year for 7 years, a typical exposure based on information provided by the Navy. If bromate ion were present at 0.7 ppb in water, this would represent 0.035% of the total bromine if the water had been treated with bromine at 2 ppm. (For comparison, a risk of 1×10^{-6} would correspond to a daily exposure of 0.054 ppb bromate ion in drinking water, over a 70-year lifetime.)

Because there is not enough information to permit the Agency to estimate the dietary exposure to bromate ion via potable water aboard Navy vessels, the Agency has required representative monitoring data for the pH and bromate ion concentration of brominated, desalinated water.

Occupational and Residential Exposure

EPA is not concerned with potential human exposure from the surface sanitizer uses of bromine. The active ingredient in sanitizer products is present as bromide, and exposure to only very small amounts, below the level of toxicological concern, is expected. For large volume applications such as fogging, product labels instruct users to wear protective clothing, gloves and a respirator, to adequately ventilate spaces treated, and to avoid reentry of treated spaces for at least one hour after treatment.

Human Risk Assessment

Human health risks from exposure to bromine residues in potable drinking water are expected to be minimal because water must be tested to ensure that residues are at a sufficiently low level prior to consumption,

and since the principal residue in water purification systems is bromide rather than bromine.

The two surface sanitizer products have a very low bromide content (0.04%). The potential for human exposure to bromide in these products is low and will not pose an unacceptable risk to humans, provided that current end-use product labeling which requires Personal Protective Equipment (gloves, protective clothing and respirator for large volume applications) and reentry restrictions is maintained.

Environmental Fate

Bromine is a naturally occurring element that normally is found as bromide in living organisms and the environment. It is a common component in seawater and volcanic rocks.

The current use patterns of pesticide products containing bromine do not result in environmental exposure. Therefore, the RED includes no discussion of bromine's environmental fate.

Ecological Effects and Risk Assessment

Since bromine is only used indoors, EPA did not prepare an ecological effects risk assessment. Only two studies were required (a fish acute and an aquatic invertebrate acute study). These studies were used to determine the environmental hazard statement for labeling. These data show that bromine is highly toxic to freshwater fish and aquatic invertebrates.

ADDITIONAL DATA REQUIRED

The generic data base for bromine is substantially complete. The Agency is requiring product-specific data, including product chemistry, acute toxicity and efficacy studies, as well as revised Confidential Statements of Formula and revised labeling, for reregistration of pesticide products containing bromine.

Product Labeling Changes Required

The labels of all registered pesticide products containing bromine must comply with EPA's current pesticide labeling requirements. All end-use bromine products must comply with EPA's current pesticide product

labeling requirements. In addition, since bromine is highly toxic to aquatic organisms, end-use labels must contain the following statement:

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

Regulatory Conclusion

The use of currently registered pesticide products containing bromine as labeled and specified in the RED document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These bromine products may be reregistered, if all active ingredients in the product are eligible, once the product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision Document (RED) for bromine 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 bromine 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 bromine 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 bromine, please contact Frank Rubis, Product Reregistration Branch (7508W), OPP, US EPA, Washington, DC 20460, telephone (703)308-8184.

REREGISTRATION ELIGIBILITY DECISION

BROMINE

LIST D

CASE 4015

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

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe as designated by FDA
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin Of Exposure (PAD)
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
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
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.

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency, hereafter referred to as the "Agency", has completed its reregistration assessment of the available data and scientific literature on the pesticide active ingredient bromine.

This Reregistration Eligibility Decision document (RED) addresses the eligibility for reregistration of products containing bromine for currently registered uses. Pesticide products containing bromine are currently used in water purification filters and as general disinfectant in non-food contact areas. The Agency has determined that the uses of bromine as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration.

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Bromine
- **Chemical Name:** Bromine
- **Chemical Family:** Halogen
- **CAS Registry Number:** 7726-95-6
- **OPP Chemical Code:** 8701
- **Empirical Formula:** Br_2

B. Use Profile

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

Type of Pesticide: Water purification filter and as a fungicide, mildewcide/mildewstat, general disinfectant, sanitizer for non-food contact areas.

Use Sites:

INDOOR FOOD SITES:
Livestock Vehicles
Poultry Houses
Agricultural/Farm Premises
Human Drinking Water Systems
Household/Domestic Dwellings Food Handling Areas

INDOOR NON-FOOD SITES:
Commercial/Institutional/Industrial Premises/Equipment (Indoor)
Commercial/Institutional/Industrial Floors
Upholstery (Hospital/Commercial)
Carpets (Commercial Sanitizer)

INDOOR MEDICAL SITES:
Hospitals/Medical Institutions Premises (Human/Veterinary)
Hospitals Noncritical Items (Bedpans/Furniture)
Hospitals/Medical Institutions Non-conductive Floors
Carpets (Hospital Sanitizer)
Upholstery (Hospital/Commercial)

INDOOR RESIDENTIAL SITES:
Pet Living/Sleeping Quarters
Household/Domestic Dwellings Indoor Premises
Household/Domestic Dwellings Contents
Residential Floors
Laundry (Household/Coin-Operated)
Carpets (Household Sanitizer)
Bathroom Premises/Hard Surfaces
Refuse/Solid Waste Sites (Indoor)
Refuse/Solid Waste Containers (Garbage Cans)
Human Bedding/Mattresses

Target Pests: Common human and environmental bacteria and fungi, odor-causing bacteria. Two of the products are also formulated with an insecticide and synergist for the control of certain insects and arachnids.

Formulation Types Registered: TYPE: End use

FORM: Solid soluble concentrate, Ready to use liquid

METHODS AND RATES OF APPLICATION:

TYPES OF TREATMENT:
Feeding and watering appliance treatment, Premise

treatment, Transportation vehicle treatment, Fog, Spray, Bacteriostatic filter treatment, Contact and/or surface treatment, Space spray, Spot treatment

EQUIPMENT:
Hand held sprayer, Power sprayer, Fogger, Automated metering systems, Gravity drip dispensers, Bacteriostatic filter unit

TIMING:
As needed

RATE OF APPLICATION:
Human drinking water systems (water purification filter treatment):
From 0.2 to 1.0 ppm available bromine by weight

Other antimicrobial sites: 400 ppm available bromine by weight

USE PRACTICES LIMITATIONS:
Heavily treated areas should be adequately ventilated and not re-entered for at least one hour after treatment.

C. Regulatory History

Bromine was first registered in May of 1976 for use in treating potable water through a polybrominated ion exchange resin aboard naval surface ships. The bromine registered for this use was in the polybromide form of trimethylbenzyl ammonium resin.

A food additive tolerance for 1.0 ppm residual bromine in potable water aboard naval surface ships was established in April 1976 by the Agency. Bromide ion levels in potable water were exempted from the requirement of a tolerance (40 CFR § 185.425).

In 1991, based on information submitted by two of the registrants, the Agency changed the name of the active ingredient in two products from polybromide form of trimethylbenzyl ammonium resin (chemical code 008711, case 3116) to bromine (chemical code 008701, case 4015), the active ingredient and case covered in this RED document.

There are currently four registered products containing bromine as an active ingredient. The technical grade (manufacturing use) bromine product registration is pending at this time.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Elemental bromine occurs in the diatomic state as Br_2. It is a naturally occurring element that is normally found as bromide in living organisms and the environment. It is a common component of seawater and igneous rocks. Its physical and chemical properties are widely reported in the published scientific literature.

Chemical name:	Bromine
Chemical Formula:	Br_2
Molecular Weight:	159.808
Color:	dark reddish brown
Physical state:	liquid
Odor:	suffocating
Melting point:	-7.25°C
Boiling Point:	59.7°C
Density:	3.1023g/ml at 25°C
Solubility:	3.6 g/100 ml in water at 25°C

B. Human Health Assessment

1. Toxicology Assessment

In water, and in living organisms, bromine forms bromide. When used in water purification, the bromine itself is contained in a sealed tube and is used in a closed system, therefore exposure is negligible. Bromide is the form of the chemical assumed to be ingested by exposed individuals. When used in disinfectants, the bromine content of the Microban antimicrobial (0.04%) is considered to be toxicologically insignificant due to its low relative total percentage in comparison with the much higher toxicological potential of some of the other active ingredients. The company, Microban Germicide Company, has also informed the Agency that the bromine in Microban Institutional Spray (EPA Reg. No. 6768-8) and Microban Hospital Spray (EPA Reg. No. 6768- 9) exists as "bromide." Therefore the relevant species for both uses is bromide. The toxicological data base on bromide, per se, is adequate and will support reregistration eligibility.

a. Human Toxicology

Much information on bromide is available in the literature, including human data. The physiology of bromide is well known from the long use of bromides as human drugs. Bromides have been used as oral sedatives, diuretics, and antiepileptics and are known to have low toxicity in mammalian systems. The levels of bromides consumed as drugs are far greater than that which would be ingested from their registered use in water purification. In the treatment of epilepsy, a moderate dose was considered to be 50 mg/kg/day (Levine, 1983). The maintenance dose of bromide ion was 0.9 g/day, which would produce no ill effects. A dose of 3 g of bromide, given to a 60 kg adult (50 mg/kg/day), resulted in a rise in blood bromide to 50 mg/dl, which was considered a "no-ill effect" level.

The lowest LOEL of alleged bromide intoxication reported was 100 mg/dl, but typical signs of bromide intoxication may not occur even when blood levels are over 200 mg/dl (Millikan, 1945). In a study of 36 patients given sodium bromide over a long period of time, 11 developed symptoms of bromide intoxication (Millikan, 1946). The lowest blood bromide level at which any patient developed bromide intoxication was 195 mg/dl. Eight patients first showed evidence of bromide intoxication at blood bromide levels between 200 and 300 mg/dl. Upon termination of bromide treatment, six patients did not become clear mentally from the effects of bromide until their blood bromide levels dropped below 100 mg/dl.

Doses of 1.9 to 2.9 g/day, given to patients over a four month period, did not induce warning signs of bromide intoxication, rash or drowsiness (Flinn, 1941). The average blood bromide level among patients taking 1.9 g/day was 16.55 mg/dl and the average among those taking 2.9 g/day was 50.09 mg/dl. It was noted that there was tremendous variation among patients and such variation has also been found in animal studies. Acute overdoses in humans have produced vomiting or stupor, while chronic use has caused depression, ataxia, and psychoses (Clayton and Clayton, 1982).

One case has been reported in which a woman with two normal children had two retarded boys, 1.5 years apart, while taking bromides. The retarded boys had growth retardation and reduced head size. A case was cited in which bromide intoxication was found in a seven day old nursing infant. The infant's mother was taking high doses of over-the-counter bromides; the blood bromide level in the mother was 320 mg/dl and her milk had 120 mg/dl bromide. The infant was cured by

substituting cow's milk (Federal Register 40:57292).

b. Animal Toxicology

(1) Acute Toxicity

The acute oral LD_{50}s of sodium bromide has been reported as 3500 mg/kg in rats and as 7000 mg/kg in mice (Sax and Lewis, 1989).

(2) Subchronic Toxicity

A 90-day rat study used 0, 75, 300, 1,200, 4,800, or 19,200 ppm of sodium bromide in the diet. At the high dose (960 mg/kg/day), rats showed lack of grooming, motor incoordination, growth retardation, increased percentage of neutral granulocytes, and thyroid activation. In high dose males only, there were increased relative thyroid weight, pituitary gland cysts, decreased relative prostate weight, decreased prostate secretory activity, and decreased spermatogenesis. High dose females had a decreased number of corpora lutea. The next highest dose (240 mg/kg/day) also showed decreased relative prostate weight and decreased prostate secretory activity in males, and decreased thyroid activation in females. The biological half-life for bromide was estimated to be 3-5 days under the conditions of this study (Van Logten et al., 1974)

(3) Chronic Toxicity

A one-year dietary study in rats using feed fumigated with methyl bromide (a dose of 20.7-36.4 mg/kg/day) or fed 0.1% sodium bromide (a dose of 24.3-40.9 mg/kg/day) found a chronic NOEL of >40 mg/kg/day (equivalent to 27-64 mg/dl in blood) (Spencer et al., 1944).

In dogs, a one-year study employed doses of 100 mg/kg/day of bromide as sodium bromide or doses up to 150 mg/kg/day of bromide as food fumigated with methyl bromide. At the highest dose of methyl bromide, signs of bromide intoxication were seen. The NOEL was 100 mg/kg/day as sodium bromide (Rosenblum, et al. 1960).

(4) Reproduction and Development

Pregnant rats were given a total dosage of 192 mg/kg of bromide on the fourth to twelfth days of gestation. The offspring had reduced learning ability (Harned, Hamilton and Cole, 1944).

(5) Metabolism

Bromide has a half-life of about 12 days in the human body. It is treated by the kidney in much the same way as the chloride ion, being filtered at the glomerulus and largely reabsorbed in the tubules. Bromide is not incorporated into fat or blood proteins and does not interfere with thyroid activity, even at large daily doses for extended periods of time. At a dose rate of 1 g potassium bromide given three times a day to a 60 kg person (50 mg/kg/day), the plasma levels of bromide would be expected to reach 28 mg/dl by day 3. The expected plasma levels would be 55 mg/dl in one week, 110 mg/dl in 3 weeks, and 120 mg/dl in one month, with bromide intoxication likely at 3 weeks (Levine, 1983).

(6) Other Toxicological Considerations

Bromine in water, besides existing as the bromide, has the potential to form other species including bromate, depending on pH. Bromate in drinking water has been shown to be carcinogenic to animals.

According to the Agency's Office of Water, there is sufficient and clear evidence that chronic oral exposure to bromate causes increased renal tumors in rats. The animal carcinogenicity data for the bromate ion that follows was used to arrive at this conclusion.

Kurokawa et al. (1986a) supplied groups of about 50 male and 50 female F344 rats (4-6 weeks old) with drinking water containing 0, 250 or 500 mg/L (the maximum tolerated dose) of $KBr0_3$. The high dose (500 mg/L) caused a marked inhibition of weight gain in males, and so at week 60 this dose was reduced to 400 mg/L. Exposure was continued through week 110. The authors stated the average doses for low dose and high dose groups were 12.5 or 27.7 mg $KBr0_3$/kg/day in males (equivalent to 9.6 and 21.3 mg $Br0_3^-$/kg/day) and 12.5 or 25.5 mg/$KBr0_3$/kg/day in females (equivalent to 9.6 and 19.6 mg $Br0_3^-$/kg/day). The incidence of renal tumors in the three groups (control, low dose, high dose) was 6%, 60% and 88% in males and 0%, 56% and

80% in females. The effects were statistically significant ($P<0.001$) in all exposed groups. The incidence of peritoneal mesotheliomas in males at the three doses was 11% (control), 33% (250 mg/L, $P<0.05$) and 59% (500 mg/L, $P<0.001$). The authors concluded that $KBrO_3$ was carcinogenic in rats of both sexes.

In a subsequent study, Kurokawa et al. (1986b) supplied male F344 rats with water containing $KBrO_3$ at 0, 15, 30, 60, 125, 250 or 500 mg/L for 104 weeks. The authors reported that these exposures resulted in average doses of 0, 0.9, 1.7, 3.3, 7.3, 16.0 or 43.4 mg/kg/day of $KBrO_3$, equivalent to doses of 0, 0.7, 1.3, 2.5, 5.6, 12 or 33 mg/kg/day of BrO_3^-. The incidence of renal cell tumors in these dose groups was 0%, 0%, 0%, 4%, 21% $P<0.05$), 25% ($P<0.05$) and 45% ($p<0.001$). Incidence of dysplastic foci (considered to be preneoplastic lesions) were 0%, 5%, 25% ($P<0.05$), 25% ($P<0.05$), 50% ($P<0.001$), 95% ($P<0.001$) and 95% ($P<0.001$).

Kurokawa et al. (1987) supplied male F344 rats with water containing 500 mg/L of $KBrO_3$ for 13, 26, 39, 51 or 104 weeks to assess the time-course of renal cell tumor induction. The average daily consumption of $KBrO_3$ was 41.9 mg/kg (32.3 mg BrO_3^-/kg). Each group was sacrificed after the exposure interval ended and examined histopathologically for dysplastic foci, renal adenomas and adenocarcinomas, thyroid follicular cell tumors and peritoneal mesotheliomas. Dysplastic foci and renal adenomas were first observed following 26 weeks of treatment but the incidence (10%) was not statistically significant. Renal dysplastic foci (62%) and adenomas (58% were significantly increased over controls by week 52 of treatment. Continuous $KBrO_3$ administration over 104 weeks resulted in renal adenocarcinomas in 3/20 (15%) and adenomas in 6/20 (30%) rats for a combined incidence, of 9/20 (45%). The combined incidence of follicular adenomas and adenocarcinomas of the thyroid were also increased significantly (7/35; $P<0.01$) in rats receiving treatment for 104 weeks. The authors concluded that the minimum induction time for renal adenoma development was 26 weeks.

In a related study, Kurokawa et al. (1987) exposed F344 rats to water containing 500 ppm $KBrO_3$ (29.6-35.5 mg BrO_3^-/kg) for 13, 26, 39, 52 or 104 weeks followed by distilled water until sacrifice of all groups at 104 weeks. The incidence of renal dysplastic foci was 65% in animals exposed for weeks 1-13, and

the incidence increased to 100% in animals exposed for 39 or 52 weeks. The incidence of dysplastic foci in control animals was 0%. The incidence of adenomas and adenocarcinomas in rats exposed for 13-52 weeks ranged from 47-74%, similar to or higher than the value observed in animals exposed continuously for 104 weeks (45%). All values were significantly higher in exposed animals than in controls ($P<0.001$). The authors concluded that the minimum total cumulative dose necessary for the induction of renal adenomas and adenocarcinomas was 4 g $KBrO_3$/kg (3.1 g BrO_3^-/kg), and the minimum treatment period was 13 weeks for the induction of tumors within 2 years.

Kurokawa et al. (1986a) investigated the carcinogenic potential of $KBrO_3$ in mice. Groups of 50 female $B6C3F_1$ mice were supplied with water containing 0, 500, or 1,000 mg/L $KBrO_3$ for 78 weeks. The authors reported the average doses were 0, 56.5 and 119 mg/kg/day (equivalent to 43.5 and 91.6 mg BrO_3^-/kg/day). Based on histological examination of tissues at week 104, no significant differences in tumor incidence between exposed and control animals were apparent.

Based on the incidence of renal tumors in male rats, the Agency has assigned the bromate ion a Group B2 (probable human carcinogen) classification. A low dose linearized extrapolation model was used to quantitatively characterize risk for humans. A Q_1* of 4.9×10^{-1} $(mg/kg/day)^{-1}$ for the potassium bromate was derived from the combined renal adenoma and adenocarcinoma data (Kurokowa et al., 1986a). It is expected that other soluble salts of bromate are equally carcinogenic. Adjusting for the molecular weight, the unit risk for the bromate ion is calculated to be 6.5×10^{-1} $(mg/kg/day)^{-1}$.

2. Exposure Assessment

a. Dietary Exposure

The only food use of Bromine is in potable water (aboard ships and offshore oil well platforms). The registered products for this use ("Everpure® Brominating Cartridge" EPA Reg. No. 2623-3 and "Purolite® Brominating Cartridge" EPA Reg. No. 59454-1) contain 30% bromine as active ingredient and 70% resin as inert ingredient. The use rate is 0.2 - 1.0 ppm residual bromine as verified by test kit.

A food additive tolerance for residual bromine in potable water at 1.0 ppm was established (CFR 40 §185.425) as follows:

> "The food additives bromide ion and residual bromine, may be present in potable water in accordance with the following conditions: (a) The food additives are present as a result of treating water aboard ships with a polybrominated ion-exchange resin (as a source of bromine) under the supervision of trained personnel. (b) Residual bromine levels are controlled to not exceed 1.0 ppm in the final treated water. Control is effected using calibrated recirculating or proportioning bromine feeder equipment and periodic checks of residual bromine using a bromine test kit. To assure safe use of the additives, the label and labeling of the disinfectant formulation containing the food additives shall conform to the label and labeling registered by the U.S. Environmental Protection Agency. (c) No tolerance is established for bromide ion levels."

The controls in effect, i.e., closed system, limited use, trained applicators, and use of the test kit, are adequate to assure that residual bromine will not exceed 1.0 ppm, in accordance with 40 CFR 185.425.

However, there are no data on the amount of bromate, a species of potential concern. In the absence of actual data on the magnitude of bromate ion in potable water generated via bromination, the Agency attempted to determine the likelihood of the presence of bromate ion based on theoretical considerations.

Information obtained from product manufacturers and users indicate that when at port, virtually all potable water is obtained from an approved water source, and bromination is not necessary as such water has already been chlorinated. It is treated on rare occasions, however, if total available chlorine tests reveal an unacceptable chlorine level. Also, virtually all (99%) brominated potable water used on board naval vessels has been derived via desalination using distillation.

The pH of distilled water is known generally to be close to 6. A Navy representative stated that the pH of equipment feed water (which is distilled, unbrominated stored water after deaerating) was acidic (ca. pH 6). The only pH data that the Navy has available was collected recently from one ship over a 90-day period: the pH of an unknown number of samples was 5.55 - 5.61 as the water comes off the distilling unit. Reliable direct pH measurements of the distilled water cannot be made

because the conductance of the water is too low and Navy ships generally do not have pH meters on board. Neither of the two polybrominated resin cartridge registrants have access to any pH data. The pH of municipal water sources, which may be used while Navy ships dock, may be 8.6 or higher in certain areas or if water softening is necessary. However, such water is very rarely brominated.

A representative of Navy Occupational Health, Norfolk, VA stated that "total available bromine" (TAB) concentrations in the potable water are initially ≤ 2 ppm (usually much less) but that the typical (and required) concentration is about 0.2 ppm in water after exposure to bromine for 30 min. [Note that 40 CFR 185.425 limits residual bromine levels to ≤ 1 ppm in the final treated water.] According to Lamont Chemicals, Inc., Chestertown, MD, the manufacturers of the test kit used by the Navy, TAB was defined as the total oxidizing agent level, which, at the typical pH of potable water, would be largely HBrO. In the case of distilled water, few, if any, interfering oxidants would be expected.

The Agency believes that the concentration of bromate ion in water cannot be calculated because the kinetics of bromine disproportionation have not been elucidated as they have for chlorine and iodine. However, that bromate ion is expected to be nondetectable (<0.5 ppb) in water of pH 5-6.

The available information does not allow the Agency to calculate the bromate ion concentration in potable water because: (1) data are not available concerning the bromate ion concentration; (2) the kinetics of the bromine disproportionation reactions have not been elucidated; and (3) the range of water pH aboard ship is unknown.

A concentration of approximately 0.7 ppb bromate ion in water would correspond to a risk of 1×10^{-6} assuming 1.2 liters of water consumed per day and that ship personnel would be exposed for 6 months a year for 7 years, a typical exposure based on information provided by the Navy. If bromate ion were present at 0.7 ppb in water, this would represent 0.035% of the total bromine if the water had been treated with bromine at 2 ppm. (For comparison, according to the Agency's Office of Water, a risk of 1×10^{-6} would correspond to a daily exposure of 0.054 ppb bromate ion in drinking water, over a 70-year lifetime.)

Because there is not enough information to permit the Agency to estimate the dietary exposure to bromate ion via potable water aboard Navy vessels, the following are required under data requirement guideline 171-4(f) Magnitude of residue in potable water:

Representative monitoring data for the pH and bromate ion concentration of brominated, desalinated water. Such data must reflect actual shipboard Navy conditions and equipment, including distilling units (or reverse osmosis units), typical storage tanks, and duration of water storage after bromination but prior to consumption (i.e., the pH and bromate ion concentration data associated with water immediately prior to typical human consumption to determine the likelihood of bromate ion formation and/or concentration). An appropriate method to analyze bromate ion may be ion chromatography, the sensitivity of which can be as low as 0.5 ppb bromate ion.

b. Occupational and Residential

The bromine water purification product is packaged in and dispensed by a closed system, trickle brominating feeder, from a cartridge for treatment of human drinking water systems on U. S. naval ships and offshore oil well platforms. Treated water is maintained at 0.2 to 1 ppm available bromine. Exposure to applicators is thought to be minimal for this use.

The surface sanitizer use (i.e. surface spray) may expose applicators via inhalation. The ingredient to which users are exposed is bromide. although no acute inhalation data are available for bromide, such data will be required for each end use product with this use. Currently, these products have instructions to users to wear protective clothing, gloves and a respirator, to adequately ventilate spaces ventilate spaces to be treated and to avoid reentry of treated spaces for at least one hour after treatment. The exposure to these products is probably low, but because bromide toxicity is not known, these requirements are needed to minimize exposure.

3. Risk Assessment

a. Dietary

The toxicological effects of bromine (as bromide) are well known; bromine-containing pharmaceuticals are administered at much higher concentrations of bromine than the available levels of bromine maintained in treated water. Human health risks from exposure to bromine when used in potable water are expected to be minimal due to the fact that water must be tested prior to consumption, and the principal residue in water purification systems is bromide ion (0.2 to 1.0 ppm available bromine)

rather than elemental bromine gas. The risk from ingestion of bromate is believed to be low. However, in order to confirm this assessment, exposure data has been requested from the registrants.

b. Occupational and Residential

The risks to workers from the use of brominated cartridges for water treatment are minimal because a closed delivery system is used. However, bromine is toxic. Accordingly, the following precautionary statement which is currently on the labels must be retained:

> "Avoid breathing vapor, especially when opening container. Do not open package in confined area. Ingredients are permanently sealed inside cartridge. Do not puncture or attempt to open cartridge. If fumes are noticed, ventilate area."

The Agency believes that exposure to the sanitizer use of bromide-containing products is probably low. However, because the inhalation toxicity of these products is not adequately known, the current labeling restrictions (i.e. gloves, protective clothing and respirator for large volume applications) must remain in place until the product specific toxicity data are submitted. These restrictions will assure that humans are not exposed to an unacceptable risk.

C. Environmental Assessment

1. Environmental Fate

The environmental fate and chemical characteristics of bromine are well researched and documented in the public literature, including that elemental bromine is a highly reactive, strong oxidizing agent and would not be expected to hydrolyze under standard study conditions. However, a discussion of bromine's environmental fate is not necessary here because the current use patterns of pesticide products containing bromine do not result in environmental exposure.

2. Ecological Effects

Because of the strictly indoor use of bromine the Agency has not prepared an ecological effects risk assessment, since exposure to non-target organisms in the enviroment is negligible. The target data base for reregistration would have been four studies: one avian acute oral, one avian dietary, one fish acute, and one aquatic invertebrate acute. These studies are used to provide precautionary

statements describing environmental hazards to be used on labeling. studies were used to determine the environmental hazard statement for labeling. However in the case of bromine, the target data base is reduced to exclude the avian requirements. Since bromine is a highly volatile, corrosive liquid, standard avian tests would not provide useful toxicity data. Available aquatic ecotoxicity data show that bromine chloride, measured as bromine, is highly toxic to freshwater fish and aquatic invertebrates.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Eligibility Decision

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing bromine as an active ingredient. Appendices B and C identify the generic data that the Agency reviewed as part of its determination of reregistration eligibility of bromine, and lists the submitted studies that the Agency found acceptable. The Agency has completed its review of these generic data, and has determined that they are sufficient to support reregistration of all uses of currently registered products containing bromine as an active ingredient. The Agency concludes that bromine can be used without resulting in unreasonable adverse effects to human health or the environment. The Agency therefore finds that all products containing bromine as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

Although the Agency has found that all uses of bromine are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing bromine, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all uses of all currently registered bromine products are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

A food additive tolerance for bromine in potable water at 1.0 ppm was established (CFR 40 §185.425) as follows:

> "The food additives bromide ion and residual bromine, may be present in potable water in accordance with the following conditions: (a) The food additives are present as a result of treating water aboard ships with a polybrominated ion-exchange resin (as a source of bromine) under the supervision of trained personnel. (b) Residual bromine levels are controlled to not exceed 1.0 ppm in the final treated water. Control is effected using calibrated recirculating or proportioning bromine feeder equipment and periodic checks of residual bromine using a bromine test kit. To assure safe use of the additives, the label and labeling of the disinfectant formulation containing the food additives shall conform to the label and labeling registered by the U.S. Environmental Protection Agency. (c) No tolerance is established for bromide ion levels."

The Agency has reassessed this tolerance and found that it is set at an appropriate level and provides an adequate margin of safety to protect the public health.

2. Dietary Risk and Confirmatory Data

The Agency recognizes that the use of bromine to purify water for human consumption may result in dietary exposure to bromate, a probable human carcinogen. However, the Agency believes the concentration of bromate in treated water is likely to be relatively low, resulting in an acceptable level of risk. Data to confirm the concentration have been required prior to the issuance of this

document.

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 bromine for the above eligible uses has been reviewed and determined to be substantially complete. However, the Agency has required residue monitoring data from the drinking water use to confirm the level of bromate in drinking water. This data requirement was imposed prior to the issuance of this Reregistration Eligibility Decision document (RED).

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.

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

2. Labeling Requirements for End-Use Products

Current label precautions as well as statements regarding protective clothing must be maintainded. In addition, the labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10.

Because of the high toxicity of bromine to aquatic organisms, all labels must contain the following statement:

"This pesticide is toxic to fish and aquatic invertebrates"

C. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

APPENDIX A - Case 4015, [Bromine] Chemical 008701 [Bromine]

Application Type	Application Timing	Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations		Use Pattern Limitations
										Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
Site: Livestock Use Group(s): Indoor Food												
Feeding and watering appliance treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. Potable water rinse (non-residual claim).
Feeding and watering appliance treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. Potable water rinse (non-residual claim).
Premise treatment, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Premise treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Premise treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Site: Poultry (Egg/Meat) Use Group(s): Indoor Food												
Feeding and watering appliance treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. Potable water rinse (non-residual claim).
Feeding and watering appliance treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. Potable water rinse (non-residual claim).

APPENDIX A - Case 4015, [Bromine] Chemical 008701 [Bromine]

Application Type / Application Timing / Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
Site: Poultry (Egg/Meat) Use Group(s): Indoor Food (*Continued from previous page*)										
Premise treatment, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Premise treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Premise treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Site: Agricultural/Farm Premises Use Group(s): Indoor Food										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.
Transportation vehicle treatment, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment.

APPENDIX A - Case 4015, [Bromine] Chemical 008701 [Bromine]

Application Type / Application Timing / Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
Site: Human Drinking Water Systems Use Group(s): Indoor Food										
Water treatment, Not on label, Water purifier unit Surface Type: na Efficacy Influencing Factor: na	SC/S	300,000 ppm by Wt*	300,000 ppm by Wt*	not spec	not spec	not spec	not spec	na	na	*Treated water must be maintained at 0.2 to 1 ppm available bromine.
Water treatment, Not on label, Water purifier unit Surface Type: na Efficacy Influencing Factor: na	SC/S	300,000 ppm by Wt*	300,000 ppm by Wt*	not spec	not spec	not spec	not spec	na	na	*Treated water must be maintained at 0.2 to 1 ppm available bromine.
NON-FOOD/NON-FEED USES										
Site: Commercial/Institutional/Industrial Premises/Equipment (Indoor) Use Group(s): Indoor Non-Food										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Commercial/Institutional/Industrial Floors Use Group(s): Indoor Non-Food										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Upholstery (Hospital/Commercial) Use Group(s): Indoor Non-Food										
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.

APPENDIX A - Case 4015, [Bromine] Chemical 008701 [Bromine]

Application Type	Application Timing	Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations		Use Pattern Limitations
										Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION												
Site: Carpets (Commercial Sanitizer) Use Group(s): Indoor Non-Food												
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Hospital/Medical Institutions Premises (Human/Veterinary) Use Group(s): Indoor Medical												
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Hospital Noncritical Items (Bedpans/Furniture) Use Group(s): Indoor Medical												
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Hospital/Medical Institutions Non-Conductive Floors Use Group(s): Indoor Medical												
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na			RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).

APPENDIX A - Case 4015, [Bromine] Chemical 009701 [Bromine]

Application Type / Application Timing / Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
Site: Carpets (Hospital Sanitizer) Use Group(s): Indoor Medical										
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Upholstery (Hospital/Commercial) Use Group(s): Indoor Medical										
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Household/Domestic Dwellings Indoor Premises Use Group(s): Indoor Residential										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Household/Domestic Dwellings Contents Use Group(s): Indoor Residential										
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Residential Floors (Antimicrobials Only) Use Group(s): Indoor Residential										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.

Application Type / Application Timing / Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
Site: Residential Floors (Antimicrobials Only) Use Group(s): Indoor Residential *(Continued from previous page)*										
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Laundry (Household/Coin-Operated) Use Group(s): Indoor Residential										
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Carpets (Household Sanitizer) Use Group(s): Indoor Residential										
Spray, Not on label, Hand held sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Spray, Not on label, Power sprayer Surface Type: Porous Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim.
Site: Bathroom Premises/Hard Surfaces Use Group(s): Indoor Residential										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Refuse/Solid Waste Sites (Indoor) Use Group(s): Indoor Residential										
Fog, Not on label, Fogger Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. Proper ventilation required.

APPENDIX A - Case 4015, [Bromine] Chemical 008701 [Bromine]

Application Type / Application Timing / Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
Site: Refuse/Solid Waste Sites (Indoor) Use Group(s): Indoor Residential *(Continued from previous page)*										
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Site: Refuse/Solid Waste Containers (Garbage Cans) Use Group(s): Indoor Residential										
Spray, Not on label, Hand held sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).
Spray, Not on label, Power sprayer Surface Type: Hard Efficacy Influencing Factor: na	RTU	400 ppm by Wt	400 ppm by Wt	not spec	not spec	not spec	not spec	na	na	Preclean claim. 10 minute(s) contact time (minimum).

Abbreviations used

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

Form: SC/S = Soluble Concentrate/Solid; RTU = Ready-to-use Liquid
Rate: Wt = ppm of active ingredient calculated by weight; Vol = ppm of active ingredient calculated by volume
In general: na = not applicable; not spec = 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 active ingredients within the case Bromine covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Bromine in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Bromine

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-2A	Start. Mat. & Mnfg. Process	All	40708401, 41293601
61-2B	Formation of Impurities	All	40708401
62-1	Preliminary Analysis	All	40708402, 41293602
63-2	Color	All	40708403, 41293603
63-3	Physical State	All	40708403, 41293603
63-4	Odor	All	40708403, 41293603
63-5	Melting Point	All	40708403, 41293603
63-6	Boiling Point	All	40708403, 41293603
63-7	Density	All	40708403, 41293603
63-8	Solubility	All	40708403, 41293603
63-9	Vapor Pressure	All	40708403, 41293603
63-10	Dissociation Constant	All	40708403, 41293603
63-11	Octanol/Water Partition	All	40708403, 41293603
63-12	pH	All	40708403, 41293603
63-13	Stability	All	40708403, 41293603

ECOLOGICAL EFFECTS

All ecotoxicity requirements were waived

TOXICOLOGY

All toxicology data requirements were waived.

Data Supporting Guideline Requirements for the Reregistration of Bromine

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
All environmental fate data requirements were waived.			
RESIDUE CHEMISTRY			
171-4F	Magnitude of Residues - Potable H2O	L	Data Gap

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Bromine

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
40708401	Handy, R. (1988) Product Chemistry Data: Product Identity and Composition: Bromine: RFH-88-156-2. Unpublished study prepared by Great Lakes Chemical Corp. 9 p.
40708402	Handy, R. (1988) Product Chemistry Data (Analysis and Certification of Product Ingredients): Bromine: RFH-156-3. Unpublished study prepared by Great Lakes Chemical Corp. 27 p.
40708403	Handy, R. (1988) Product Chemistry Data: Physical and Chemical Charateristics: Bromine: RFH-88-156-4. Unpublished study prepared by Great Lakes Chemical Corp. 6 p.
41293601	Handy, R. (1989) Bromine Product Chemistry Data: Product Identity and Composition. Unpublished study prepared by Great Lakes Chemical Corp. 9 p.
41293602	Handy, R. (1989) Bromine Product Chemistry Data: Analysis and Certification of Product Ingredients: Lab Project Number: QCS/84/35 : QCS/79/01 : QCS/79/02. Unpublished study prepared by Great Lakes Chemical Corp. 27 p.
41293603	Handy, R. (1989) Bromine Product Chemistry Data: Physical and Chemical Characteristics. Unpublished study prepared by Great Lakes Chemical Corp. 6 p.

References cited in this document:

(1) Clayton, G. D., and Clayton, F. E., eds., 1982. Patty's Industrial Hygiene and Toxicology, 3rd Revised Ed. Wiley Interscience, NY.

(2) EPA, Office of Drinking Water, Office of Science and Technology, Health and Ecological Criteria Division, "Rough Final draft for the Drinking Water Criteria Document on Bromate" EPA Contract 68-C2-0139-clement International Corporation.

(3) Harned, Hamilton, and Cole, 1944. J. Pharm. and Ther. 82:215-226.

BIBLIOGRAPHY

MRID	CITATION

(4) Flinn, 1941. J. Lab. and Clin. Med. 26:1325-1329.

(5) Kurokawa, Y. et al., 1986a J. Natl. Cancer Inst. 77:977-982.

(6) Kurokawa, Y. et al., 1986b Environ. Health Perspec. 69:221-236.

(7) Kurokawa, Y. et al., 1987 Jpn. J. Cancer Res. 78:358-364.

(8) Levine. 1983. Pharmacology: Drug Actions and Reactions. 3rd ed. pp. 240-241.

(9) Millikan, 1945. J. Iowa State Med Soc. 35:120-125.

(10) Millikan, 1946. J. Iowa State Med Soc. 36:39-48.

(12) Rosenblum, Stein, and Eisinger, 1960. Arch. Envrn. Health 1:316-323.

(13) Sax, N. I., and Lewis, R. J. Sr, 1989. Dangerous Properties of Industrial Materials, 7th Ed. Van Nostrand Reinhold, New York.

(14) Spencer, et al., 1944. Food Research 9:11-18.

(15) Van Logten, et al., 1974. Toxicology 2:257-267.

APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Bromine RED Fact Sheet

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

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

APPENDIX E. PR Notices 86-5 and 91-2

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.

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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 _____

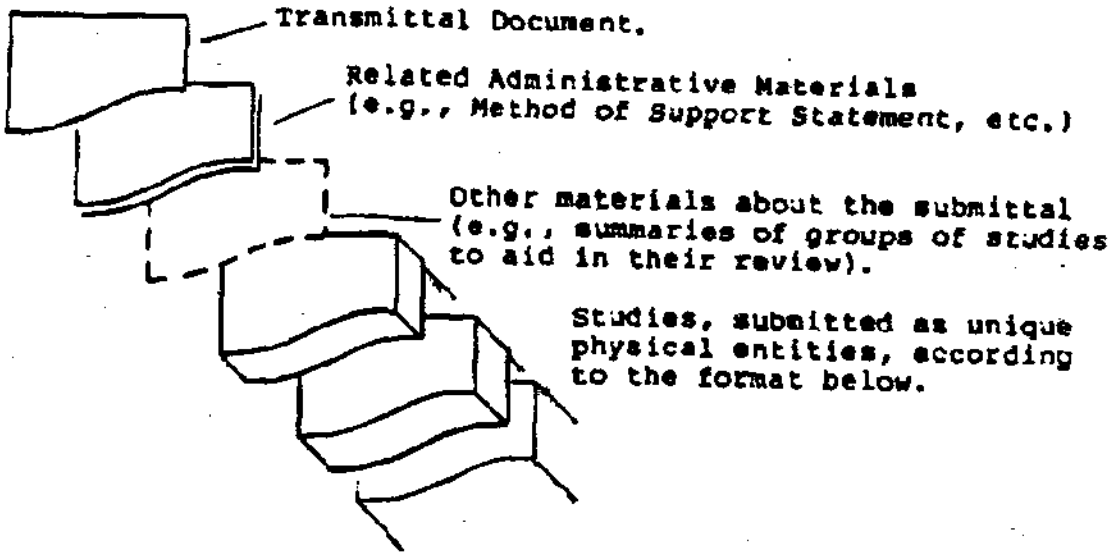
Example 3.

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.

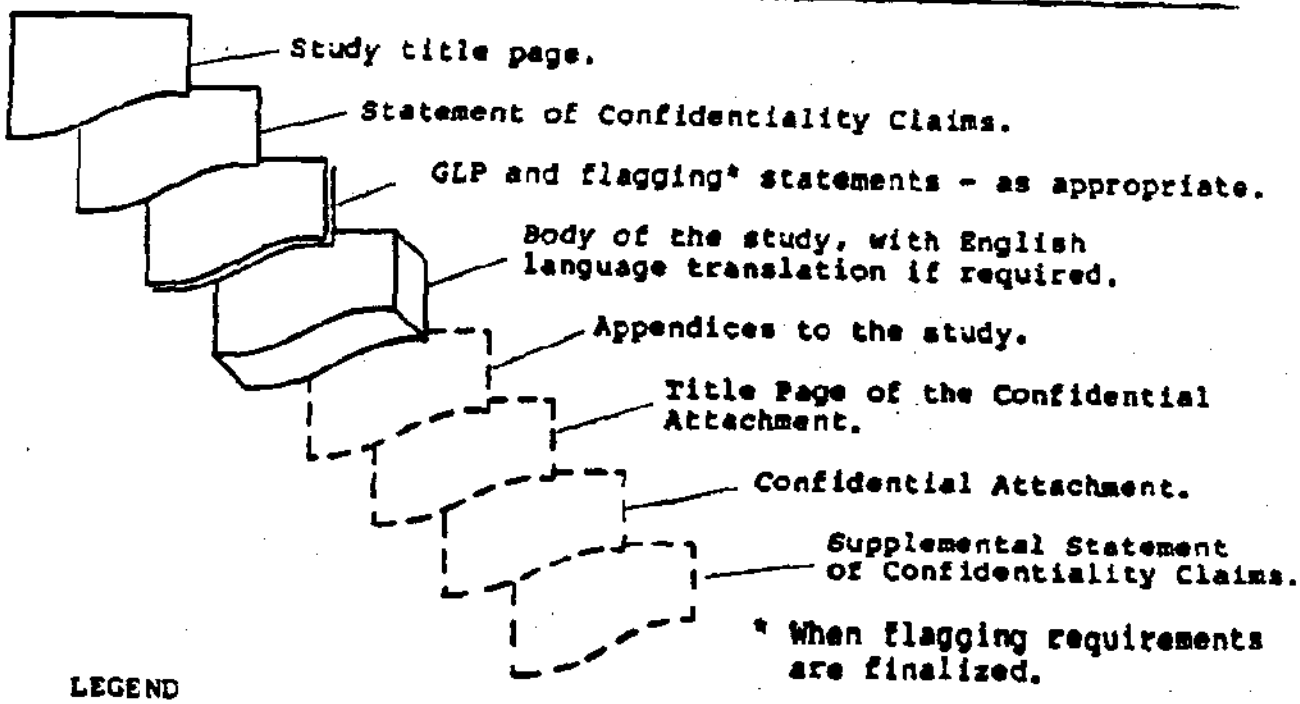
Submitter _____

ATTACHMENT 7.

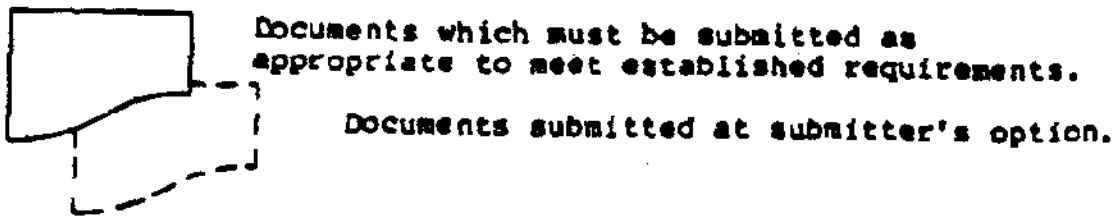
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



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) 308-7031.

Anne E. Lindsay

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

APPENDIX F. Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment F).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data

requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the

six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending

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

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

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

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

Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

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

Attachment 1. Chemical Status Sheet

BROMINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Bromine, please contact Mark Wilhite at (703) 308-8586.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Rubis (703) 308-8184

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

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

RE: **Bromine**

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

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

Item 1-4. Already completed by EPA.

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

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration 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 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 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and 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 guidelines 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 patters (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 Documents unless EPA determines that a longer time period is necessary.

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

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

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 on 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 my 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 require 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 upgrade (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) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant'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 require 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 chosen. I also understand that the deadline for submission of data as specified by the original data cal-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 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF BROMINE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient bromine, 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, and frequently acute toxicity data on individual 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 product should the need arise.

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

Table I shows the two products which were batched together.

EPA REG. NO.	% of Bromine	Formulation Type
2623-3	30.0% - Bromine	Impregnated Material
59454-1	30.0% - Bromine	Impregnated Material

Table II shows the two remaining products which was not batched. These products were not considered similar for purposes of acute toxicity. The registrant of these products is responsible for meeting the acute toxicity data requirements specified in the data matrix.

EPA REG. NO.	% of Bromine & Other Active Ingredients	Formulation Type
6768-8	00.04% - Bromine 25.00% - Isopropyl Alcohol 00.21% - O-Phenylphenol 00.69% - Diisobutylphenoxyethoxy Ethyl Dimethyl Benzyl Ammonium Chloride Monohydrate 00.33% - N-Octyl Bicycloheptene Dicarboximide 00.20% - Piperonyl Butoxide 00.10% - Pyrethrins	Ready to Use Spray
6768-9	00.04% - Bromine 00.21% - O-Phenylphenol 00.69% - Diisobutylphenoxyethoxy Ethyl Dimethyl Benzyl Ammonium Chloride Monohydrate	Ready to Use Spray

Attachment 5. 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

63-10 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 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Form, and Confidential Statement of Formula Form

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

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

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

United States Environmental Protection Agency
Washington, DC 20460

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)	

EPA Form 8570-31 (4-90)