UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Frank Rubis (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Ron Kendall (703) 308-8068.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

   c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must

make sure that they meet the Agency's acceptance criteria (attached to the DCI).

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

BRONOPOL

LIST B

CASE 2770

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

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BRONOPOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Kathleen Vinlove	Economic Analysis Branch
Michelle Cottril	Biological Analysis Branch
Phyllis Johnson	Biological Analysis Branch

Environmental Fate and Effects Division

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Bipin Gandhi	Registration Support Branch
Mark Perry	Registration Support Branch

Special Review and Reregistration Division

Kathleen Depukat	Accelerated Reregistration Branch
Ron Kendall	Accelerated Reregistration Branch

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Rick Colbert

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

Reregistration Eligibility and Background

The U.S. Environmental Protection Agency (referred to as "the Agency") has completed an assessment of the potential human health and environmental risks associated with the pesticide uses of 2-bromo-2-nitropropane-1,3-diol, hereafter referred to as "bronopol." The Agency has determined that pesticide products containing this chemical as an active ingredient, labeled and used as specified in this Reregistration Eligibility Decision document (RED), will not cause unreasonable risk to humans or the environment. This document is requiring the use of closed metering systems for liquid applications to cooling water systems and the use of personal protective equipment to mitigate risks to handlers. Therefore, the Agency has concluded that the products containing bronopol for all currently registered uses are eligible for reregistration.

Use Patterns

Bronopol products are currently registered for use in oil-field systems, air washer systems, industrial processing water and scrubbing systems, laboratory equipment water baths, coatings, emulsions, air conditioning/humidifying systems, cooling water systems, pulp and papermill water systems, components used in papermaking, metal working cutting fluids, printing inks, paints, and adhesives as well as consumer/institutional products. A formulating technical material is also registered.

Health Effects and Occupational Exposure

Studies suggest that bronopol is a corrosive eye irritant and a moderate to severe dermal irritant in rabbits. However, the Agency does not categorize bronopol as a dermal sensitizer. The short and intermediate-term occupational/residential risks for bronopol are based on the maternal and developmental toxicity NOEL of 40 mg/kg/day. The NOEL of 10 mg/kg/day from a chronic rat feeding study is used to estimate risk. A reference dose (RfD) was established because of possible long-term exposure to bronopol containing products. The Agency has concluded there is an unacceptable risk to handlers from open pouring of liquid bronopol products into cooling water systems. The use of a closed metering system will mitigate this risk. Risks from other exposures are within acceptable limits.

Environmental Fate and Ecological Effects

Bronopol is moderately to highly toxic to estuarine/marine invertebrates; slightly toxic to estuarine/marine fish; slightly toxic to birds on a acute oral basis; and practically nontoxic to slightly toxic to birds on a subacute dietary basis. However, a quantitative risk assessment has not been conducted. For bronopol, risk to the aquatic environment is addressed under the NPDES permitting program by the EPA, Office of Water. The Agency currently requires that labels for all bronopol products require that discharges to aquatic environments comply with an NPDES permit.

Product Reregistration

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

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of bronopol. The document consists of six sections. Section I is the introduction. Section II describes bronopol, 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 bronopol. Section V discusses the reregistration requirements for bronopol. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Bronopol
- **Chemical Name:** 2-Bromo-2-nitropropane-1,3-diol
- **CAS Registry Number:** 52-51-7
- **OPP Chemical Code:** 216400
- **Empirical Formula:** $C_3H_6BrNO_4$
- **Trade and Other Names:** Onyxide 500
- **Basic Manufacturer:** The Boots Company, Nottingham, England
  John W. Kennedy Consultants
  (U.S. Agent)

B. Use Profile

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

TYPE OF PESTICIDE: Microbiocide/Microbiostat (Slime-Forming Bacteria, Fungi, and Algae); may be used in formulating disinfectants and sanitizers, as well as microbiocides.

USE SITES:

Aquatic Non-Food Industrial

Air Conditioner/Refrigeration Condensate Water Systems
Air Washer Water Systems
Commercial/Industrial Water Cooling Systems
Evaporative Condenser Water Systems
Heat Exchanger Water Systems
Humidifier Water (commercial/industrial humidifying systems)
Industrial Processing Water
Industrial Scrubbing System

Laboratory Equipment Water Baths
*Oil Recovery Drilling Muds/Packer Fluids (off-shore sites)
Pulp/Paper Mill Water Systems
Secondary Oil Recovery Injection Water

Indoor Non-Food

Adhesives, Industrial
Coatings, Industrial
Emulsions, Resin/Latex/Polymer
Fuels/Oil Storage Tank Bottom Water Additive
Metalworking Cutting Fluids
Paints, Latex (In-Can)
Paper/Paper Products
Pasteurizer/Warmer/Cannery Cooling Water Systems
Specialty Industrial Products
Wet-End Additives/Industrial Processing Chemicals

Terrestrial Non-Food Crop

*Oil Recovery Drilling Muds/Packer Fluids (terrestrial sites)

*Registrants must specify on labels, as per Section V of this document, whether the product is used on off-shore and/or terrestrial sites.

PESTS: Slime-forming bacteria, fungi, and algae; sulfate-reducing bacteria; aerobic and anaerobic bacteria; odor-causing bacteria; spoilage bacteria.

FORMULATION TYPES REGISTERED:

TYPE: End-Use, Manufacturing-Use.

FORM: Pelleted/Tableted, Crystalline, Soluble Concentrate/Liquid, Soluble Concentrate/Solid.

METHODS AND RATES OF APPLICATION:

TYPES OF TREATMENT: Water treatment, Water treatment (recirculating system), Impregnation treatment (absorbent clays), Industrial preservative treatment, Preservative treatment.

EQUIPMENT: Metering Pump, Sprayer, Injection Equipment, Not specified on label (registrant needs to specify on labeling).

TIMING: Continuous feed (initial), Continuous feed (subsequent), Intermittent (slug)(initial), Intermittent (slug)(subsequent), Intermittent feed (initial), Shock/slug, During manufacture, Initial, Subsequent/maintenance, Not specified (registrant needs to specify on labeling).

RATE OF APPLICATION (Microbiocide/Microbiostat):

Adhesives: 34-5156 ppm active ingredient.

Emulsions: 11-498 ppm active ingredient.

Latex paints: 82-498 ppm active ingredient.

Absorbent clay: 20-200 ppm active ingredient.

Consumer, household, and institutional products; water-based agricultural pesticide concentrates; raw materials; surfactants; water-based printing inks and fount solutions: 2-498 ppm active ingredient.

Polymers, defoamers, dyes, alum, starch, pigment slurries, extender slurries, coating components, titanium dioxide, calcium carbonate, and clay slurries for use in papermaking systems: 2-498 ppm active ingredient.

Metalworking cutting fluids: For metalworking cutting fluids concentrates, the amount to be incorporated during manufacture will depend on the dilution factor recommended for the concentration; for diluted metalworking cutting fluids: 82-1000 ppm active ingredient.

Oil recovery drilling muds/packer fluids: 21-200 ppm active ingredient.

Bottom water in oil or transportation tanks, pipeline maintenance: 10-200 ppm active ingredient.

Humidifier water (commercial/industrial systems): 24-100 ppm active ingredient.

Air conditioner/refrigeration condensate and air washer water systems: 24-100 ppm active ingredient.

Commercial/industrial water cooling systems/evaporative condenser, pulp/paper mill, and heat exchanger water systems: 8.6-264 ppm active ingredient.

Pasteurizer/warmer/cannery cooling water systems: 17-57 ppm active ingredient.

Industrial processing water: 8-102 ppm active ingredient.

Industrial scrubbing system: 17-57 ppm active ingredient.

Secondary oil recovery injection water: 24-488 ppm active ingredient.

Laboratory equipment water baths: 101 ppm active ingredient.

Paper products: No dosage specified on label. Registrant must specify dosage on labeling.

USE PRACTICES LIMITATIONS:

Do not discharge effluent containing bronopol into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing bronopol into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Bronopol is not cleared for use in defoamers and/or coatings that may come in contact with food.

C. Regulatory History

Pesticide products containing 2-bromo-2-nitropropane-1,3-diol (bronopol) as an active ingredient were initially registered in the United States in 1984 for use in industrial bactericides, slimicides and preservatives.

There are currently 21 products registered that contain bronopol as the active ingredient. A formulating technical material is also registered. Three Data Call-Ins were issued by EPA for this chemical. The Antimicrobial Data Call-In was issued in March 1987. A second Data Call-In was issued as part of the Phase 4 reregistration in June 1991. The Agency required additional exposure data or compensation for available data to support the risk assessment for reregistration in a third Data Call-In in October 1995.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The chemical bronopol is a propanediol-type compound containing nitro and bromine groups. It is a white, crystalline powder with a faint odor and a melting point of 130°C. Bronopol is soluble in polar solvents such as water, ethanol and ethylene glycol, but only slightly soluble in non-polar solvents like chloroform. It has a low vapor pressure of 1.26×10^{-5} mm of Hg at 20°C. It is stable to room temperature, high temperature, and

in sunlight. It decomposes in alkaline medium. An aqueous solution of bronopol degrades in the presence of cupric and ferric ions as well as aluminum and tin metals. (MRIDs 108808, 141875, and 141876)

B. Human Health Assessment

1. Toxicology Assessment

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

a. Acute Toxicity

Acute toxicity studies with bronopol have been submitted and adequately satisfy the Agency's requirements. Table 1 below summarizes the values and categories for the various acute toxicology studies.

Table 1. Acute Toxicity Values

STUDY	RESULTS	CATEGORY
Acute Oral LD_{50}- rat	males 307 mg/kg females 342 mg/kg	II
Acute Dermal LD_{50}- rabbit	64 - 160 mg/kg	I
Acute Inhalation LC_{50} - rat (MRID 43530401)	> 0.588 mg/L	III
Eye Irritation - rabbit*	corrosive	I
Dermal Irritation - rabbit*	slight to severe	II
Dermal Sensitization - guinea pig*	negative	-

* This study is a requirement for manufacturing-use and end-use products (40 CFR 158). The bronopol data have been generated on the TGAI and are presented here for informational purposes.

In an acute oral toxicity study with rats dosed with bronopol (ai $\geq$ 98.8%), clinical signs of sedation, nasal exudate, gasping, wheezing, cyanosis, and convulsions were noted. The acute oral LD_{50} was 307 mg/kg for males and 342 mg/kg for females. Bronopol is moderately toxic by the oral route. (MRID 00098396)

Results from an acute dermal toxicity study while inadequate, suggest bronopol is highly toxic by the dermal route. Bronopol (ai

$\geq$ 98.8%) was administered to 2 male rats per dose at the dose levels of 0, 64, 160, 400 or 1000 mg/kg. Clinical signs noted were edema, hemorrhage, labored breathing, prostration, and lung congestion. The results of this study suggest that the acute dermal LD_{50} is 64 to 160 mg/kg. (MRIDs 00098396 and 00138755) A new study is not required due to the corrosive properties of bronopol.

Two acute inhalation studies suggest bronopol is slightly toxic to practically non-toxic for this end point. For risk assessment purposes the Agency has used the most conservative data and placed bronopol in toxicity category III for the inhalation route.

In one inhalation study, piloerection, hunched posture and hydronephrosis were observed in male and female rats at the 0.089 mg/L concentration of bronopol (ai $\geq$ 98.8%). Clinical signs observed in the 0.588 mg/L group included diffuse red lungs, sore eyelids, and severe dermatitis and ulceration on the head (attributed to dermal exposure). Particle size was 1.3-6.7 µm. The Agency concludes from the results of this study that bronopol is slightly toxic with an acute inhalation LC_{50} > 0.588 mg/L. (MRID 43530401)

In the second inhalation study, male rats were exposed to concentrations of 0, 0.05, 0.5 or 5.0 mg/L of bronopol (ai $\geq$ 98.8%). Particle size was 1-5µ (50-81%) and 1-15µ (78-92%). Clinical signs noted were eye irritation, dyspnea, profuse mucus production and lethargy during exposure and chronic pneumonitis thereafter. The LC_{50} determined in this study is > 5 mg/L.(MRID 00098397)

In a primary eye irritation study, bronopol (ai $\geq$ 98.8%) was instilled as a 5% solution in polyethylene glycol 400 to rabbits. Strongly irritating (redness and swelling of the conjunctiva, with moderate discharge) effects were noted 1 hour after dosing and subsided in all but one rabbit by the 7th day after treatment. The results of this study determined that bronopol is a corrosive eye irritant, placing it in toxicity category I. (MRID 00160998)

In a primary dermal irritation study, bronopol (ai $\geq$ 98.8%) was tested at 0, 0.5, 2 or 5% in aqueous methylcellulose. Slight to moderate erythema and slight to severe edema was noted on the intact skin of females at 24 hours after termination of the 6-hour exposure. The results of this study determined that bronopol was a slight to severe irritant, placing it in toxicity category II. (MRID 00098396)

In a study to determine the dermal sensitization potential of bronopol (ai $\geq$ 98.8%), guinea pigs received dermal applications of 1% in acetone. Bronopol was determined not to be a skin sensitizer after three induction treatments on the outer surface of each ear and one week later, one challenge treatment on the back and flank. A positive control response was obtained with DCNB (dinitrochlorobenzene). (MRIDs 00098398 and 00138755)

b. Subchronic Toxicity

In an oral toxicity study, male and female SPF rats, 20/sex/group, were administered bronopol (ai $\geq$ 98.8%) daily by gavage for 13 weeks. The dose levels used were 0, 20, 80 or 160 mg/kg/day. Due to high mortality, dosing at the 160 mg/kg level was stopped after 8 days and survivors were sacrificed on day 9. In the low-dose group, 1 female died during week 10, 1 male had kidneys with distended tubules containing eosinophilic material and another male had kidneys with dilated tubules containing the eosinophilic material in the corticomedullary junction. In the mid-dose group, 7 males (35%) and 9 females (45%) died, and gaseous and fluid distention of the gastrointestinal (GI) tract was seen at autopsy. Other toxic signs observed in the mid-dose group were respiratory distress (gasping, wheezing) in the majority of rats, decreased body weight gain in males (7-20%) throughout the study and in females (12-16%) during the first 2 weeks of treatment when compared with the controls, and distended or dilated tubules with eosinophilic material in the kidneys of one male. In the high-dose group, males and females weighed 29% and 13%, respectively, less than did the controls before they died during the first week after dosing. Other toxic signs in the high-dose group included severe respiratory distress and gaseous or fluid distention of the GI tract in the majority or rats, and hemorrhagic foci in and raised white areas on the mucosa of the glandular stomach in a few rats. Many rats exhibited GI lesions (superficial ulceration with underlying inflammation, epithelial hyperplasia and hyperkeratosis) and regressive changes in the thymus marked by almost complete absence of lymphatic tissue. The macroscopic and microscopic changes noted above indicate that bronopol is a severe GI irritant. Based on the above findings, the NOEL and LOEL for systemic toxicity, for both sexes, are 20 mg/kg/day and 80 mg/kg/day, respectively. (MRID 00098384)

In an oral toxicity study with male and female beagle dogs, 3/sex/group were administered bronopol (ai $\geq$ 99.2%) daily by gavage for 13 weeks. The dose levels used were 0, 4, 8 or 20 mg/kg/day and were based on the results of a preliminary study in which 2 beagle dogs (male and female) were dosed daily at levels of 20-40 mg/kg for 2 weeks.

Treatment-related effects, observed only in the high-dose group, were increased liver (15%) and spleen (39%) weights, when organ weights were expressed as percentages of body weights. Based on these findings, the NOEL and LOEL for systemic toxicity, for both sexes, are 8 mg/kg/day and 20 mg/kg/day, respectively. (MRID 00098399)

In a dermal toxicity study, male and female New Zealand white rabbits, 5/sex/group, were exposed (abraded skin, dorsolumbar region) to bronopol (ai $\geq$ 98%) for 3 weeks (6 hours/day, 7 days/week). Bronopol was suspended in 2.5% aqueous methyl cellulose solution at concentrations of 0, 0.2% or 0.5% (w/v) and a dose volume of 1 mL/kg was applied to an area of 10 cm^2 (5% of total body surface). Treatment with the vehicle (methyl cellulose) produced local skin irritation (slight to well defined erythema) in all of the control rabbits. Similar reactions, although possibly more persistent, were seen in rabbits treated with 0.2% bronopol. Treatment with 0.5% bronopol caused stronger dermal reactions (moderate erythema and edema, thickening, hardening and sloughing) and involved extensive scabbing in the treated area. Neither test suspension induced any other signs of toxicity or mortality. Based on dermal irritation, 0.2% bronopol (2 mg/kg/day) is the NOEL and 0.5% bronopol (5 mg/kg/day) is the LOEL. (MRID 00098401)

c. Chronic Toxicity and Carcinogenicity

In a chronic feeding/carcinogenicity study, Sprague-Dawley rats, 45/sex/dose in the main group and 15/sex/dose in the satellite group, were administered bronopol (purity or a.i. content: $\geq$ 99.7%) in acidified (pH 4) drinking water for 104 weeks. Based on the results of a preliminary study, the doses of bronopol selected for this study were 0, 10, 40 or 160 mg/kg/day (Groups 1, 2, 3 and 4, respectively). The actual intake of bronopol (group mean values for weeks 0-104) was 0, 10.5, 40.2 or 152.2 mg/kg/day for the males and 0, 10.4, 40.7 or 158.4 mg/kg/day for the females. The satellite group was used for the laboratory investigations (hematology, clinical chemistry and urinalysis).

Treatment-related effects were observed only in Groups 3 and 4. However, the unpalatability of bronopol reduced the water intake, in a dose-related manner, in all treated groups. Relative to the control values, the statistically significant ($P < 0.001$) reduction in water intake in Group 2 (10 mg/kg/day) occurred mostly during the first 52 weeks and was 14-25% for the male rats and 10-12% for the female rats.

In Group 3 (40 mg/kg/day), treatment-related effects included (a) lower food intake (7%) during weeks 53-78 for the males; (b) reduced

weight gain (20-52%, $P < 0.01$ or 0.001) during weeks 27-78 for the males; and (c) squamous metaplasia, inflammation or atrophic acini in the salivary glands of 12/25 (48%) males and 3/23 (13%) females. Relative to the control values, water consumption was reduced by 22-37% ($P < 0.001$) for the male rats during weeks 1-78 and by 15-24% ($P < 0.05$, 0.01 or 0.001) for the female rats throughout the dosing period.

In Group 4 (160 mg/kg/day), treatment-related statistically significant ($P < 0.01$ and/or 0.001) effects included (a) reduced grooming activity in both sexes during the second year of dosing; (b) high mortality in the males (80% in each the main and the satellite groups) and the females (62% in the main group and 67% in the satellite group); (c) decreased weight gain during weeks 3-78 among males (13-84%) and during weeks 7-78 among females (11-53%); (d) weight loss during weeks 78-104 among males and females; (e) lower food intake among males (9-16%) during weeks 13-104; (f) decreased absolute weights of heart (29%), liver (35%), lungs (12%), seminal vesicles (47%), testes (20%) and thyroid (26%), all in males; (g) increased relative weights of adrenals, brain, kidneys, liver and lungs in males and females; (h) increased relative weights of pituitary in males; (i) stomach lesions in 20/54 (37%) males and 15/52 (29%) females, whereas only 1/56 (1.8%) control males and 1/59 (1.7%) control females had these lesions; (j) increased incidence of progressive glomerulonephrosis in males (48% vs 28% in controls) and females (38% vs 7.7% in controls); (k) sinusoid dilatation in the gastric lymph node in 33% males and 23% females, whereas none was observed in the controls; and (l) squamous metaplasia, dilatation of the ducts, acinar atrophy and/or inflammation of the salivary glands in 12/13 (92%) males and 11/20 (55%) females. Relative to the control values, water consumption was reduced by 32-53% for the male rats and by 24-40% for the female rats throughout the dosing period. Because of a significant decrease in water consumption, the urine output was also reduced (10-46% for males and 31-40% for females). Based on the above findings, the systemic NOEL and LOEL for both sexes are 10 mg/kg/day and 40 mg/kg/day, respectively.

Bronopol was not carcinogenic in this study. The most frequently observed tumors were pituitary adenoma in both sexes and mammary fibroadenoma in the females, but the incidence (number of rats with tumor/number of rats examined) was dose-unrelated and was lowest in the high-dose group. The incidence of pituitary adenoma in the control, low-dose, mid-dose and high-dose male rats was 10/43 (23%), 14/43 (32%), 7/42 (17%) and 2/41 (5%), respectively. The corresponding incidences in the female rats were 20/44 (45%), 21/45 (47%), 23/42 (55%) and 14/38 (37%), respectively. The incidence of mammary fibroadenoma in the

control, low-dose, mid-dose and high-dose female groups was 35/44 (79%), 36/45 (80%), 30/42 (71%) and 19/38 (50%), respectively. (MRIDs 00098386, 00115645 and 00138766)

In another carcinogenicity study, groups of CFLP mice of Swiss origin, 52/sex/dose, were administered bronopol dermally on Monday, Wednesday and Friday of each week, for 80 weeks. The purity of bronopol used was $\geq$ 99.7%. Based on the results of a 4-week dermal preliminary study, the concentrations (doses) of bronopol selected for this study were 0, 0.2% and 0.5% as solutions in acetone (90%): water (10%), 0.3 mL/mouse/day. These doses were equivalent to 0, 0.6 and 1.5 mg of bronopol/mouse/day, respectively, or (assuming the weight of a mouse to be about 30 g) to 0, 20 mg/kg/day and 50 mg/kg/day, respectively. Dermal exposure was used because, at that time, bronopol was intended for use in topical preparations, as a preservative at a minimal concentration of 0.01% and as an antibacterial agent at a maximal concentration of 0.5%.

The only treatment-related effects observed were a minimal hair loss in the high-dose (0.5%) males and females, and a decreased body weight gain in the high-dose males. Hair loss was observed at the periphery of the shaved area during the first 3 weeks of treatment among "some mice" (numbers were not reported). Decreased body weight gain occurred during weeks 26-80, but especially during weeks 26-52 when the high-dose males gained 47% ($P < 0.01$) less weight than did the controls.

Bronopol was not carcinogenic in this study. Although only two dose levels were used, these appeared sufficient to evaluate the carcinogenicity of bronopol by dermal route. The numbers of tumor-bearing male mice in the control, low-dose and high-dose groups were 24/50 (48%), 21/50 (42%) and 23/50 (46%), respectively. The corresponding incidences for the female tumor-bearing mice [number with tumor(s)/number examined] were 25/51 (49%), 18/50 (36%) and 22/49 (45%), respectively. The most frequently observed tumors were lymphoma in the lymphoreticular system and lung tumors reported only as tumors Grades 1, 2, 3 or 4. The incidence of lymphoma in the control, low-dose and high-dose male mice was 5/50 (10%), 3/50 (6%) and 6/50 (12%), respectively. The corresponding values for the female groups were 5/51 (9.8%), 8/50 (16%) and 10/49 (20.4%), respectively. The incidence of lung tumors (all grades) in each one of the male groups was 13/50 (26%). The incidence of lung tumors in the control, low-dose and high-dose female mice was 10/51 (19.6%), 9/50 (18%0) and 11/49 (22.4%), respectively. None of the tumor incidences observed in the treated male and female mice was statistically significant when compared with the control mice.

Non-neoplastic lesions were observed most frequently in the lungs (lymphoid aggregations and/or alveoli with macrophages) and liver (vacuolated, distended or degenerated hapatocytes) of male and female mice, and in the ovaries (cysts), but were treatment-unrelated. (MRID 00098387)

The carcinogenic potential of bronopol was evaluated by the Agency's Office of Pesticide Programs, Reference Dose (RfD)/Peer Review Committee in 1995. The Committee classified bronopol as a Group E carcinogen (evidence of noncarcinogenicity for humans), based on a lack of evidence of carcinogenicity in acceptable studies with two animal species, rat and mouse. The dose levels used in both studies were considered to be adequate for carcinogenicity testing. This conclusion was based on high mortality, stomach lesions and severe reduction in body weight gain or weight loss in the rats, and on moderate reduction in body weight gain in the mice and lack of statistically significant increases in tumor frequencies between dose groups.

d. Developmental Toxicity

Bronopol (purity: 98%) was administered by gavage in acidified (pH 4) purified water to groups of 24 mated Sprague-Dawley rats at dose levels of 0, 10, 28 or 80 mg/kg/day from gestation day (g.d.) 6 through 15 (g.d. 0 = detection of sperm in vaginal lavage). Females were observed for appearance of clinical signs and mortality, and body weight and food consumption were determined at intervals during gestation. Animals were sacrificed on g.d. 20 and reproductive observations were made. Uteri were weighed and examined for live fetuses and intrauterine deaths. Fetuses were weighed, sexed and examined for external, visceral and skeletal alterations.

Marginal evidence of maternal toxicity was reported at the highest dose tested and was evidenced by decreased body weight gain (80% less than that for the control; $P \leq 0.01$) during g.d.s 6-7, and slightly reduced (1%) body weight at day 7 when compared with the controls. No animals were described in the report as having dose-related clinical signs. There were no developmental effects that could be attributed to the administration of bronopol. Based on these findings, the NOEL for maternal toxicity is $\geq$ 80 mg/kg/day (HDT) and the NOEL for developmental toxicity is also $\geq$ 80 mg/kg/day. The highest dose tested is considered adequate because the results of a range-finding study indicated that doses $\geq$ 100 mg/kg/day, administered by gavage, caused severe gastrointestinal irritation that led to death. (MRIDs 43598701 and 43608501)

In another developmental toxicology study, groups of 18, 19 or 20 mated female New Zealand White Rabbits received bronopol (purity: 99.8%) by gavage during g.d. 7 through 19 and were sacrificed on g.d. 28. Aqueous solutions of bronopol, prepared just before use and acidified to pH 4, were administered daily at the nominal dose levels of 0 (vehicle control), 5, 20, 40 or 80 mg/kg/day and the dose volume of 2 mL/kg. Separate solutions were prepared for each dose level and individual body weights were obtained daily during the treatment period. The analytical concentrations of bronopol in dosing solutions were very close to the nominal concentrations (95-100%). The dose levels of bronopol used in this study were selected by the sponsor after examination of data from a range-finding study in mated rabbits (Report No. BON/2/91; not submitted to the Agency for review).

The following maternal effects were observed only in the 80 mg/kg/day group: (a) body weight loss (0.06 kg, $P < 0.001$) during the first 3 days of treatment (g.d. 7-9); (b) decreased body weight gain during g.d. 9-15 (13%); and (c) decreased food consumption during g.d.s 7-11 (38%, $P < 0.001$) and during g.d. 11-15 (19%).

The following developmental effects were observed only in the 80 mg/kg/day group: (a) decreased fetal body weight in both sexes (10%, $P < 0.05$); (b) increase in fetuses with major external/visceral and skeletal abnormalities (6.9% vs 0% in the concurrent control group and 1.8% in the historical controls); (c) increase in fetuses with minor skeletal abnormalities (29.5%, $P < 0.01$ vs 10.2% in the concurrent control group; and (d) an increased incidence of fetuses with skeletal variants (unossified forelimb [8%] and hindlimb [16%] epiphyses). Based on these findings, the NOEL and LOEL for maternal toxicity are 40 mg/kg/day and 80 mg/kg/day, respectively. The developmental NOEL and LOEL are also 40 mg/kg/day and 80 mg/kg/day, respectively. (MRIDs 42319601 and 42648201)

e. Reproductive Toxicity

Charles River COBS CD strain rats (13 males and 26 females/group) were administered bronopol (purity: 99.9%) in drinking (tap) water during the premating (80-87 days), mating, gestation and lactation periods. The water was adjusted to a pH4 with hydrochloric acid to ensure the stability of bronopol. The study involved parental group F_o and litters F_{1a} and F_{1b}, and parental group F_1 and litters F_{2a} and F_{2b}. The F_{1b} rats were used as the F_1 parents. The target concentrations of bronopol were 0, 0.025, 0.07 and 0.2%, corresponding to 0, 25, 70 and 200 mg/kg/day, respectively. The mean achieved doses of bronopol for the F_o

and F_1 males and females were 0, 22.5, 55.2 and 147 mg/kg/day, respectively. Dose concentrations were based on the results of a range-finding study. (MRID 40660907)

Nothing remarkable was observed in the low-dose (25 mg/kg/day group. Systemic toxicity was observed mostly in the mid-dose (70 mg/kg/day) and high-dose (200 mg/kg/day) groups, in both generations. Compared with the concurrent controls, toxic signs observed in the mid-dose group included an increase in kidney weight of the F_o females (14.5%, $P < 0.01$), decreased liver weight of the F_1 males (11%) and females (11%, $P < 0.05$, relative weight or organ/body weight ratio) and an increased incidence of nephropathy in the F_o males (4/10 vs 2/10 in the controls) and the F_o females (3/10 vs 0/10 in the controls).

Toxic signs noted in the high-dose group were (a) decreased body weights of the F_o and/or F_1 females during the premating (7-24%, $P < 0.05$ or 0.01), gestation (5-16%) and/or lactation (8-11%) periods; (b) decreased body weights of the F_1 males (11-22%, $P < 0.05$ or 0.01); (c) decreased food consumption of the F_o males (5-18%) and the F_o and F_1 females (6-16%); (d) increases in organ weights as follows: adrenals (22%, $P < 0.05$, F_o females), kidneys (36%, $P < 0.01$, F_o females and 14%, $P < 0.05$, F_1 males, both relative) and thyroid/parathyroid (26%, $P < 0.05$, F_1 males); (e) decreases in liver weight of the F_1 males (21%, $P < 0.01$); and (f) and an increased incidence of nephropathy in the F_o males (6/10 vs 2/10 in the controls) and females (9/10 vs 0/10 in the controls).

Reproductive toxicity was observed only in the high-dose group as evidenced by a slight decrease in the female fertility index during the F_{1a} mating (75% vs 87.5% in the controls).

Based on the above findings, the NOEL and LOEL for systemic toxicity are 25 mg/kg/day and 70 mg/kg/day, respectively. The NOEL and LOEL for reproductive toxicity are 70 mg/kg/day and 200 mg/kg/day, respectively. (MRID 40660901 main study; MRID 41916502 - additional data; and MRID 40660907 - range-finding study)

f. Mutagenicity

Bronopol was negative for mutagenicity in the Ames test using *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100, with and without metabolic activation. The metabolic activation system (S-9 microsomal fraction) was obtained from the liver of male rats induced with Aroclor 1254. The highest concentrations of bronopol tested were 125 µg and 62.5 µg/plate, in the presence and absence of S-9,

respectively. Concentrations of bronopol higher than those tested were cytotoxic. The following positive controls were used: cyclophosphamide (TA1535), neutral red (TA1537) and 2-aminofluorene (TA1538, TA98 and TA100). Distilled water was the solvent for bronopol and dimethyl sulfoxide (DMSO) for positive controls. This study satisfies the requirements for genetic effects, Gene Mutations. (MRID 40660902)

Bronopol was negative for mutagenicity in the V79 cell mutation assay (Chinese hamster lung fibroblasts), with and without metabolic activation, when tested at concentrations up to 8 µg/mL, the maximum allowed by cytotoxicity. The metabolic activation system (S-9 microsomal fraction) was obtained from the livers of male rats induced with Aroclor 1254. N-methyl-N'-nitro-N-nitrosoguanidine (MNNG) was used as a positive control in the absence of S-9 and 7,12-dimethylbenz(a)anthracene (DMBA) in the presence of S-9. Distilled water was the solvent for bronopol and dimethyl sulfoxide (DMSO) was the solvent for the positive controls. Mutagenic potential was evaluated by comparing the frequencies of the 6-thioguanine (6-TG)-resistant mutants observed in the treated cultures with those observed in the negative control (distilled water) cultures. This study satisfies the requirements for genetic effects, Gene Mutations. (MRID 40660903)

In the mammalian cells (human lymphocytes) in culture cytogenetic assay, bronopol was not clastogenic in the presence of the metabolic activation system (S-9 microsomal fraction) and was clastogenic in the absence of S-9, but only at 30 µg/mL, the highest concentration allowed by cytotoxicity. Other concentrations of bronopol tested were 10 and 20 µg/mL without S-9 and 20, 30 and 40 µg/mL with S-9. Positive controls used were mitomycin C (0.5 µg/mL) in the absence of S-9 and cyclophosphamide (25 µg/ mL) in the presence of S-9. Distilled water was a solvent for all test compounds and was also a negative control. The observed clastogenicity (significant increases in the percentage of cells with aberrations, relative to the negative control values) was attributed by the testing facility to formaldehyde, one of the degradation products of bronopol and a known clastogen. Other degradation products of bronopol were not identified. This study satisfies the requirements for genetic effects, Structural Chromosomal Aberrations. (MRID 40660904)

Bronopol was negative in the *in vivo* micronucleus assay, in which male and female CD1 mice received single oral doses of bronopol (80 or 160 mg/kg of body weight) and then were sacrificed at 24, 48 and 72 hours after dosing. At all sampling times, the bronopol-treated and negative control mice had similar numbers of micronuclei per 1000 polychromatic erythrocytes of femur bone marrow examined, per animal. The 160 mg/kg

dose was the maximum tolerated dose (MTD), as judged by mortality (4/24 males and 4/24 females) and by reduced numbers of polychromatic erythrocytes (indicative of a reduction in hemopoiesis) in some surviving mice, 72 hours after treatment. The positive control, cyclophosphamide (75 mg/kg), significantly increased the numbers of micronuclei in both sexes. Sterile double-distilled water was used as solvent for the test materials and was also a negative control. This study satisfies Guideline requirements for genetic effects classified as Other Genotoxic Effects. (MRID 40660905)

g. Metabolism

The rat metabolism data for bronopol consist of four separate studies conducted with male and female Sprague-Dawley rats. Animals were treated by gavage with ^{14}C bronopol (radiochemical purity: > 95-100%). In the first study animals received a single dose of 10 mg/kg. The second study employed a higher dose of 50 mg/kg. Doses higher the 50 mg/kg caused respiratory problems and death. The third study's dose was 10 mg/kg (14 daily doses of nonradioactive, 100% pure, bronopol, followed by one dose of ^{14}C-bronopol). Urine, feces and CO_2 were collected for 7 days after dosing, at which time the rats were killed and the tissues examined for radioactivity. Because, irrespective of the dose, most of the administered ^{14}C was excreted in urine (64-78% in 24 hours and 68-83% in 7 days), urine was used for the identification of metabolites in the fourth study. Feces, CO_2 and tissues represented minor routes of excretion of ^{14}C. Very little ^{14}C was also detected in the whole blood and plasma.

From the results of these four studies the Agency concluded that bronopol administered orally was rapidly absorbed and rapidly excreted by the rats of both sexes, with urine being the major route of excretion. The only metabolite identified in urine was BTS 23 913 (2-nitropropane-1,3-diol or desbromo-bronopol), accounting for 45-50% of the radioactivity taken for analyses. The remaining radioactivity was not identified (one radioactive peak and radioactivity not resolved into peaks). Unchanged bronopol was not detected. (MRID 43289501)

h. Reference Dose

The Agency's Office of Pesticide Programs, Reference Dose (RfD)/Peer Review Committee recommended that the RfD for bronopol be established at 0.1 mg/kg/day. This value was based on the systemic NOEL of 10 mg/kg/day from the rat chronic feeding study (MRIDs 00098386, 00115645 or 00138766) and an uncertainty factor (UF) of 100 (10 for interspecies and 10 for intraspecies variability). Decreased food

consumption and body weight gain, and squamous metaplasia and inflammation in ducts of salivary glands were observed at the next level tested, 40 mg/kg/day. (RfD Peer Review Committee Report, June 12, 1995) Although bronopol has no food uses at this time, the RfD has been established because the data base is available and because of possible long-term exposure to bronopol containing products.

It should be noted that this class of chemicals (disinfectants, microbiocides, microbiostats, sanitizers) has not been reviewed by the FAO/WHO Joint Committee on Pesticide Residues (JMPR).

i. Toxicological Endpoints of Concern

EPA believes the appropriate toxicological endpoint for assessing short-term (1-7 days) or intermediate-term (7-90 days) occupational or residential exposure from bronopol is the 40 mg/kg/day NOEL for maternal and developmental toxicity which was observed in the rabbit developmental toxicity study. (MRID 42319601) Decreased maternal body weight gain and food consumption during most of the gestation period and several developmental effects were observed in that study at 80 mg/kg/day, the LOEL.

The toxicological endpoint for assessing chronic occupational exposure is the NOEL of 10 mg/kg/day from the 2-year rat feeding study. This study was also used to establish the RfD.

In the absence of dermal absorption data (due to the corrosive properties of bronopol), NOELs derived from oral studies were used directly and without modification to estimate NOELs for dermal exposure. Therefore, the Agency assumed a default of 100% dermal absorption.

2. Exposure and Risk Assessment

a. Dietary Exposure and Risk Assessment

Currently there are no registered food uses of bronopol, therefore, a dietary exposure and risk assessment is not needed.

b. Occupational Handler Exposure Assessment

(1) Occupational Exposure Scenarios

The Agency conducts an occupational exposure assessment for a pesticide active ingredient if (1) certain toxicological criteria

are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. The Agency believes this is the case from the use of bronopol products. Above, the Agency described its conclusions regarding toxicology end points of concern for bronopol. Below there is discussion of potential exposures from the use of these products.

The Agency has determined that there is a potential for exposures to mixers, loaders, applicators, or other handlers from applications of bronopol containing products in commercial and industrial settings. The Agency has identified two levels of handler exposures:

> primary handlers -- persons or handlers using (mixing, loading, applying) end-use bronopol products;
>
> secondary handlers -- persons using (mixing, loading, applying or otherwise handling) products, such as paints and adhesives, to which a bronopol product has been added.

Based on the use patterns, the Agency has identified four major bronopol exposure scenarios for primary occupational handlers: (1) metering-pump applications with the soluble concentrate liquid formulation, (2) open-pour applications with the soluble concentrate liquid formulation, (3) open-pour applications with the soluble concentrate solid formulation, and (4) application of solid tablets and pellets. The application of paint treated with bronopol is considered by the Agency the worse-case for secondary handler exposure and risk.

(2) Occupational Exposure Estimations

Exposure data specific to bronopol are unavailable nor are there surrogate exposure data for all use-patterns. However, the exposure scenarios selected for assessment are representative of reasonable worst-case exposures to bronopol. To estimate unit exposure (UE) and actual daily exposure (ADE), the Agency relied on surrogate data from a study (amended 1992) submitted by the Chemical Manufacturers Association (CMA) for antimicrobial pesticide products. Based on these data, inhalation exposure is believed to be minimal for the scenarios evaluated. Actual daily

exposure (ADE), which is used to estimate risk, is calculated using the following formula:

$$ADE = \frac{unit\ exposure\ (\mu gm/lb\ a.i.\ X\ application\ rate\ (lb.\ a.i./A.)}{body\ weight\ (kg)}$$

The Agency's assumptions for mixers and loaders include both short-term (1-7 days per year) and intermediate-term (7-90 days per year) exposure as a reasonable worst-case estimate. The Agency also assumes dermal absorption is 100% and body weight is 60 kg.

Estimates for short and intermediate-term exposures from the above equation and assumptions are presented in Table 2 for the different occupational primary handler scenarios. The estimates suggest occupational exposures of bronopol to handlers are low ($\leq$0.127 mg/kg/day) except for the liquid soluble concentrate pour applications for cooling water systems (2.849 mg/kg/day).

Table 2: Short and Intermediate-Term Exposures and Risks (MOEs) for Handlers from uses of Bronopol

Application Method	Setting	ADE (mg/kg/day)	**MOE**
Metered Pump Soluble Concentrate Liquid	Oil Well Mud Packer Fluid	< 0.001	40,000.00
	Oil Well Injection Fluid	0.0235	1,702.13
	Paint Manufacturing	< 0.001	40,000.00
	Pulp and Paper	0.00339	11,799.41
	Cooling Water Systems	0.02507	1,595.53
	Metal Working Fluids	0.02264	1,766.78
Open Pouring Soluble Concentrate Liquid	Oil Well Mud Packer Fluid	0.00877	4,561.00
	Cooling Water Systems	2.849	14.04
	Paint Manufacturing	0.00975	4,102.56
	Metal Working Fluids	0.00927	4,314.99
Open Pouring Soluble Concentrate Solid	Oil Well Mud Packer Fluid	0.0273	1,465.20
	Cooling Water Systems	0.12741	313.95
	Paint Manufacturing	0.03185	1,255.89
	Metal Working Fluids	0.03792	1,054.85
Place Solid (tablets and package)	Laboratory Water Recirculating Waterbaths	0.06233	641.75
	Industrial and commercial air conditioning and humidifying systems	< 0.001	40,000.00

For the secondary handler exposure scenario (painters) the Agency has no bronopol specific exposure data for painter exposure. Surrogate exposure data were used from the Pesticide Handlers Exposure Database. In this database gloves were not worn and, the Agency assumes from bronopol product label directions for use that the paint contains 500 ppm of bronopol. Also assumed is a painter exposure frequency of 250 times per year which is considered chronic exposure. Estimated exposures were calculated for occupational painters and are presented in Table 3.

Table 3. Chronic Term Exposures and Risk (MOE) to Painters from Bronopol-Treated Paint

Setting	UE[1] mg/lb ai	lb ai/day[2]	BW (kg)	Actual Daily[3] Exposure (mg/kg/day)	MOE[4]
Paint Brush	290 (dermal) single layer, no gloves	0.025	60	0.12	333
	38 (dermal) single layer, chemical resistant gloves (used 90% PF)	0.025	60	0.016	2,500
	0.57 (inhalation)	0.025	60	2.4×10^{-4}	N/A[5]

[1] Dermal grade A,B,C from PHED.
n = 15 medium confidence. Inhalation grade C, n = 15 medium confidence
[2] 500 ppm (bronopol). One gallon paint equal to 10 lbs
[3] ADE (mg/kg/day) = UE x (lb ai used per day) / 60 kg
[4] MOE = NOEL / ADE x dermal absorption
[5] Inhalation exposure is very small relative to the dermal exposure and therefore MOEs for the inhalation component were not estimated (either alone or combined with the dermal.)

c. Occupational Handler Risk Assessments

To estimate risks from exposures to bronopol, the Agency compared the margin of exposure (MOE) between the NOELs from the toxicological end points of concern and the estimates of exposure (ADE). Where 40 mg/kg/day is the NOEL for short-term and intermediate-term exposures from the developmental toxicity study described above, the Agency calculated occupational exposures as presented in Table 2. The following equation was used for estimating the risk, expressed as a margin of exposure (MOE).

$$MOE = \frac{NOEL}{ADE} = \frac{40\ mg/kg/day}{ADE}$$

As shown in Table 2, the calculated MOEs for the short and intermediate-term exposure scenarios are very high, the application scenario of pouring liquid concentrates into cooling water systems. Here the MOE is 14. Use of a metering pump delivery system for the liquid application of bronopol products to this use site would adequately mitigate this risk (see Sections IV and V).

Using the assumptions described above for secondary occupational exposure and the chronic endpoint NOEL of 10 mg/kg/day the MOEs are greater than 100 for painters (Table 3). Since the MOEs for painter exposure do not suggest adverse risk and this use represents the worst case

chronic exposure scenario, assessments for other chronic scenarios were not conducted.

d. Occupational Post-Application Exposure and Risk

The Agency believes there are potential exposures following applications of bronopol containing end-use products in commercial and industrial settings. Two levels of post-application exposures have been identified. The first is primary post-application exposures -- persons in and near areas where bronopol products are being or have recently been applied. In these areas there may be airborne exposures to bronopol, resulting in dermal and inhalation exposures from mists or steams. The key exposure scenarios include: (1) exposures following applications of bronopol to open vats of liquids, such as paper-pulp, adhesives, coatings, emulsions, and paints; and (2) exposures to persons maintaining equipment, such as water systems and other industrial equipment, which contain a product treated with bronopol. The other occupational post-application exposure is secondary exposure to persons occupying areas recently painted with bronopol-containing paint and exposures in areas where bronopol containing paper products are being manufactured. The Agency's concerns about potential post-application exposures to bronopol are minimal because the MOEs for occupational exposure are not exceeded (except for the open pouring of liquid concentrates in cooling water systems) and even less exposure would be expected during post-application.

e. Residential Exposure and Risk

At this time there are no end-use pesticide products containing bronopol that are intended for homeowner use. Therefore, there is no concern for the homeowners as primary handlers.

However, based on the use patterns, the Agency has identified two potential secondary homeowner handler exposure scenarios. They are (1) exposure while handling bronopol-containing paint, and (2) exposure while handling bronopol-containing adhesives. The Agency has also identified two bronopol exposure scenarios for secondary homeowner post-application exposures: (1) exposures while occupying areas recently painted with bronopol-containing paint, and (2) exposures while occupying areas where bronopol-containing adhesives have been used. Based on the occupational painter risk assessment as a worst case scenario, EPA believes risk associated with these residential exposures are not of concern.

f. Formaldehyde Exposure and Risk

The Agency has also looked at potential formaldehyde exposure to products containing bronopol since formaldehyde has been identified as a degradate of bronopol under aqueous alkaline conditions. However, the Agency is not concerned about handlers or post-application exposures to formaldehyde because of bronopol's slow decomposition rate. When mixed with water the half-life of bronopol decomposition to formaldehyde is 18 years at pH 4; 1.5 years at pH 6; and 2 months at pH 8 at 20°. Also, post-application settings are addressed for formaldehyde by the Occupational Safety and Health Administration(OSHA). OSHA has a comprehensive workplace standard for formaldehyde for the protection of workers in the industrial setting due to formaldehyde release in the workplace. The OSHA formaldehyde standard was established as a rule in May 1992, and set a permissible exposure level (PEL) of 0.75 ppm in the workplace. The standard also prescribes that certain actions should be taken if monitoring shows levels of 0.50 ppm. This standard requires monitoring before workers enter the premises following use of formaldehyde, or when potential ambient formaldehyde is generated from other chemicals.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the hazard of bronopol to nontarget terrestrial and aquatic organisms for the uses specified in the RED.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of bronopol to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); one subacute dietary study (LC_{50}) on one species of waterfowl (preferably the mallard duck) or one species of upland game bird (preferably bobwhite quail or ring-necked pheasant). Tables 4 and 5 summarize the available data for avian acute oral toxicity and avian subacute dietary toxicity.

Table 4.	Avian Acute Oral Toxicity Findings			
Species	**% A.I.**	**LD_{50} mg/kg**	**MRID No.**	**Toxicity Category**
Mallard	99.4	509.5	00104689	slightly toxic

Table 5.	Avian Subacute Dietary Toxicity Findings			
Species	**% A.I.**	**LC_{50} ppm**	**MRID No.**	**Toxicity Category**
Northern Bobwhite	100	4487.6	00148526	Slightly toxic
Mallard	100	> 10,000	00148941	Practically nontoxic

Bronopol is slightly toxic to avian species on an acute oral basis and slightly toxic to practically nontoxic on a subacute dietary basis. The guideline requirements are fulfilled. (MRID 00104689, 00148526, 00148941)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of bronopol to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study. The study should use a coldwater species (preferably the rainbow trout) or a warmwater species (preferably the bluegill sunfish). Available data for acute fish toxicity are summarized in Table 6.

Table 6.	Freshwater Fish Acute Toxicity Findings			
Species	**% A.I.**	**LC_{50} ppm a.i.**	**MRID No.**	**Toxicity Category**
Rainbow trout	100	41.6	00148563	Slightly toxic
Bluegill sunfish	99.7	36.1	00148940	Slightly toxic

The results of the 96-hour acute toxicity studies indicate that bronopol is slightly toxic to fish. The guideline requirements are fulfilled. (MRIDs 00148563, 00148940)

(2) Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity test is a minimum requirement to determine pesticide hazard to freshwater invertebrates. This is preferably done using either first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Table 7 summarizes the data available for freshwater invertebrates.

Table 7. **Freshwater Invertebrate Toxicity Findings**

Species	**% A.I.**	**EC_{50} (mg/l)**	**MRID NO.**	**Toxicity Category**
Daphnia magna	99.4	1.4	0098404	moderately toxic

The data are sufficient to characterize bronopol as moderately toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 0098404)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the estuarine/marine environment in significant concentrations. The aquatic nonfood industrial (oil recovery drilling muds, pulp/paper mill water and secondary oil recovery injection water) uses of bronopol may result in exposure to the estuarine and marine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. Table 8 summarizes available estuarine/marine acute toxicity findings.

Table 8. **Estuarine/Marine Acute Toxicity Findings**

Species	**% A.I.**	**LC_{50}/EC_{50} (ppm ai)**	**MRID No.**	**Toxicity Category**
Eastern oyster (embryo larvae)	99.7	0.77	00148979	Highly toxic
Mysid Shrimp	99.7	5.9	00150674	Moderately toxic
Sheepshead minnow	99.7	59.6	00163176	Slightly toxic

There is sufficient information to characterize bronopol from moderately toxic to highly toxic to estuarine/marine invertebrates. It is slightly toxic to estuarine/marine fish. The guideline requirements are fulfilled. (MRIDs 00148979, 00150674, 00163176).

2. Environmental Fate

The environmental fate database for bronopol is adequate for reregistration purposes. Under current Agency policy for microbiocides, the environmental fate data requirement is minimal -- only a hydrolysis study is required. The hydrolysis study is satisfactory. In addition, the Agency has a partially satisfactory photolysis study; physical and chemical properties (product chemistry).

a. Environmental Fate Assessment

From the limited data and summary information available, the Agency infers that bronopol would have a relatively short half-life upon release into the environment. This conclusion is based on the compound's photoreactivity in water (its activity decreases by one-half in two days), high number of reactive sites, and presumptive degradation by microbes.

The Agency does not have specific data for mobility of bronopol in soil; however, the Agency does not anticipate ground water contamination from the use of bronopol. Although bronopol has high water solubility (approximately 25% w/v), high solubility in polar solvents, low solubility in nonpolar solvents, and favorable partitioning into water, the Agency believes that bronopol's short-lived environmental persistence reduces the potential for groundwater contamination.

Bronopol is stable to hydrolysis under normal conditions. However, at warmer temperatures and/or higher pHs (as encountered in some industrial applications or under atypical environmental conditions), rapid hydrolysis may occur. Under these high temperatures and pHs, hydrolysis products include formaldehyde and lesser amounts of other degradates.

Judging from its low octanol/water ratio (1.5/1) and high solubility in water, bronopol is not expected to bioaccumulate. Accumulation reportedly does not occur in tested mammals and metabolism is also reported to be rapid and complete, as described above.

b. Environmental Fate and Transport

(1) Hydrolysis

An adequate hydrolysis study exists. Hydrolysis is strongly correlated with temperature and pH. Hydrolysis may or may not occur appreciably, depending on conditions. An acceptable study, conducted under conditions different from the Agency's present testing guidelines, concluded that bronopol is stable against hydrolysis in "typical" natural settings. At elevated temperatures (30, 40, 50, and 60°C), in ambient laboratory light and at concentrations of 2000 ppm or higher, the half-life was extrapolated to be the following at 20°C: about 18 years at pH 4, about 1.5 years at pH 6, and approximately 2 months at pH 8. At higher temperatures and/or pHs, as may occur in industrial applications, hydrolysis is greatly accelerated. At 60°C (140°F), half-lives range roughly from 4 days at pH 4 to only 3 hours at pH 8. Under accelerated conditions, degradation is extensive, and formaldehyde is a major hydrolysate. Other degradates produced under these circumstances are 2-hydroxymethyl-2-nitropropane-1,3-diol (tris); 2-bromo-2-nitroethanol; unidentified products which were possibly polymeric; bromide; nitrite (not nitrate); and other trace products such as aliphatic nitro compounds and lightweight gases, but not carbon dioxide. (MRIDs 00164535 and 00163783)

(2) Degradation

A partially satisfactory photodegradation in water study indicates that bronopol rapidly photodegrades at pH 4 under continuous xenon irradiation; approximately one-half of its activity remained after about 24 hours. An equivalent exposure time under natural sunlight would be approximately 2 days (assuming 12 hours each of light and dark). Tris (2-hydroxymethyl-2-nitropropane-1,3-diol), also named tris-hydroxymethyl-nitromethane, a tentatively identified major degradate (up to about 60 percent), which appears to further degrade, but at a slower rate. Another major, but unidentified, "relatively polar" product (component "B") steadily increased, and at the end of the 168 hour (one week) study was up to about 30 percent of the dose. Component "B" was not the putative degradate, 2-bromo-2-nitroethanol. Steadily increasing levels of labeled carbon dioxide derived from the central carbon atom of bronopol indicate that at least one reaction leads to extensive degradation. Although carbon dioxide increased in parallel with unknown component "B," formation of component

"B" and carbon dioxide appears to occur by separate pathways. (MRID 429413-03)

3. Environmental Exposure and Risk

Aquatic nonfood industrial uses of bronopol containing products can result in discharge of effluent to surface waters. These discharges may adversely affect aquatic life in the receiving stream waters. As described above bronopol is moderately toxic to freshwater invertebrates; slightly toxic to freshwater fish; moderately to highly toxic to estuarine/marine invertebrates; and slightly toxic to estuarine/marine fish.

While the hazard to aquatic organisms from bronopol has been characterized, a quantitative risk assessment has not been conducted because the potential risks to aquatic environments are regulated under the EPA Office of Water, National Pollution Discharge Elimination System (NPDES) permitting program. The Agency currently requires that labels for all bronopol products require that discharges to aquatic environments comply with an NPDES permit.

The fuel use of bronopol may be associated with periodic releases into the environment based on purging of the storage tanks. This terrestrial use may result in minimal to no exposure to the environment. All bronopol product labels are required by the Agency to have language that is consistent with disposal of unwanted treated fuel or bottom waters that complies with any applicable federal laws

4. Endangered Species

The Agency does not anticipate any exposure of concern to fish and wildlife, providing that all bronopol products are labeled, handled, and applied as specified in this document and product labels require that discharges to the environment comply with NPDES permitting requirements and Federal laws.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing bronopol active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing bronopol. However, the

Agency is requiring data for compliance purposes on occupational exposure to workers with a Data Call-In that was issued in September 1995. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of bronopol, and lists the submitted studies that the Agency found acceptable.

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

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of bronopol, as specified in this document, 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 bronopol, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of bronopol, as modified in this document, are eligible for reregistration.

C. Regulatory Position

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

1. Occupational Risk Mitigation Measures/Labeling Rationale

a. Personal Protective Equipment/Engineering Controls

For each bronopol end-use product, PPE requirements for pesticide handlers are being set during reregistration for the following reasons:

The Agency is requiring PPE for occupational handlers of bronopol in the loading of (1) liquid bronopol end-use products using open-pouring and metering-pump techniques and (2) dry (pellets, tablets, crystals, or flakes) bronopol end-use products using open-pouring and hand-placement techniques. PPE (long sleeved shirt, long pants, chemical resistant gloves, socks and shoes) were worn by the handlers in the CMA studies that were used to estimate exposures. This requirement will mitigate risks to occupational workers.

The Agency is also concerned about occupational exposure in the cooling water systems use where open pouring of liquid bronopol end-use products can occur. When using the Agency established method to calculate margin of exposure (MOE), this use pattern exceeds the Agency's acceptable levels of exposure. In Section V the Agency outlines the specific application restriction of a metering pump system to mitigate potential risk to occupational workers for this use.

Post-application entry restrictions are not being established at this time for occupational uses of bronopol end-use products, because the Agency believes the potential exposure to bronopol would be less than that to handlers due to dilution, industrial processes, and the stability or slow degradation of bronopol in products that contain it. Additionally, the Agency is not establishing PPE for people applying bronopol treated products (such as paint and adhesives) since exposures are expected to be less than those for handlers applying bronopol end use products.

2. Aquatic Risk Mitigation/Labeling Rationale

The Agency believes that potential hazards to aquatic organisms could exist from the industrial uses of bronopol. All bronopol product labels are required by the Agency to have language that is consistent with NPDES permitting

requirements when direct effluent discharges to aquatic environments occur and that disposal of unwanted treated fuel or bottom waters complies with any applicable federal laws. These environmental risk reduction measures are appropriate to retain for bronopol products.

3. Other Labeling Requirements

The Agency is requiring additional use and safety information to be placed on the labeling of all end-use products containing bronopol to afford supplemental protection to handlers. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of bronopol for the above uses has been reviewed and determined to be substantially complete. The following generic data were required in a September 1995 Data Call-In.

Handler Studies

Any bronopol registrant who has not satisfied generic data requirements for Guidelines 233 and 234, Dermal and Inhalation Exposure, must do so to meet the requirements of reregistration. Failure to do so will result in suspension of affected product registrations under FIFRA, Section 3(c)(2)(B). Compliance is also necessary for product reregistration. Compliance with these generic data requirements can be met in one of two ways. First, affected registrants can make an irrevocable offer to pay compensation to owners of the existing data from the CMA study. These data are MRIDs 41412201, 41742601, and 42587501. Second, affected registrants can offer to conduct and submit new studies. The Agency has issued a DCI to affected registrants in which both options are provided.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Registrants of end-use product registrations which are subject to generic data requirements, and who have not satisfied the generic data requirements for the above handler exposure studies must do as described above.

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

a. PPE/Engineering Control Requirements for Pesticide Handlers

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

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

Minimum (Baseline) PPE/Engineering Control Requirements -- EPA is establishing active ingredient-based minimum (baseline) PPE/engineering control requirements for bronopol end-use products that are intended for occupational use. The minimum (baseline) PPE for such occupational uses of bronopol end-use products are:

"Applicators and other handlers must wear:
--long-sleeve shirt and long pants,
--socks plus shoes, and
--chemical-resistant gloves."*

* For the glove statement, use the statement established for bronopol through the instructions in Supplement 3 of PR Notice 93-7.

For end-use products classified as toxicity category I or II for eye irritation, protective eyewear is also required.

For liquid product formulations applied to cooling water systems the following engineering control restriction is required on product labels.

1. "Do not apply by open pouring of liquid to cooling water systems; a metering pump delivery system is required for this use and application method."

b. Other Application Restrictions

Other application restrictions for bronopol product labels are:

1. For all end-use products: "Do not apply this product in a way that will contact workers or other persons."

2. For all end-use products: "Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

3. For liquid end-use products only: "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

c. User Safety Recommendations

Add the following user safety recommendations to labels of all bronopol end-use products:

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

2. "If pesticide gets inside clothing remove clothing immediately, wash thoroughly, and put on clean clothing."

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

d. Effluent Discharge and Disposal Labeling Statements

To reduce environmental risk from bronopol discharge and disposal, product labels must continue to have the statements pertaining to effluent discharge under the NPDES permitting system (refer to PR Notice 93-10 or 40 CFR 152.46(a)(1)) and disposal under any applicable federal laws.

e. Directions for Use

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

f. Clarification of Oil/Gas Drilling Mud Packer Fluids Use

To clarify the intent of the oil recovery drilling muds/packer fluids use, as an aquatic or terrestrial non-food use pattern, the following statements must be added to the labels. For bronopol products labeled for this use and the registrant intends applications to be limited to terrestrial sites, add the following:

"For use in terrestrial wells only. Do not apply in marine and/or estuarine oil fields."

For products intended for applications for aquatic sites add the following:

"For use in off-shore wells only."

For use in both terrestrial and aquatic sites add:

"This product may be used in terrestrial and off-shore oil drilling muds and packer fluids."

3. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision

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

The Agency has determined that registrants may distribute and sell bronopol products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	# Apps Max. /crop cycle	Max. Dose /year	[(AI Tex. @ Max. Rate otherwise)/A]	Min. Interv /crop cycle	Restr. Interv /year	Geographic Limitations Entry (days)	Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
ADHESIVES, INDUSTRIAL				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	V 89	V 444	*	NS	NS	NS	NS	NS	NS [day(s)]			C18, C24
	CR	W 95	W 475	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 949	W 4726	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 969	W 4826	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 82	V 408	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 91	V 454	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 100	V 498	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 948	W 4691	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 1036	W 5065	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 1042	W 5156	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 1049	W 5033	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 95	W 475	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 97	W 485	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 949	W 4726	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 969	W 4826	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 34	V 40	*	NS	NS	NS	NS	NS	NS			A38, C18, C24
	SC/L	V 62	V 71	*	NS	NS	NS	NS	NS	NS			A38, C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year	Max. Rate /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Min. Interv (days) /year	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
AIR CONDITIONER/REFRIGERATION CONDENSATE WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 48	W 48	*	NS	NS	NS	NS	NS	NS		C18, C24
	SC/S	W 48	W 48	*	NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 24	*	NS	NS	NS	NS	NS	NS		C18, C24
	SC/S	W 24	W 24	*	NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Intermittent feed (initial), Not on label, Not Applicable, Not applicable for this use	CR	W 100	W 100	*	NS	NS	NS	NS	NS	NS		A25(60), C18, C24
	SC/S	W 95	W 95	*	NS	NS	NS	NS	NS	NS		A25(60), C18, C24
AIR WASHER WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 48	W 48	*	NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 24	*	NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Intermittent feed (initial), Not on label, Not Applicable, Not applicable for this use	CR	W 100	W 100	*	NS	NS	NS	NS	NS	NS		A25(60), C18, C24
COATINGS, INDUSTRIAL				Use Group: INDOOR NON-FOOD								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS		A38, C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

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USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Chemical pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS			A30, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Metering pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS			A30, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 96	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS			A30, C18, C24
	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	@ Max. Rate	Max. # Apps /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Shock/slug, Metering pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS	NS			A30, C18, C24
Water treatment (recirculating system), Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS	NS			A30, C18, C24
	SC/S	U 100	U 100	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 24	W 96	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/S	U 15	U 50	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
EMULSIONS, RESIN/LATEX/POLYMER				Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	V 89	V 444	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 95	W 475	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 82	V 408	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 91	V 454	*	NS	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 100	V 498	*	NS	NS	NS	NS	NS	NS	NS			C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	@ Max. Rate	Max. # Apps /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
EMULSIONS, RESIN/LATEX/POLYMER (con't)				Use Group: INDOOR NON-FOOD (con't)										
	SC/S	W 95	W 475	*	NS	NS	NS	NS	NS	NS				C18, C24
	SC/S	W 97	W 485	*	NS	NS	NS	NS	NS	NS				C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 11	V 16	*	NS	NS	NS	NS	NS	NS				A38, C18, C24
	SC/L	V 19	V 29	*	NS	NS	NS	NS	NS	NS				A38, C18, C24
EVAPORATIVE CONDENSER WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS				A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS				A08, C18, C24
Water treatment (recirculating system), Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS				A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS				A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Chemical pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS				A30, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Metering pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS				A30, C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
EVAPORATIVE CONDENSER WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)							
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 96	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
Water treatment (recirculating system), Shock/slug, Metering pump, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
Water treatment (recirculating system), Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/L	W 25	W 102	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W 24	W 96	*	NS	NS	NS	NS	NS	NS	C18, C24
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE				Use Group: INDOOR NON-FOOD							
Industrial preservative treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/S	U 100	U 100	*	NS	NS	NS	NS	NS	NS	C18, C24
Industrial preservative treatment, Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/S	U 10	U 25	*	NS	NS	NS	NS	NS	NS	C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE (con't)				Use Group: INDOOR NON-FOOD (con't)									
Preservative treatment, Intermittent (slug)(initial), Injection equipment, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 20	V 163	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 20	V 163	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Injection equipment, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 20	V 163	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 46	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE (con't)				Use Group: INDOOR NON-FOOD (con't)							
	SC/L	V 50	V 100	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 48	W 95	*	NS	NS	NS	NS	NS	NS	C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 20	V 163	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS	C18, C24
Preservative treatment, Not on label, Sprayer, Not Applicable, Not applicable for this use	CR	W 48	W 95	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 46	V 91	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 50	V 100	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 48	W 95	*	NS	NS	NS	NS	NS	NS	C18, C24
HEAT EXCHANGER WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS	A08, C18, C24

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Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
HEAT EXCHANGER WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)							
Water treatment (recirculating system), Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
HUMIDIFIER WATER				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 48	W 48	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 48	W 48	*	NS	NS	NS	NS	NS	NS	C18, C24
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 24	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 24	W 24	*	NS	NS	NS	NS	NS	NS	C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
HUMIDIFIER WATER (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)							
Water treatment, Intermittent feed (initial), Not on label, Not Applicable, Not applicable for this use	CR	W 100	W 100	*	NS NS	NS NS	NS	NS			A2512(60), C18, C24
	SC/S	W 95	W 95	*	NS NS	NS NS	NS	NS			A25(60), C18, C24
INDUSTRIAL PROCESSING WATER				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 48	W 48	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	W 50	W 50	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	W 51	W 51	*	NS NS	NS NS	NS	NS			C18, C24
	SC/S	W 48	W 48	*	NS NS	NS NS	NS	NS			C18, C24
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	CR	W 9.5	W 9.5	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 8.16	V 8.16	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 9.1	V 9.1	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 10	V 10	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	W 10	W 10	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	W 100	W 100	*	NS NS	NS NS	NS	NS			A25(60), C18, C24
	SC/S	W 9.1	W 9.1	*	NS NS	NS NS	NS	NS			C18, C24
Water treatment, Intermittent feed (initial), Not on label, Not Applicable, Not applicable for this use	CR	W 95	W 95	*	NS NS	NS NS	NS	NS			A25(60), C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
INDUSTRIAL PROCESSING WATER (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
	SC/L	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 82	V 82	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
	SC/L	V 91	V 91	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
	SC/L	V 100	V 100	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
	SC/L	W 100	W 100	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
	SC/L	W 102	W 102	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
	SC/S	W 96	W 96	*	NS	NS	NS	NS	NS	NS			A25(60), C18, C24
INDUSTRIAL SCRUBBING SYSTEM				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
INDUSTRIAL SCRUBBING SYSTEM (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
LABORATORY EQUIPMENT WATER BATHS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 101	W 101	*	NS	NS	NS	NS	NS	NS			
METALWORKING CUTTING FLUIDS			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Initial, Not on label, Not Applicable, Not applicable for this use	CR	W 238	W 950	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 204	V 816	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 228	V 950	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 250	V 1000	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 273	V 910	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	U 250	U 1000	*	NS	NS	NS	NS	NS	NS			C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
METALWORKING CUTTING FLUIDS (con't)				Use Group: INDOOR NON-FOOD (con't)									
	SC/S	W 238	W 950	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	CR	W 190	W 380	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 82	V 163	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 91	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 95	V 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 100	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	U 100	U 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 95	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Preservative treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 97	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Injection equipment, Not Applicable, Not applicable for this use	CR	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 25	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. Rate /crop cycle	# Apps @ Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)	Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)												
	SC/L	V 21	V 171	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 45	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 85	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 50	V 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 25	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 21	V 171	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 45	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 97	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 50	V 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
				Use Group: TERRESTRIAL NON-FOOD CROP									
Preservative treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 97	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Injection equipment, Not Applicable, Not applicable for this use	CR	W 25	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 21	V 171	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24

APPENDIX A REPORT

Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 45	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 85	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 50	V 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 25	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 48	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 50	W 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 21	V 171	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 23	V 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 25	V 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 41	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 45	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 49	V 97	*	NS	NS	NS	NS	NS	NS			C18, C24

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Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)					Use Group: TERRESTRIAL NON-FOOD CROP (con't)						
	SC/L	V 50	V 100	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 54	V 107	*	NS NS	NS NS	NS	NS			C18, C24
	SC/S	No Calc	No Calc	*	NS NS	NS NS	NS	NS			C18, C24
	SC/S	W 48	W 95	*	NS NS	NS NS	NS	NS			C18, C24
PAINTS (IN-CAN)					Use Group: INDOOR NON-FOOD						
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	V 89	V 444	*	NS NS	NS NS	NS	NS			C18, C24
	CR	W 95	W 475	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 82	V 408	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 91	V 454	*	NS NS	NS NS	NS	NS			C18, C24
	SC/L	V 100	V 498	*	NS NS	NS NS	NS	NS			C18, C24
	SC/S	W 95	W 475	*	NS NS	NS NS	NS	NS			C18, C24
	SC/S	W 97	W 485	*	NS NS	NS NS	NS	NS			C18, C24
PAPER/PAPER PRODUCTS					Use Group: INDOOR NON-FOOD						
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	No Calc	No Calc	*	NS NS	NS NS	NS	NS			A38, C18, C24
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS					Use Group: INDOOR NON-FOOD						

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Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS (con't)			Use Group: INDOOR NON-FOOD (con't)										
Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 32	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 57	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/S	W 17	W 25	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
	SC/S	W 30	W 46	*	NS	NS	NS	NS	NS	NS			A08, C18, C24
PULP/PAPER MILL WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment, Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 19	W 32	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 20	W 32	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 34	W 57	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24

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Case 2770[Bronopol] Chemical 216400[Bronopol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	*	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
PULP/PAPER MILL WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
	SC/L	W 36	W 57	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 105	W 132	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 106	W 132	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 189	W 236	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 190	W 237	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
Water treatment, Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 19	W 25	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 20	W 26	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 34	W 46	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 36	W 47	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 105	W 114	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 106	W 119	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 189	W 205	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
	SC/L	W 190	W 213	*	NS	NS	NS	NS	NS	NS				A30, A38, C18, C24
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 48	W 194	*	NS	NS	NS	NS	NS	NS				C18, C24
	SC/L	V 41	V 163	*	NS	NS	NS	NS	NS	NS				C18, C24
	SC/L	V 45	V 182	*	NS	NS	NS	NS	NS	NS				C18, C24
	SC/L	V 50	V 200	*	NS	NS	NS	NS	NS	NS				C18, C24

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Case 2770[Bronopol] Chemical 216400[Bronopol]

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USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
PULP/PAPER MILL WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
	SC/L	W 19	W 32	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 20	W 32	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 34	W 57	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 36	W 57	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 50	W 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 51	W 203	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 105	W 132	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 106	W 132	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 189	W 236	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 190	W 237	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/S	W 43	W 209	*	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 19	W 25	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 20	W 26	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 34	W 46	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 36	W 47	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 105	W 114	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 106	W 119	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	W 189	W 205	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24

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USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
PULP/PAPER MILL WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
	SC/L	W 190	W 213	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 34	V 40	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
	SC/L	V 62	V 71	*	NS	NS	NS	NS	NS	NS			A30, A38, C18, C24
Water treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use	CR	W 8.6	W 215	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 9.5	W 237	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 9.6	W 240	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 10	W 261	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 11	W 264	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 9.5	W 237	*	NS	NS	NS	NS	NS	NS			C18, C24
SECONDARY OIL RECOVERY INJECTION WATER				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment, Continuous feed (initial), Injection equipment, Not Applicable, Not applicable for this use	CR	W 24	W 98	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 27	W 108	*	NS	NS	NS	NS	NS	NS			C18, C24
Water treatment, Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 98	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 27	W 108	*	NS	NS	NS	NS	NS	NS			C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
SECONDARY OIL RECOVERY INJECTION WATER (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)							
Water treatment, Intermittent (slug)(initial), Injection equipment, Not Applicable, Not applicable for this use	CR	W 24	W 98	*	NS NS	NS	NS	NS			C18, C24
	CR	W 27	W 108	*	NS NS	NS	NS	NS			C18, C24
	CR	W 98	W 488	*	NS NS	NS	NS	NS			C18, C24
	SC/L	W 24	W 101	*	NS NS	NS	NS	NS			C18, C24
	SC/L	W 25	W 102	*	NS NS	NS	NS	NS			C18, C24
	SC/L	W 60	W 104	*	NS NS	NS	NS	NS			C18, C24
	SC/S	W 27	W 108	*	NS NS	NS	NS	NS			C18, C24
	SC/S	W 54	W 108	*	NS NS	NS	NS	NS			C18, C24
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 98	*	NS NS	NS	NS	NS			C18, C24
	SC/S	W 27	W 108	*	NS NS	NS	NS	NS			C18, C24
SPECIALITY INDUSTRIAL PRODUCTS				Use Group: INDOOR NON-FOOD							
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	V 89	V 444	*	NS NS	NS	NS	NS			C18, C24
	CR	W 95	W 475	*	NS NS	NS	NS	NS			C18, C24
	SC/L	V 82	V 408	*	NS NS	NS	NS	NS			C18, C24
	SC/L	V 91	V 454	*	NS NS	NS	NS	NS			C18, C24
	SC/L	V 100	V 498	*	NS NS	NS	NS	NS			C18, C24

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USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
SPECIALITY INDUSTRIAL PRODUCTS (con't)			Use Group: INDOOR NON-FOOD (con't)										
	SC/S	W 95	W 475	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 97	W 485	*	NS	NS	NS	NS	NS	NS			C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 2.12	V 159	*	NS	NS	NS	NS	NS	NS			A38, C18, C24
	SC/L	V 3.8	V 285	*	NS	NS	NS	NS	NS	NS			A38, C18, C24
Preservative treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use	CR	V 22	V 89	*	NS	NS	NS	NS	NS	NS			C18, C24
	CR	W 24	W 95	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 16	V 82	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 18	V 91	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	V 20	V 100	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 24	W 97	*	NS	NS	NS	NS	NS	NS			C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS			Use Group: INDOOR NON-FOOD										
Impregnation treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	CR	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 20	W 163	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 23	W 182	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W 25	W 200	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/S	W 24	W 190	*	NS	NS	NS	NS	NS	NS			C18, C24

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS (con't)				Use Group: INDOOR NON-FOOD (con't)							
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	CR	V 89	V 444	*	NS	NS	NS	NS	NS	NS	C18, C24
	CR	W 95	W 475	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 82	V 408	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 91	V 454	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	V 100	V 498	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 95	W 475	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/S	W 97	W 485	*	NS	NS	NS	NS	NS	NS	C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 2.12	V 159	*	NS	NS	NS	NS	NS	NS	A38, C18, C24
	SC/L	V 3.8	V 285	*	NS	NS	NS	NS	NS	NS	A38, C18, C24

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Case 2770[Bronopol] Chemical 216400[Bronopol]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

CR	: CRYSTALLINE
P/T	: PELLETED/TABLETED
SC/L	: SOLUBLE CONCENTRATE/LIQUID
SC/S	: SOLUBLE CONCENTRATE/SOLID

ABBREVIATIONS

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

APPLICATION RATE

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

Case 2770[Bronopol] Chemical 216400[Bronopol]

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USE LIMITATIONS CODES
A08 : Preclean claim.
A25 : __ minute(s) contact time (minimum).
A25 : __ minute(s) contact time (minimum).
A30 : Preclean for heavily soiled areas.
A38 : This product is not cleared for use in defoamers and/or coatings that may come in contact with food.
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case bronopol covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to bronopol 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 BRONOPOL

	REQUIREMENT	USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	**MRID#s 108808, 141875, 141876, 163783**
61-2A	**Start. Mat. & Mnfg. Process**	ALL	**MRID#s 108808, 141875, 141876, 163783, 42941302**
61-2B	**Formation of Impurities**	ALL	**MRID#s 108808, 141875, 141876, 163783**
62-1	**Preliminary Analysis**	ALL	**MRID#s 108808, 141875, 141876, 163783**
62-2	**Certification of limits**	ALL	**MRID#s 108808, 141875, 141876, 163783**
62-3	**Analytical Method**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-2	**Color**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-3	**Physical State**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-4	**Odor**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-5	**Melting Point**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-7	**Density**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-8	**Solubility**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-9	**Vapor Pressure**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-10	**Dissociation Constant**	ALL	**MRID#s 108808, 141875, 141876, 163783, 42941301**
63-11	**Octanol/Water Partition**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-12	**pH**	ALL	**MRID#s 108808, 141875, 141876, 163783**
63-13	**Stability**	ALL	**MRID#s 108808, 141875, 141876, 163783**

Data Supporting Guideline Requirements for the Reregistration of BRONOPOL

	REQUIREMENT	USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	FM	**MRID# 104689**
71-2A	**Avian Dietary - Quail**	FM	**MRID# 148562**
71-2B	**Avian Dietary - Duck**	FM	**MRID# 148941**
72-1A	**Fish Toxicity Bluegill**	FM	**MRID# 148940**
72-1C	**Fish Toxicity Rainbow Trout**	FM	**MRID# 148563**
72-2A	**Invertebrate Toxicity**	FM	**MRID# 98404**
72-3A	**Estuarine/Marine Toxicity - Fish**	FM	**MRID# 163176**
72-3B	**Estuarine/Marine Toxicity - Mollusk**	FM	**MRID# 148979**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	FM	**MRID# 150674**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	FM	**MRID# 98396**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	FM	**MRID# 138755**
81-3	**Acute Inhalation Toxicity - Rat**	FM	**MRID#s 98397, 43530401**
81-4	**Primary Eye Irritation - Rabbit**	FM	**MRID# 160998**
81-5	**Primary Dermal Irritation - Rabbit**	FM	**MRID# 98396**
81-6	**Dermal Sensitization - Guinea Pig**	FM	**MRID#s 98398, 138755**
82-1A	**90-Day Feeding - Rodent**	FM	**MRID# 98384**
82-1B	**90-Day Feeding - Non-rodent**	FM	**MRID# 98399**
82-2	**21-Day Dermal - Rabbit/Rat**	FM	**MRID# 98401**
83-1A	**Chronic Feeding Toxicity - Rodent**	FM	**MRID#s 98386, 115645, 138766**

Data Supporting Guideline Requirements for the Reregistration of BRONOPOL

	REQUIREMENT	USE PATTERN	CITATION(S)
83-2A	**Oncogenicity - Rat**	FM	**MRID#s 98386, 115645, 138766**
83-2B	**Oncogenicity - Mouse**	FM	**MRID# 98387**
83-3A	**Developmental Toxicity - Rat**	FM	**MRID#s 43598701, 43608501**
83-3B	**Developmental Toxicity - Rabbit**	FM	**MRID#s 42319601, 42648201**
83-4	**2-Generation Reproduction - Rat**	FM	**MRID#s 40660907, 41916502,40660907**
84-2A	**Gene Mutation (Ames Test)**	FM	**MRID#s 40660902, 40660903**
84-2B	**Structural Chromosomal Aberration**	FM	**MRID# 40660904**
84-4	**Other Genotoxic Effects**	FM	**MRID# 40660905**
85-1	**General Metabolism**	FM	**MRID# 43289501**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
233	**Estimation of Dermal Exposure at Indoor Sites**	FM	**CONFIRMATORY DATA REQUIRED**
234	**Estimation of Inhalation Exposure at Indoor Sites**	FM	**CONFIRMATORY DATA REQUIRED**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	FM	**MRID#s 164535, 163783**
161-2	**Photodegradation - Water**	FM	**MRID# 42941303**

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of

your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

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

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share, Data Compensation Forms and Confidential Statement of Formula 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 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent

to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the

laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

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

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3

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

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

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

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

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

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

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to

upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

BRONOPOL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 bronopol. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this bronopol Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of bronopol, please contact Ron Kendall at (703) 308-8068. If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

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

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

RE: **bronopol**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Items 10-13. Self-explanatory.

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

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. lt 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.

EPA'S BATCHING OF 2-BROMO-2-NITROPROPANE-1,3-DIOL PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

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 2-Bromo-2-nitropropane-1,3-diol as the active ingredient, 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.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing 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 registrant's 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. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant 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.

Twenty-one products were found which contain 2-Bromo-2-nitropropane-1,3-diol as an active ingredient. The products have been placed into five batches and a "no batch" group in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% 2-Bromo-2-nitropropane-1,3-diol	Formulation Type
1	33753-17	10.0	Liq
	48301-35	10.0	Liq
2	33753-6	18.2	Liq
	48301-29	18.2	Liq
3	33753-7	40.8	Liq
	48301-28	40.8	Liq
4	3876-148	9.5 Dodecylguanidine Hydro-chloride 4.7	Liq
	45017-40	9.5 Dodecylguanidine Hydro-chloride 4.7	Liq
5	5009-50	95.0	Solid
	33753-1	99.0	Solid
	33753-3	95.0	Solid
	33753-5	95.0	Solid
	33753-11	97.0	Solid
	48301-18	95.0	Solid
	48301-27	95.0	Solid
	48301-36	97.0	Solid
	67212-1	95.0	Solid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these producs are responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

EPA Reg. No.	% active ingredient	Formulation Type
3876-147	2-Bromo-2-nitropropane - 1,3-diol 5.3 N-alkyl dimethylbenzyl ammonium chloriode 10.0	Liq
33752-13	2-Bromo-2-nitropropane - 1,3-diol 55.0	Solid
33753-18	2-Bromo-2-nitropropane - 1,3-diol 81.2	Solid
48301-25	2-Bromo-2-nitropropane - 1,3-diol 38.0	Solid

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

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

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents related to bronopol. 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 bronopol 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. bronopol 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