United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substances (7510P)
EPA 739-R-07-001
September 2007

# Reregistration Eligibility Decision for Halohydantoins (Case 3055)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial halohydantoins. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for halohydantoins on September 30, 2004. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for halohydantoins and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for the halohydantoins are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2004-0303 at: http://www.regulations.gov.

The halohydatnoins RED was developed through EPA's public participation process, published in the Federal Register on July 20, 2005, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the halohydantoins risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to halohydantoins alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required

responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that halohydantoins will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by halohydantoins. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, ShaRon Carlisle, at (703) 308-6427. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Emily Mitchell at (703) 308-8583.

Sincerely,

Frank T. Sanders, Director
Antimicrobials Division (7510C)

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# GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| a.i. | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| APHIS | Animal and Plant Health Inspection Service |
| ARTF | Agricultural Re-entry Task Force |
| BCF | Bioconcentration Factor |
| CDC | Centers for Disease Control |
| CDPR | California Department of Pesticide Regulation |
| CFR | Code of Federal Regulations |
| ChEI | Cholinesterase Inhibition |
| CMBS | Carbamate Market Basket Survey |
| cPAD | Chronic Population Adjusted Dose |
| CSFII | USDA Continuing Surveys for Food Intake by Individuals |
| CWS | Community Water System |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| DL | Double layer clothing {i.e., coveralls over SL} |
| DWLOC | Drinking Water Level of Comparison |
| EC | Emulsifiable Concentrate Formulation |
| EDSP | Endocrine Disruptor Screening Program |
| EDSTAC | Endocrine Disruptor Screening and Testing Advisory Committee |
| 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 |
| EXAMS | Tier II Surface Water Computer Model |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FOB | Functional Observation Battery |
| FQPA | Food Quality Protection Act |
| FR | Federal Register |
| GL | With gloves |
| GPS | Global Positioning System |
| HIARC | Hazard Identification Assessment Review Committee |
| IDFS | Incident Data System |
| IGR | Insect Growth Regulator |
| IPM | Integrated Pest Management |
| RED | Reregistration Eligibility Decision |
| LADD | Lifetime Average Daily Dose |
| $LC_{50}$ | Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. |
| LCO | Lawn Care Operator |
| $LD_{50}$ | Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LOAEC | Lowest Observed Adverse Effect Concentration |
| LOAEL | Lowest Observed Adverse Effect Level |
| LOC | Level of Concern |
| LOEC | Lowest Observed Effect Concentration |
| mg/kg/day | Milligram Per Kilogram Per Day |
| MOE | Margin of Exposure |

| | |
|---|---|
| MP | Manufacturing-Use Product |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| MRL | Maximum Residue Level |
| N/A | Not Applicable |
| NASS | National Agricultural Statistical Service |
| NAWQA | USGS National Water Quality Assessment |
| NG | No Gloves |
| NMFS | National Marine Fisheries Service |
| NOAEC | No Observed Adverse Effect Concentration |
| NOAEL | No Observed Adverse Effect Level |
| NPIC | National Pesticide Information Center |
| NR | No respirator |
| OP | Organophosphorus |
| OPP | EPA Office of Pesticide Programs |
| ORETF | Outdoor Residential Exposure Task Force |
| PAD | Population Adjusted Dose |
| PCA | Percent Crop Area |
| PDCI | Product Specific Data Call-In |
| PDP | USDA Pesticide Data Program |
| PF10 | Protections factor 10 respirator |
| PF5 | Protection factor 5 respirator |
| PHED | Pesticide Handler's Exposure Data |
| PHI | Pre-harvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| PRZM | Pesticide Root Zone Model |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RPA | Reasonable and Prudent Alternatives |
| RPM | Reasonable and Prudent Measures |
| RQ | Risk Quotient |
| RTU | (Ready-to-use) |
| RUP | Restricted Use Pesticide |
| SCI-GROW | Tier I Ground Water Computer Model |
| SF | Safety Factor |
| SL | Single layer clothing |
| SLN | Special Local Need (Registrations Under Section 24C of FIFRA) |
| STORET | Storage and Retrieval |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TRAC | Tolerance Reassessment Advisory Committee |
| UF | Uncertainty Factor |
| USDA | United States Department of Agriculture |
| USFWS | United States Fish and Wildlife Service |
| USGS | United States Geological Survey |
| WPS | Worker Protection Standard |

## ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for halohydantoins and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of halohydantoins that pose risks of concern. As a result of this review, EPA has determined that the halohydantoin groups of chemicals are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

## I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data to the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database 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" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be accomplished through this reregistration process. The Act also required that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. At this time, the Agency has not identified any other chemical substances that have a mechanism of common toxicity with that of the halohydantoins group. For reregistration purposes, EPA has assumed that the halohydantoins do not have a common mechanism of toxicity and will not perform a cumulative risk assessment as part of the tolerance reassessment for these pesticidal chemicals. This document presents the Agency's revised human health and ecological risk assessments and the reregistration eligibility decision for the halohydantoins.

These antimicrobial chemicals are registered for use in indoor food and non-food, indoor residential, aquatic non-food residential, aquatic food, aquatic non-food, and aquatic non-food industrial sites for control of bacteria, fungi, and algal slimes.

The Agency has concluded that the FQPA Safety Factor for the halohydantoins should be removed (equivalent to 1X). Although there is quantitative evidence of increased sensitivity of neonatal rabbits, the Agency considered this effect not indicative of susceptibility, based upon the very high dose level at which the effect occurred, the minimal nature of the effect, and the likelihood that the effect was due to a greater dose received by pups from ingestion of both milk and feed during the lactation period. Therefore, the Agency determined that the special hazard-based FQPA safety factor could be removed for the halohydantoins and that the use of a standard uncertainty factor of 100 would be sufficient.

Risks summarized in this document are those that result only from the use of the active ingredient, halohydantoins. The FFDCA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic

effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for the halohydantoins and any other substances. The halohydantoins do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that the halohydantoins have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative .

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of halohydantoins. In an effort to simplify the RED, the information presented herein is summarized from more detailed information, which can be found in the technical supporting document for halohydantoins referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0303).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of halohydantoins, and its regulatory history. Section III, Summary of Halohydantoins Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

## II. CHEMICAL OVERVIEW

### A. Regulatory History

The halohydantoins were first registered in October 1961. There are currently 114 active products containing a halohydantoin registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In 1987, EPA issued a Data Call-In (DCI) for antimicrobial products, which covered the halohydantoins. In response to this DCI, generic toxicology, environmental fate and ecotoxicity data were submitted. Generic data were developed on the breakdown products, dimethylhydantoin (DMH) and ethylmethylhydantoin (EMH). The primary reason for developing generic data on DMH and EMH rather than the entire halohydantoin molecule is that these ring structures represent the persistent component of the halohydantoins. A secondary reason for evaluating the halohydantoin moieties is that the corrosive properties of the released halogens would limit the amount of chemical that could be administered to laboratory animals; thereby precluding a meaningful evaluation of the halohydantoin moieties. The Agency also determined that data developed on DMH was applicable to EMH and vice versa. The basis for this decision was the similarity of the chemical structure of these two chemicals and the similarity of results from studies conducted on both the DMH and EMH compounds.

### B. Chemical Identification

The halohydantoins are a group of chemicals comprised of several halogenated compounds. This group of chemicals includes the following: 1-Bromo-3-chloro-5,5-dimethylhydantoin, 1.3-Dibromo-5,5-dimethylhydantoin, 1,3-Dichloro-5,5-dimethylhydantoin, and 1,3-Dichloro-5-ethyl-5-methylhydantoin. In addition, the Agency has determined that the 5,5-Dimethylhydantoin (DMH) and 5-Ethyl-5-methylhydantoin (EMH) metabolites of the halogenated hydantoins are appropriate test substances for assessing the toxicity of this group. However, since the hydroxymethylhydantoins as listed above have the potential for release of formaldehyde, the risks associated with this release need to be assessed. The Agency has determined that the risks from exposure to formaldehyde via the hydroxymethylhydantoins will be addressed when registration review is conducted on hydroxymethylhydantoin.

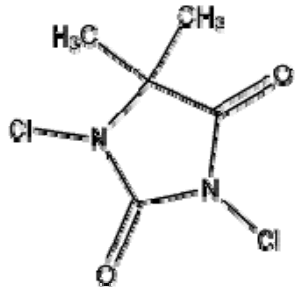
The common names, chemical names, empirical formulas, and CAS numbers of the halohydantoins are presented in Table 1.

Table 1. Common Names, Chemical Names, Empirical Formulas, and CAS Numbers

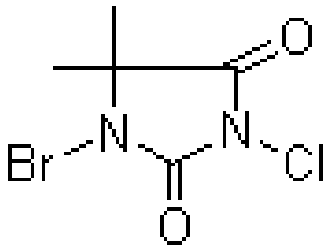
| Common Name | Chemical Name | Empirical Formula | CAS No. |
|---|---|---|---|
| Dichlorodimethylhydantoin | 1,3-dichloro-5,5-dimethylhydantoin | $C_5H_6Cl_2N_2O_2$ | 118-52-5 |
| Bromochlorodimethylhydantoin | 1-Bromo-3-Chloro- | $C_5H_6BrClN_2O_2$ | 16079-88-2 |

| Common Name | Chemical Name | Empirical Formula | CAS No. |
|---|---|---|---|
| | Dimethylhydantoin | | |
| Dichloroethylmethylhydantoin | 1,3-dichloro-5-ethyl-5-methylhydantoin | $C_6H_8Cl_2N_2O_2$ | 89415-87-2 |
| Dibromodimethylhydantoin | 1,3-dibromo-5,5-dimethylhydantoin | $C_5H_6Br_2N_2O_2$ | 77-48-5 |
| Bromochlorodimethylhydantoin | 1-Bromo-3-chloro-5,5-dimethylhydantoin | $C_5H_6BrClN_2O_2$ | 32718-18-6 |

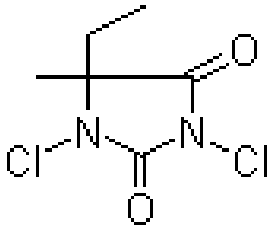
Structures of the halohydantoins considered in this document are below:



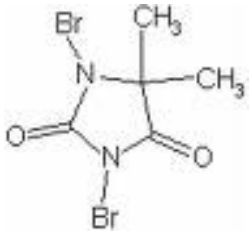

1,3 Dichloro-5,5-Dimethylhydantoin



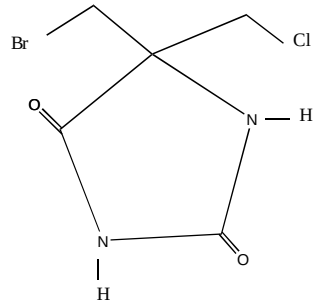

1-Bromo-3-Chloro-Dimethylhydantoin




1,3-Dichloro-5-Ethyl-5-Methylhydantoin




1,3,-dibromo-5,5-dimethylhydantoin




1-bromo-3-chloro-5-5-dimethylhydantoin

Physical and chemical properties of a typical halohydantoin are shown in Table 2.

**Table 2. Physical and Chemical properties of a typical Halohydantoin product**

| Parameter | Value |
|---|---|
| Color | Off-white |
| Physical State | Solid |
| Odor | Slight halogen odor |
| Stability | Stable in the dry state. It decomposes exothermally at 180°C. It is attacked by strong alkali's, acids, and moisture. |
| Oxidation/Reduction | Oxidizer |
| pH of water solution, 1% slurry at 25$^{o}$C | 6.5 |
| Melting point | between 120 and 148$^{o}$C |
| $K_{ow}$ | unknown |
| Water solubility at 25$^{o}$C | 0.54 g / 100 g |
| Vapor Pressure | NA |

Structurally, the halohydantoins consist of a central organic hydantoin ring moiety (either dimethylhydantoin or ethylmethylhydantoin) to which halogen atoms (bromine and/or chlorine) can be attached at both the 1 and 3 positions on the hydantoin ring.

In concentrated form, the halohydantoins are very stable. Upon usage, which involves dilution in water or a water system, the halohydantoins rapidly decompose to release chlorine and/or bromine and dimethylhydantoin (DMH) and, for certain products, ethylmethylhydantoin (EMH). These released halogens react with water to form either hypochlorous or hypobromous acid, which is the actual biocidal agent. Accordingly, the halohydantoins are essentially delivery systems for hypochlorous and hypobromous acid.

### a. Use Profile

The halohydantoins are used for microbial control in water and water systems. In particular, the halohydantoins are used as disinfectants in commercial and residential swimming pools, spas and hot tubs; as sanitizers for treatment of toilet bowl water in homes; and for controlling bacterial and fungal contamination in a variety of industrial water systems. (i.e., industrial cooling water systems, pulp and paper mill process water, wastewater treatment systems, air washer water systems, sewage systems, industrial processing water, irrigation systems, and ornamental ponds).

The only food-use for the halohydantoins is as a slimicide in the manufacture of food-contact paper and paperboard. The 1998 Antimicrobial Regulation Technical Corrections Act (ARTCA) gave the U.S. Food and Drug Administration (FDA) jurisdiction for regulating dietary residues of food-contact slimicides under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). In addition, EPA is responsible for registering the slimicide product under FIFRA. The FDA regulation that permits the halohydantoins to be used as slimicides in the manufacture of food-contact paper and paperboard is in 21 C.F.R. Part 176.300.

**USE SITES:**

**Indoor Non-Food**

Hydrostatic Sterilizer Water Systems
Pasteurizer/Warmer/Cannery/Retort Water Systems
Transportation Cleaning

**Indoor Residential**

Toilet Bowls and Urinals
Bathroom Premises/Hard Surfaces

**Non-Food Residential**

Swimming Pool Water Systems
Air Conditioner
Hot Tubs & Spas

**Indirect Food**

Pulp and Paper Mill Water (food contact paper)

**Aquatic Nonfood**

Ornamental Ponds/Aquaria
Irrigation Systems

**Aquatic Non-Food Industrial**

Air Washer Water Systems (includes air scrubbing and washing)
Evaporative Condenser Water Systems
Pulp and Paper Mill Systems
Sewage/Wastewater Treatment Systems
Commercial/Industrial Water Cooling Tower Systems
Heat Exchanger Water Systems
Industrial Processing Water
Photo Processing Water
Secondary Oil Recovery Injection Water
Oil Recovery Drilling Muds and Packer Fluids
Recirculating Cooling Water (Greenhouses & Nurseries)

**APPLICATION RATES AND METHODS:**

**Indoor Non-Food**

For ***recirculating cooling water systems*** the typical rate of application ranges from 0.1 to 0.75 lbs per 1,000 gallons of water with 5-70 ppm halohydantoins with 0.5 - 5 ppm halogen by method of Place Solid (PLS), Pour Solid (PS) Feeders, Pour Liquid (PL) and Pour Undiluted (PU). End Use pack size ranges from 25 to 2,200 lb. for briquettes**,** tablets and in granular form. The end-use pack size for gels range from 22 oz to 400 pounds.

For ***transportation cleaning***, 1 to 5 ppm of halohydantoins with 1 to 3 ppm halogen is used at a typical rate of .025 to 0.1 lbs per 1,000 gallons of water. PLS or PS feeder is used for briquettes and tablets in end use pack sizes that range from 20 to 50 pounds.

**Indoor Residential**

For ***toilet bowls and urinals***, 1 to 5 ppm of halohydantoins with 2 to 10 ppm of halogen is used by method of Place Solid at a typical rate of 17 to 25 grams per month in briquette and tablet form.

For ***bathroom premises and hard surfaces***, 588 ppm of halohydantoins with 1,125 ppm of halogen is used at a typical rate of 0.45 ounces per every 3 gallons of water applied by mop and brush. For bathroom and hard surface use, the product is in granular and tablet form; end use pack sizes range from 1 to 50 pounds.

**Non-food Residential**

For ***residential and commercial pools***, 50 to 300 ppm of halohydantoins with 1 to 4 ppm of halogen is used at a weekly rate of 0.5 to 2.5 pounds per 10,000 gallons of water. Product is dispensed through a PLS/PS feeder in tablet, briquette and granular form from end use packs that range from 20 to 50 pounds.

For ***residential and commercial spas***, 30 to 100 ppm of halohydantoins with 2 to 6 ppm of halogen is used at a weekly rate of 0.1 to 0.5 pounds per 1,000 gallons of water. Product is dispensed through a PLS/PS feeder in tablet, briquettes and granular form from end use packs that range from 1 to 50 pounds.

For use in ***air conditioner and dehumidifier basin/drip pans***, one or more 20 gram tablets are placed in the basin or drip pan from end use pack sizes of 25 or 50 pounds.

**Indirect Food**

For ***Pulp & Paper*** with food contact, 5 to 25 ppm of halohydantoins with 1 to 5 ppm of halogen is used at a typical rate of 0.16 to 2.0 pounds per ton of paper. A PLS/PS feeder or PU is used to dispense product in briquette, granular, powder, tablet and gel form. End use product pack sizes range from 25 to 2,200 lbs. for briquettes**,** tablets and granular formulations. The end-use pack size for gel products range from 22 oz to 400 pounds.

**Aquatic Non-Food**

For ***Decorative Waters*** without fish, 50 to 260 ppm of halohydantoins with 1 to 3 ppm of Halogen is used at a weekly rate of 0.5 to 1.4 pounds per 10,000 gallons of water. A PLS/PS feeder is used to dispense product in briquette, granular, tablet and gel form. End use product pack size ranges from 22 oz to 400 pounds for gel and 20 to 50 pounds for all other forms.

For ***irrigation and automatic water distribution systems*** (not for use on food crops) 8 to 24 ppm of halohydantoins with 5 to 15 ppm of halogen is used at a typical rate of 15 to 45 grams per 1,000 gallons of water. A PLS/PS feeder, PU, or PL is used to dispense product in granular, powder and tablet form. End use products are packaged in 3 and 25 pound containers.

**Aquatic Non-Food Industrial**

For ***Recirculating cooling systems***, 5 to 70 ppm of halohydantoins with 0.5 to 5 ppm of halogens is used at a typical rate of 0.1 to 0.75 pounds per 1,000 gallons of water dependent on level of biological control.A PLS/ PS feeder, PU, or PL is used to dispense product in granular, briquettes, tablet and gel form. End use product package sizes range from 22 oz to 400 pounds for the gel formulation and 25 to 2,200 pounds for all other formulations.

For ***once through cooling systems***, 5 to 35 ppm of halohydantoins with 0.5 to 5 ppm of halogen is used at a typical application rate of 0.1 to 0.3 pounds per 1,000 gallons of water. A PLS/ PS feeder, PU, or PL is used to dispense product in granular, briquettes, tablet and gel form. End use product package sizes range from 22 oz to 400 pounds for the gel formula and 25 to 2,200 pounds for all other formulations.

For ***Pulp and Paper***, 5 to 25 ppm of halohydantoins with 1 to 5 ppm of halogen is used at a typical application rate of 0.16 to 2.0 pounds per ton of paper. A PLS/ PS feeder or PU is used to dispense the product in granular, powder, tablet and gel form. End use product package sizes range from 22 oz to 400 pounds for gel formulations and 25 to 2,200 pounds for all other formulations.

For ***sewage and wastewater treatment systems***, 5 to 35 ppm of halohydantoins with 0.5 to 5 ppm of halogen is used at a typical application rate of 0.1 to 0.75 pounds per 1,000 gallons of water. A PLS/ PS feeder, PU, or PL is used to dispense product in briquette, granular, tablet and gel forms. End use product package sizes range from 22 oz to 400 pounds for gel formulations and 25 to 2,200 pounds for all other formulations.

For ***photo processing***, 1 to 5 ppm of halohydantoins with 1 to 3 ppm of halogen is used at a typical application rate of 0.006 to 0.02 pounds per 1,000 gallon of water. A PLS/ PS feeder is used to dispense product in granular, briquettes and tablet forms. End use product package sizes range from 1 to 50 pounds.

For ***secondary oil recovery injection water***, 300 ppm of halohydantoins with 280 ppm of halogen is used at a typical application rate of 2.3 pounds per 1,000 gallons of water. A PLS/ PS feeder is used to dispense the product in granular and tablet forms. End use pack sizes range from 25 to 2,200 pounds.

For ***oil recovery drilling mud & packer fluids***, 940 ppm of halohydantoins with 1,800 ppm of halogen is used at a typical application rate of 15 pounds per 1,000 gallons of water. A PLS/ PS feeder is used to dispense the product in granular and tablet form. End use product package sizes range from 25 to 2,200 pounds.

For ***recirculating cooling water for greenhouses and nurseries***, 8 to 24 ppm of halohydantoins with 5 to 15 ppm of halogen is used at a typical rate of 15 to 45 grams per

1,000 gallons of water. A PLS/ PS feeder is used to dispense product in granular, powder and tablet forms. End use product package sizes are 3 and 25 pounds.

**TARGET PESTS**:

Slime-forming bacteria and fungi; pathogens in swimming pools, spas, hot tubs, toilet bowls and urinals; mollusks and algae.

**FORMULATION TYPES:**

Powder**,** granular, tablets (including nuggets), briquettes and gel.

## III. Summary of Halohydantoins Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for halohydantoins. While the risk assessments and related addenda are not included in this document, they are available to the public in EPA's Pesticide Docket EPA-HQ-OPP -2004-0303 at http://www.regulations.gov . Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

### A. Human Health Risk Assessment

The halohydantoins are a group of chemicals comprised of several halogenated compounds. This group of chemicals includes the following: 1-Bromo-3-chloro-5,5-dimethylhydantoin, 1.3-Dibromo-5,5-dimethylhydantoin, 1,3-Dichloro-5,5-dimethylhydantoin, and 1,3-Dichloro-5-ethyl-5-methylhydantoin. In addition, the Agency has determined that the 5,5-Dimethylhydantoin (DMH) and 5-Ethyl-5-methylhydantoin (EMH) metabolites of the halogenated hydantoins are appropriate test substances for assessing the toxicity of this group. However, since the hydroxymethylhydantoins as listed above have the potential for release of formaldehyde, the risks associated with this release need to be assessed. The Agency has determined that the risks from exposure to formaldehyde via the hydroxymethylhydantoins will be addressed when registration review is conducted on hydroxymethylhydantoin. Therefore, this reregistration eligibility decision (RED) document assesses the eligibility of the halohydantoins and their metabolites for reregistration.

The Agency's use of human studies in the halohydantoins risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

#### 1. Toxicity of Halohydantoins

A brief overview of the toxicity studies used for determining endpoints in the dietary risk assessments are outlined in this section; other toxicity endpoints will be presented later in this document. Further details on the toxicity of halohydantoins can be found in the *Halohydantoins Revised Risk Assessment for the Reregistration Eligibility Decision*, dated June 25, 2007. This document is available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2004-0303 at: http://www.regulations.gov

The Agency has reviewed all toxicity studies submitted for halohydantoins and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. In acute toxicity studies, summarized in Table 3 below, the halohydantoins were shown to be of low toxicity by the oral and dermal routes of exposure (Toxicity categories III and

IV, respectively). Acute toxicity by the inhalation route is more significant (Toxicity category II). The halohydantoins are significant eye and skin irritants (Toxicity category I and II, respectively). Mixed dermal sensitization has also been observed for some of the halohydantoin compounds. See Table 4 for the studies and toxicity endpoints that were used in the dietary risk assessment.

Table 3. Acute Toxicity of Halohydantoins

| Guideline No./ Study Type | MRID No. (TRID No.) | Results | Toxicity Category |
|---|---|---|---|
| 5,5-Dimethylhydantoin | | | |
| 870.1100 Acute oral (gastric intubation) toxicity (limit test)-Mouse | 45738401 | $LD_{50}$ (combined) > 5,000 mg/kg | IV |
| 1-Bromo-3-chloro-5,5-dimethylhydantoin | | | |
| 870.1100 Acute oral toxicity-Rat | 93074006, 00128244 (4226-010-01) | $LD_{50}$(males) = 1,350 mg/kg<br>$LD_{50}$(females) = 1,520 mg/kg<br>$LD_{50}$(combined) = 1,390 mg/kg | III |
| 870.1100 Acute oral toxicity-Rat | 93077008, 00147325 (4600-950-21) | $LD_{50}$(males) = 1,037 mg/kg<br>$LD_{50}$(females) = 860 mg/kg<br>$LD_{50}$(combined) = 929 mg/kg | III |
| 870.1300 Acute inhalation toxicity-Rat | 43654101 | $LC_{50}$(males) = 0.157 mg/L<br>$LC_{50}$(females) = 0.213 mg/L<br>$LC_{50}$(combined) = 0.168 mg/L | II |
| 870.2500 Acute dermal irritation-Rabbit | 93074011, 93075014, 00128242 (4225-014-10) | severe skin irritant | I |
| 870.2500 Acute dermal irritation-Rabbit | 93077009, 00147326 (4600-950-22) | severe skin irritant | I |
| 870.2600 Skin sensitization-Guinea pig | 41670001 | positive sensitizer | N/A |
| 1,3-Dibromo-5,5-dimethylhydantoin | | | |
| 870.1100 Acute oral toxicity-Rat | 93076011, 00137105 (4334-012-01) | $LD_{50}$ = 760 mg/kg | III |
| 870.1100 Acute oral toxicity-Rat | 44988002, ) | combined $LD_{50}$ = 448 mg/kg | II |
| 870.1200 Acute dermal toxicity-Rabbit | 93076025, 00137110 (4334-012-07) | $LD_{50}$ cannot be ascertained (study is classified as Unacceptable/non-guideline | -- |
| 870.1200 Acute dermal toxicity-Rat | 44988001 | LD50 > 2000 mg/kg | III |
| 870.1300 Acute inhalation toxicity-Rabbit | 44988003 | LC50 between0.51-2.02 mg/L | II |

| Guideline No./ Study Type | MRID No. (TRID No.) | Results | Toxicity Category |
|---|---|---|---|
| 870.2500 Primary dermal irritation-Rabbit | 93076017, 00137109 (4334-012-05) | severe skin irritant | I |
| 870.2500 Primary dermal irritation-Rabbit | 44988004 | corrosive | I |
| 870.2600 Dermal Sensitization - guinea pig | 44988005 | non-sensitizer | N/A |
| 1,3-Dichloro-5,5-dimethylhydantoin | | | |
| 870.1200 Acute dermal toxicity-Rabbit | 93076013, 00084176 (2402-448-05) | $LD_{50}$ > 20,000 mg/kg | IV |
| 870.2500 Acute dermal irritation-Rabbit | 93076017, 00137109 (2402-448-01) | severe skin irritant | I |

Table 4. Summary of Toxicological Dose and Endpoints for the Halohydantoins for Use in Human Risk Assessment

| **Exposure Scenario** | **Dose Used in Risk Assessment, UF** | | **Study and Toxicological Effects** |
|---|---|---|---|
| Acute Dietary <u>females 13-50 years of age</u> | NOAEL = 100 mg/kg/day<br>UF = 100<br>Acute RfD = 1 mg/kg | FQPA SF = 1<br>aPAD = <u>acute RfD</u><br>FQPA SF<br><br>= 1 mg/kg/day | developmental toxicity - rabbit<br>developmental LOAEL = 500 mg/kg/day based on skeletal variations.<br>(MRID 42413101) |
| Chronic Dietary[a] <u>all populations</u> | NOAEL= 300 mg/kg/day<br>UF = 100<br>Chronic RfD (gen Pop.) = 3 mg/kg/day | FQPA SF = 1<br>cPAD = <u>chr RfD</u><br>FQPA SF<br><br>= 3 mg/kg/day | chronic toxicity/carcinogenicity - rats<br>LOAEL = 1000 mg/kg/day based on decreased body weight/weight gain and lymph node hyperplasia.<br>(MRID 43397702) |
| Chronic Dietary[a] <u>females 13-50 years of age</u> | NOAEL= 100 mg/kg/day<br>UF = 100<br>Chronic RfD (females 13-50) = 1 mg/kg/day | FQPA SF = 1<br>cPAD = <u>chr RfD</u><br>FQPA SF<br><br>= 1 mg/kg/day | developmental toxicity - rabbit<br>developmental LOAEL = 500 mg/kg/day based on skeletal variations.<br>(MRID 42413101) |

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest

observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure

[a]The HIARC selected separate chronic RfDs for females, ages 13-50, and the general population. A separate endpoint for the general population was selected because this was an unusual case where the developmental toxicity NOAEL was lower than the NOAEL from the chronic toxicity studies. The chronic RfD for the general population provides a more appropriate endpoint for individuals other than females

General Toxicity Observations

Non-acute toxicity testing of halohydantoins (DMH/EMH) (including subchronic, developmental, reproductive, and chronic toxicity testing) all show the presence of non-specific toxicity only at relatively high doses of the test chemical. Developmental and reproductive toxicity data demonstrate no increase in susceptibility to the toxic effects of 5,5-dimethylhydantoin with the exception of one study, where fetal and litter effects (increased incidence of 27$^{th}$ presacral vertebrae) in rabbits were observed at a lower dose level than that which resulted in maternal toxicity (decreased body weight and food consumption during the dosing period) following treatment. The increase of 27$^{th}$ presacral vertebrae is a common variation found in rabbit developmental toxicity studies and was not considered an adverse effect. In a prenatal developmental toxicity study conducted in rabbits with 5-ethyl-5-methylhydantoin, there was no increased susceptibility of the fetuses observed.

Available metabolism data indicate that DMH and EMH are excreted unchanged in the rat. However, it is known that hydroxymethylhydantoins are formaldehyde releasers. The DMH portion of the molecule is assumed to behave the same as the hydantoins from the halohydantoin compounds. Any risk associated from the formaldehyde portion of the hydroxymethylhydantoin molecule will be addressed in the registration review of the hydroxymethylhydantoins.

Uncertainty Factors

Although there is quantitative evidence of increased sensitivity of neonatal rabbits, the Agency does not consider this effect indicative of susceptibility, based upon the very high dose level at which the effect occurred, the minimal nature of the effect, and the likelihood that the effect was due to a greater dose received by pups from ingestion of both milk and feed during the lactational period. Therefore, the Agency recommended that the special hazard-based FQPA safety factor could be removed for the halohydantoins and that the use of a standard uncertainty factor of 100 would be protective for offspring.

Dietary

Acute and chronic dietary endpoints were selected using the no observed adverse effect level (NOAEL) of 100 mg/kg/day for females 13-50 based on a developmental toxicity study on rabbits, in which skeletal variations were seen at 500 mg/kg/day. A chronic dietary endpoint of 300 mg/kg/day was selected for the general population based on a chronic toxicity study on rats, in which decreased body weight, weight gain, and lymph node hyperplasia were observed.

Incidental Oral

The incidental short-term oral endpoint was selected using a NOAEL of 500 mg/kg/day, based a developmental toxicity study on rabbits, in which decreased body weight gain in maternal rabbits at 1000 mg/kg/day. The intermediate- term oral endpoint was selected using a NOAEL of

300 mg/kg/day, based on a subchronic oral toxicity study in which decreased body weight and liver weight were observed at 1000 mg/kg/day.

Short-, Intermediate- and Long-term Dermal

An endpoint for dermal toxicity (all times exposure durations) was selected using a NOAEL of 390 mg/kg/day based on the results of a 90-day dermal subchronic toxicity study (MRID 43173901) in which no systemic toxicity was found at the highest dose tested. The LOAEL is greater than 390 mg/kg/day.

Inhalation (all durations)

The short-term inhalation endpoint was selected to be the same as the oral endpoint of 100 mg/kg/day, due to skeletal effects in the offspring at 500 mg/kg/day in a developmental toxicity study in rabbits. For inhalation exposures, a 100% inhalation absorption value is used for route-to-route extrapolation.

Carcinogenicity

Cancer studies in rats and mice indicated no systemic effects other than decreased body weight and body weight gains in females (rats) and males (mice) and increased hyperplasia of submandibular lymph nodes in males (rats). No evidence of carcinogenicity of the test material was reported. 5,5-dimethylhydantoin is classified as 'not likely' to be a carcinogen based upon the negative evidence for carcinogenicity in both the rat and mouse studies as well as the negative evidence of mutagenicity.

Mutagenicity

The data on mutagenicity of dimethylhydantoin shows, in large part, negative responses in the studies conducted. Literature reports indicate a positive effect for 2 in vitro mammalian cytogenetic assays in Chinese Hamster Ovary cells.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, the halohydantoins may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

### 2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The database for reproductive or developmental toxicity testing of 5,5-dimethylhydantoin is complete. Based on the overall examination of the effects of DMH, the HIARC concluded that there was some evidence for increased susceptibility, because a developmental endpoint was selected for dietary risk assessment, an additional safety factor to address FQPA concerns is not necessary.

### 3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The Agency has conducted a dietary exposure and risk assessment for the use of halohydantoins as a slimicide in food contact paper and paperboard, and for use as a preservative in inorganic slurries which are used as fillers for food contact paper and paperboard.

#### a. Acute PAD

Acute dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose (1 mg/kg/day) modified by the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rabbits in which both the NOAEL (100 mg/kg/day) and the LOAEL (500 mg/kg/day) were determined. Acute dietary exposure was estimated for females ages 13-50 only since the endpoint chosen is based on a developmental effect. The halohydantoins aPAD is 1 mg/kg/day. Uncertainty factors were included for inter-species extrapolation (10x) and intra-species variation (10x).

#### b. Chronic PAD

Chronic dietary risk for halohydantoins was assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (1 mg/kg/day females 13-50 and 3 mg/kg/day all populations) modified by the FQPA safety factor. The cPAD was derived from a developmental toxicity study in rabbits and a chronic toxicity in rats; in which both the NOAELs and LOAELs were determined. The halohydantoins cPAD is 3 mg/kg/day based on a reference dose of 3 mg/kg/day for the general populations group and 1 mg/kg/day for females age 13-50; which includes the incorporation of the FQPA safety factor (1X) for the overall U.S. population or any population subgroups. Uncertainty factors were also included for inter-species extrapolation (10x) and intra-species variation (10x).

### 4. Dietary Exposure Assumptions

Dietary exposure to the halohydantoins occurs from the slimicide use in the manufacture of paper and paperboard. Acute and chronic dietary exposures were assessed for these indirect food-contact uses. No pesticide tolerances have been established for halohydantoins. The Agency has used available methods to estimate halohydantoin residues on food due to migration of these chemicals or their breakdown products, when these substances come into contact with food-contact paper and paperboard. In this regard, the Food and Drug Administration (FDA) has developed guidelines to estimate the residues of pesticides used as slimicides on food contact paper and paperboard. The Agency has decided to use FDA methodology to estimate the residues of such chemicals and/or their breakdown products on food items and also to determine the Estimated Daily Intake (EDI) of these pesticides.

EPA used two methods to calculate dietary exposure for adult populations. In the first method, the following assumptions were made:

- Food contact surface could be a onetime use/day or repeat use material/day;
- The amount of food that comes into contact with the treated paper is based on an FDA default value;
- 100 percent of the active material present in the paper migrates into the food.

In the second (alternative) method, additional consideration is given to the type of food that is being contained in the treated paper, and factors such as the quantity of active ingredient in the paper are not considered.

The concentration of halohydantoins in the paper slurry was calculated assuming that the chemical was used both as a slimicide and as a preservative in paper. Although two types of use involve different moieties (halohydantoin for slimicide, hydroxymethylhydantoin for material preservative), the concentrations were summed together to determine a total concentration of hydantoins (EMH and DMH) in the slurry. The EDI was then calculated based on this concentration for both adults and children. The results of the calculations are shown in Tables 5 and 6.

For more details on the exposure estimates and dietary risk, see Dietary Risk Assessment of Halohydantoins, dated October 12, 2004, available under docket number EPA-HQ-OPP-2004-0303 on http://www.regulations.gov .

### 5. Dietary Risk Assessment

#### a. Dietary Risk from Food

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Tables 5 and 6.

The Agency has determined that the acute dietary risk estimates do not exceed the Agency's level of concern (less then 100% of the aPAD) for females between 13-50 years, the pertinent sub-population tested. The acute dietary exposure for an adult female is 0.533% of the acute PAD using method #2 for estimating exposure.

The chronic dietary risk assessment concluded the chronic risk estimates are also below the Agency's level of concern (less than 100% of the cPAD) for the general U.S. population (0.533% of the cPAD) and all population subgroups. The highest exposed population subgroup was children 3-5 years old at 1.6% of the cPAD using method #2 for estimating exposure.

Table 5. Summary of Dietary Exposure and Risk for Halohydantoins (1st Method)

| Population Subgroup | EDI mg/day | Acute Dietary | | Chronic Dietary | |
|---|---|---|---|---|---|
| | | Dietary Exposure[a] (mg/kg/day) | % aPAD [b] | Dietary Exposure (mg/kg/day) [a] | % cPAD [b] |
| Adult Male | 0.0276 | -- | -- | $3.94x10^{-4}$ | 0.0131 |
| Adult Female | 0.0276 | $4.60x10^{-4}$ | 0.046 | $4.60x10^{-4}$ | 0.0153 |
| Children | 0.0138 | -- | -- | $1.38x10^{-3}$ | 0.046 |

a-- acute and chronic exposure analysis based on daily consumption of 0.00276 mg/person/day for adults and body weights of 70 kg and 60 kg for males and females, respectively. For infants/children, exposure based on daily consumption of 0.0138 mg/person/day; and a 10 kg body weight.
b--%PAD = dietary exposure (mg/kg/day) * 100 / aPAD or cPAD, where aPAD for females between 13-50 years of age = 1.0 mg/kg/day and cPAD for the general population = 3.0 mg/kg/day

Table 6. Summary of Dietary Exposure and Risk for Halohydantoins (2nd Method)

| Population Subgroup | EDI mg/day | Acute Dietary | | Chronic Dietary | |
|---|---|---|---|---|---|
| | | Dietary Exposure[a] (mg/kg/day) | % aPAD [b] | Dietary Exposure (mg/kg/day) [a] | % cPAD [b] |
| Adult Male | 0.96 | -- | -- | 0.0137 | 0.457 |
| Adult Female | 0.96 | 0.016 | 1.6 | 0.016 | 0.533 |
| Children | 0.48 | -- | -- | 0.048 | 1.6 |

a-- acute and chronic exposure analysis based on daily consumption of 0.96 mg/person/day for adults and body weights of 70 kg and 60 kg for males and females, respectively. For infants/children, exposure based on daily consumption of 0.48 mg/person/day; and a 10 kg body weight.
b--%PAD = dietary exposure (mg/kg/day) * 100 / aPAD or cPAD, where aPAD for females between 13-50 years of age = 1.0 mg/kg/day and cPAD for the general population = 3.0 mg/kg/day

### b. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and groundwater contamination. The Agency is presently relying on predicted environmental concentrations (PECs) of pesticides in surface water to estimate drinking water exposures to halohydantoins. Considering all of the uses of this pesticide, the once-through cooling tower water system can be expected to have the greatest impact on water, since the scenario has the greatest quantity of effluent being produced and has the greatest chance of bacterial fouling, needing a pesticide application. Using the PDM4 model, the short-term Estimated Environmental Concentration (EEC) in surface water use was estimated to be 36 ug/L. The chronic maximum EEC using this model was determined to be 313 ug/L.

## 6. Residential Exposure Assessment

The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Residential exposure may occur while using household cleaning products, paint, adhesives, and deodorizers. For the purposes of this screening level assessment, handler scenarios have been developed that encompass multiple products but represent a worst-case scenario for all products represented in the assessment. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose.

### a. Residential Toxicity

The toxicity endpoints and associated uncertainty factors used for assessing the non-dietary risks for halohydantoins are listed in Table 7. Although the dermal endpoint represents short-, intermediate-, and long-term durations, the exposure duration of most homeowner applications of cleaning products is believed to be best represented by the short-term duration. The inhalation endpoint used in the assessment represents the short-term duration. The calculated dermal and inhalation MOEs are not of concern for any of the scenarios (MOE greater than 10,000 for all scenarios).

However, since the hydroxymethylhydantoins have the potential for release of formaldehyde, the risks associated with this release need to be assessed. The Agency has determined that the risks from exposure to formaldehyde via the hydroxymethylhydantoins will be addressed when registration review is conducted on hydroxymethylhydantoin.

| Table 7. Toxicological Endpoints | | | |
|---|---|---|---|
| **Exposure Scenario** | **Dose Used in Risk Assessment, UF** | | **Study and Toxicological Effects** |
| Short-Term Oral (1-30 days)<br><br>(Incidental) | oral study<br>NOAEL= 500 mg/kg/day<br>UF = 100 | Residential, includes the 1x FQPA SF | developmental toxicity - rabbit<br>maternal LOAEL = 1000 mg/kg/day based on decreased body weight gain in maternal rabbits.<br>(MRID 42413101) |
| Intermediate-Term Oral (1 to 6 months)<br><br>(Incidental) | oral study<br>NOAEL= 300 mg/kg/day<br>UF = 100 | Residential, includes the 1x FQPA SF | subchronic oral toxicity - rat<br>LOAEL = 1000 mg/kg/day based on decreased body weight and liver weight.<br>(MRID 42009201) |
| <u>Dermal- all time periods</u><br>Short-,(1-30 days), Intermediate-, (1 to 6 months), Long-term (>6 months)<br>(Occupational/ Residential) | dermal study<br>NOAEL= 390 mg/kg/day (HDT)<br>UF = 100 for all populations | MOE = 100 (Occupational)<br><br>Residential, includes the 1x FQPA SF | subchronic dermal toxicity - rats<br>No systemic toxicity at the highest dose tested<br>(MRID 43173901) |
| Short-Term Inhalation (1-30 days)<br>(Occupational/ Residential) | Oral NOAEL= 100 mg/kg/day (inhalation absorption rate = 100%)<br>UF = 100 for all populations | Residential, includes the 1x FQPA SF | developmental toxicity - rabbit<br>developmental LOAEL = 500 mg/kg/day based on skeletal effects in offspring.<br>(MRID 42413101) |

It should be noted that this exposure assessment identifies short-term (1-30 days) and intermediate-term (1-6 months) noncancer exposure doses based on the reported toxicology endpoints for Halohydantoin. Because of the shorter exposure durations of these toxicological endpoints, conservative event-based exposure assumptions are used to calculate upper bound daily dose estimates. The noncancer doses are not amortized over a lifetime. However, MOEs for all scenarios are much greater than the target MOE of 100 and are not of concern.

### b. Residential Handler Exposure

#### i. Exposure Scenarios, Data and Assumptions

Halohydantoins may be added to residential-use products as disinfectants and sanitizers in in-tank toilet bowl, swimming pool and spa products. The pool/spa and air conditioner drip pan uses are represented by the application to residential (i.e., backyard) swimming pools and spas.

Hydroxymethylhydantoins may be added as a material preservative to control bacteria and fungi (EPA Reg No. 6836-271) in residential-use products such as household cleaning products, paints, adhesives, and deodorizers. For the purposes of this screening-level assessment, handler scenarios have been assessed for residential uses that represent high-end exposures for the wide variety of products. Therefore, not all products are assessed individually. Table 8 presents the handler scenarios considered to represent the high end conservative estimates of exposure for the residential assessment.

**Table 8. Residential Handler Scenarios**

| Handler Scenario | Typical Products Represented (but not limited to) |
|---|---|
| Handling of liquid general purpose cleaner | Household cleaning products, carpet shampoo, deodorizer |
| Solid placement of in-tank toilet cleaner | In-tank toilet tablet |
| Painting of a house using brush, roller, or airless sprayer | Paint, adhesives, caulk |
| Solid placement into swimming pools & spas | Pools/spas and air conditioner drip pans |

#### ii. Residential Handler Risk

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. A summary of the residential handler exposures and risks for the representative scenarios are presented in Table 9. Although the dermal endpoint represents short-, intermediate-, and long-term durations, the exposure duration of most homeowner applications of cleaning products is believed to be best represented by the short-term duration. The inhalation endpoint used in the assessment represents only the short-term duration. The calculated dermal and inhalation MOEs indicate that risks are not of concern for any of the scenarios (MOE greater than 1,000 for all scenarios). Further details on the residential risk can be found in the *Halohydantoins Revised Risk Assessment for the Reregistration Eligibility Decision*, dated June 25, 2007. This document is available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2004-0303 at: http://www.regulations.gov . As stated previously, formaldehyde is a metabolite of hydroxymethylhydantoins and there may be risk associated with this exposure. Any

risks associated with formaldehyde will be in the Registration Review Document for hydroxymethylhydantoins.

Table 9. Calculation of Short-term Dermal and Inhalation MOE for Residential Handlers

| Exposure Scenario | Method of Application | Dermal Dose (mg/kg/day) | Dermal MOE | Inhalation Dose (mg/kg/day) | Inhalation MOE [b] |
|---|---|---|---|---|---|
| **Household Cleaning Products** | Wipes | 0.014 | 28,000 | 0.00033 | 300,000 |
| | Mopping | 0.0053 | 73,000 | 0.00018 | 570,000 |
| **Toilet Bowl Tablets** | Solid Placed | 0.036 | 11,000 | 0.00091 | 110,000 |
| **Painting** | Brush/ Roller | 0.69 | 570 | 0.00084 | 120,000 |
| | Airless Sprayer | 1.8 | 220 | 0.019 | 5,400 |
| **Swimming Pools / Spas** | | | | | |
| **Swimming Pools (Residential – backyard)** | Solid Place | 0.12 | 3200 | 0.000015 | 6500000 |
| | Solid Pour | 0.85 | 460 | 0.00046 | 220000 |
| **Spas** | Solid Place | 0.396 | 984 | 0.0000506 | 1,970,000 |
| | Solid Pour | 2.8 | 139 | 0.00151 | 66,500 |

### c. Residential Post-application

#### i. Exposure Scenarios, Data and Assumptions

Residential postapplication exposures result when adults and children come into contact where pesticide end use products have recently been applied (e.g., treated hard surface floors), or when children incidentally ingest the pesticide residues through mouthing the treated products/treated articles, through hand-to-mouth or object-to-mouth contact. For the purposes of this screening level assessment, postapplication scenarios have been developed that represent high-end exposure scenarios for all products represented. Table 10 presents the postapplication scenarios considered in this assessment. Three scenarios have been considered: (1) exposure to residue from hard floors that have been cleaned/mopped with a general cleaner preserved with hydroxymethylhydantoins, (2) exposure to residue on clothing that has been treated with halohydantoin during textile processing, and (3) exposure to swimmers in treated pools. For this screening-level assessment, fabric softeners have been grouped with textile processing chemicals for calculating exposure.

**Table 10. Residential Postapplication Scenarios**

| Handler Scenario | Products Represented |
|---|---|
| Toddler exposed to residue from a hard floor | Hard surface cleaner/floor |
| Adult and toddler exposed to residue on clothing | Textile processing chemicals, fabric softener |
| Adult and Children exposed to residue in a swimming pool | Pool and spa products |

#### ii. Post Application Risk

##### a. Residential Post Application Risk (Hard Surfaces)

There is the potential for toddlers playing on treated floors to be exposed to hydantoins contributed by the hydroxymethylhydantoin material preservatives. Due to limited data, the following assumptions have been made to determine toddler exposure while playing on treated hard floors:

- Toddlers (3 years old) are used to represent the 1 to 6 year old age group.
- As a conservative estimate, it has been assumed that one gallon of mopping solution can treat 1000 $ft^2$ of floor surface.
- No data could be found regarding the quantity of treatment solution residue left on the floor after treatment. It has been assumed that 25% of the solution remains after the final mop.
- No leaching data were available that could be used to estimate the residue transfer

from the hard surface (i.e., floor). Therefore, the Residential SOP estimate of 10 percent of the amount on the floor is available for dermal transfer.

The short- and intermediate-term dermal MOE calculated is 700, which is above the target MOE of 100. See the Occupational Residential Exposure Chapter for a more detailed review, available under docket number EPA-HQ-OPP-2004-0303 on http://www.regulations.gov .

In addition to the dermal exposure from toddlers playing on treated floors, there is the potential for incidental oral exposure via hand-to-mouth activities. Although residential floors are believed to be washed/moped on an intermittent basis, facilities such as day care centers may clean the floors more frequently; therefore, both the short- and intermediate-term incidental oral endpoints are provided to assess the potential risks. Due to limited data, the following assumptions from the Residential SOPs (in addition to the assumptions listed above) have been made to estimate hand-to-mouth exposures for toddlers playing on treated carpets:

- The surface area of the portion of the hand-to-mouth per event is 20 $cm^2$;
- The number of hand-to-mouth events per hour is 20;
- Exposure time is 4 hours/day;
- Saliva extraction efficiency is 50 percent

Based on these assumptions, the potential dose rate using these assumptions is 0.07 mg/kg/day resulting in a hand-to-mouth MOE for toddlers of 7100 (short-term) and 4300 (intermediate-term) and thus, are not a concern to the Agency.

**b. Residential Post Application Risk (Clothing)**

Although hydroxymethylhydantoin has been listed for use in textile processing, it is unclear in what capacity the chemical is to be used. It has been assumed, for this risk assessment, that the chemical is impregnated into the material in the same manner as a dye would impregnate. Data on which these calculations could be based were generally unavailable; therefore, a number of conservative assumptions have been made:

- Toddlers (3 years old) are used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers (USEPA, 2000b). The median surface area for a 3 year old, minus the head, is 0.657 $m^2$. Median values for body weights and surface areas for adults have been used (70 kg and 1.69 $m^2$, not including head surface area).
- Based on rough estimates provided by the American Association of Textile Chemists and Colorists (AATCC), dyes are used on fabric at a rate of about 4% by weight (AATCC, 2003). A medium-sized polo cotton shirt of regular knit construction weighs about 250 g. Assuming that the shirt covers 0.659 $m^2$ of the body's surface area (based on the mean adult surface area for the torso, including the neck (USEPA, 1997)), the cloth weight to surface area ratio is 379 $g/m^2$. If an adult wears clothing of a similar weight over all parts of the body, minus the head (1.69 $m^2$ (USEPA, 1997)),

then the weight of clothing worn by an adult is 641 g. Using the same cloth weight to surface area ratio, the weight of clothing worn by a toddler is 214 g. Area mouthed, for lack of data, is assumed to be equivalent to the area of fingers used in the hand-to-mouth exposure estimates (i.e., 20 $cm^2$ or 20 $cm^2$ / 10,000 = 0.002 $m^2$).

- No leaching data were available that could be used to estimate a flux rate of the chemical from clothing. It has been conservatively assumed that, over the course of a day, the amount of chemical transferred is the full quantity of chemical present in the clothing. This is a conservative assumption and should not be considered as representative of the true rate at which the chemical would be transferred. However, as a screening-level assessment the risks are not of concern.

The dermal MOE's calculated for both toddler and adult scenarios are not of concern (MOE's = 119 and 185 for toddlers and adults, respectively). The short-term incidental oral MOE, as a result of mouthing treated fabric, is not of concern (MOE = 45,000). The short-term NOAELs were used instead of the intermediate-term NOAELs because all of the residues were assumed to be available for exposure in one day (for lack of any residue data). See the Occupational Residential Exposure Chapter for a more detailed review, available under docket number EPA-HQ-OPP-2004-0303 on http://www.regulations.gov .

### c. Residential Post Application Risk (Swimming)

There are potential postapplication exposures to halohydantoin associated with use of swimming pools and spas. Because the amount of exposure will most likely be much greater for swimming pools than for spas, based on the amount of time spent in the water, only swimming pool scenarios have been considered.

The SWIMODEL 3.0 was developed by EPA as a screening tool to conduct exposure assessments of pesticides found in swimming pools and spas (Dang, 2003). The SWIMODEL uses well-accepted screening exposure assessment equations to calculate the total worst-case exposure for swimmers expressed as a mass-based intake value (mg/event). The model focuses on potential chemical intakes only and does not take into account metabolism or excretion of the chemical of concern. Detailed information and the downloadable executable file are available at http://www.epa.gov/oppad001/swimodel.htm.

It should be noted that this exposure assessment identifies short-term (1-30 days) and intermediate-term (1-6 months) noncancer exposure doses based on the reported toxicology endpoints for halohydantoins. Because of the shorter exposure durations of these toxicological endpoints, conservative event-based exposure assumptions are used to calculate upper bound daily dose estimates. The noncancer doses are not amortized over a lifetime. However, as shown below in Table 11, MOEs for all scenarios are much greater than the target MOE of 100 and are not of concern.

Table11. Margins of Exposure for Swimming Pool[a]

| Age | Type of Swimmer | Dermal MOE | Inhalation MOE | Ingestion MOE |
|---|---|---|---|---|
| Adult | Competitive | 3,100,000 | 47,000 | 190,000 |
| Adult | Non-competitive | 1,900,000 | 90,000 | 56,000 |
| Child 7-10 yrs | Competitive | 7,100,000 | 100,000 | 60,000 |
| Child 7-10 yrs | Non-competitive | 1,400,000 | 38,000 | 12,000 |
| Child 7-10 yrs | Non-competitive | 1,400,000 | 38,000 | 12,000 |
| Child 11-14 yrs | Competitive | 4,100,000 | 81,000 | 96,000 |
| Child 11-14 yrs | Non-competitive | 2,800,00 | 100,000 | 32,000 |

[a]MOE = NOAEL (mg/kg/day)/Dose(mg/kg/day). Dermal route is based on an absorbed dose, and therefore, the oral endpoint is used to estimate risk. The inhalation and ingestion NOAELs are 100 mg/kg/day and 300 mg/kg/day (intermediate-term), respectively. Target MOE = 100.

### 7. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. Results of the aggregate risk assessment are summarized here, and are discussed more extensively in the document, Revised Halohydantoins Risk Assessment, dated June 25, 2007, which is available in the public docket at http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0303).

#### a. Acute Dietary Aggregate Risk

The acute aggregate assessment includes dietary and drinking water exposures only. The acute dietary risk estimates from indirect food uses (i.e., use in food-contact packaging and treated articles) are less than 2% of the aPAD in all considered scenarios. Thus, the acute dietary (food) risk estimate associated with halohydantoins is below the Agency's level of concern.

Drinking water exposure could occur from application of the pesticide to industrial water systems but is not expected. Drinking water monitoring data are not available; therefore, the Agency calculated a drinking water level of comparison (DWLOC) to account for potential drinking water exposures from the exposure from once-through cooling tower uses. The short-term EEC for halohydantoin in surface was 36 ppb, or 36 ug/L. See the Ecological Hazard Chapter for a more detailed review, available under docket number EPA-HQ-OPP-2004-0303 on http://www.regulations.gov. As shown in Table 12, the acute DWLOCs are greater than the EEC, indicating that acute aggregate food and drinking water exposure do not exceed the Agency's level of concern.

Table 12. Acute Aggregate Exposure and Risk

| Population Subgroup | aPAD mg/kg/day | Acute Food Exp[1] mg/kg/day | Max Acute Water Exp[2] mg/kg/day | Surface Water EEC[3] mg/L | Acute DWLOC[4] mg/L | Potential Risk Concern |
|---|---|---|---|---|---|---|
| Females 13-50 years | 1.0 | $4.6x10^{-4}$ | 0.999 | 0.036 | 29986 | No |
| Females 13-50 years (alternate FDA method) | | 0.016 | 0.984 | | 29520 | No |

**[1]Acute food exposure = estimated daily intake (mg/person/day) / body weight (70 kg)**
**[2] Maximum acute water exposure (mg/kg/day) = [(aPAD (mg/kg/day) - acute food exposure (mg/kg/day)]**
**[3] Based on PDM4 model.**
**[4] Acute DWLOC(µg/L) = [maximum acute water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x $10^{-3}$ mg/µg]**

### b. Short-and Intermediate-term Aggregate Risk

Only dermal and inhalation aggregate risks were considered for the short-term duration in the aggregate risk evaluation. This is because homeowner cleaning scenarios are considered short-term exposures only and thus do not involve intermediate or long-term exposure. Further, not all of the non -dietary scenarios mentioned in this risk assessment have been aggregated, as it is unlikely that all of the scenarios mentioned in the exposure assessment have a reasonable probability of occurring together. For purposes of this aggregate assessment, the dietary exposure (food + water) is aggregated only with the cleaning scenarios involving wiping of hard surfaces, mopping, and cleaning of toilets for adults. Table 13 presents a summary of the aggregate dermal and inhalation short-term risk for adults. As shown, the aggregate MOE for both the dermal and inhalation exposure was is not of concern.

For toddlers, the dietary exposure is aggregated with the single dermal scenario of floor contact, and the dietary exposure is aggregated separately with the single incidental oral floor scenario. These scenarios are aggregated separately because exposures and MOEs for short- and intermediate-term aggregate exposure risk assessment (oral, dermal, and inhalation exposures) cannot be combined due to the lack of a common endpoint of toxicity from the different routes of exposure. Clothing is not included in the aggregate risk because a screening level assessment was performed in which it was assumed that, over the course of a day, the amount of chemical transferred is the full quantity of chemical present in the clothing. This is a conservative assumption and should not be considered as representative of the true rate at which the chemical would be transferred.

Calculation of aggregate MOE's for toddlers from dietary exposure and either dermal or inhalation exposure from the floor treatment also showed no risk of concern. Short-term aggregate MOE's were calculated as 1000 and 5000 for the dermal and inhalation exposure scenario, while intermediate-term aggregate MOE's were calculated as 909 and 3333 for the dermal and inhalation exposure scenario respectively.

Table 13 Short-Term Aggregate Risk and DWLOC Calculations for Adults

| Population | *Short-Term* Scenario | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Target Aggreg. MOE** | **MOE food[1]** | **MOE dermal[2]** | **MOE inhalation[3]** | **Short-Term Aggregate MOE (food and dermal residential)[4]** | **Short-term Aggregate MOE (food + inhalation residential)[5]** | **MOE water[6]** | **Allowable water exposure[7] (mg/kg/day)** | **Surface Water EEC[8] (µg/L)** | **DWLOC[9] (µg/L)** |
| Adult | 100 | 36496 | 7090 | 196000 | 5988 | 31250 | 101 | 4.9 | 4 | 147000 |

[1] MOE food = [( short-term oral NOAEL)/(chronic dietary exposure)] Oral NOAEL of 500 mg/kg/day with chronic exposure of 0.0137.

[2]MOE dermal = [(short -term dermal NOAEL)/dermal residential exposure)] dermal NOAEL of 390 mg/kg/day used with total exposure of 0.055 mg/kg/day from cleaning scenarios.

[3] MOE inhalation = [(inhalation NOAEL)/(high-end inhalation residential exposure)] Inhalation NOAEL of 100 mg/kg/day used with total exposure of 0.00051 mg/kg/day

[4] Aggregate MOE (food and dermal residential) = 1÷[ [(1÷MOE food) + (1÷MOE dermal)]]

[5] Aggregate MOE (food and inhalation residential) = 1÷[ [(1÷MOE food) + (1÷MOE inhalation)]]

[6] Water MOE = 1÷ [[(1÷ Target Aggregate MOE) - (1÷Aggregate MOE (food and residential)]]

[7] Allowable water exposure = Short or Intermediate Term Oral NOAEL ÷ MOE water

[8]using PDM4 model

[9] DWLOC(µg/L) = $\frac{\text{[allowable water exposure (4.9mg/kg/day) x body weight (60kg)]}}{\text{[water consumption (2L) x } 10^{-3} \text{ mg/µg]}}$

### c. Chronic Dietary Aggregate Risk

Table 14 presents the total chronic dietary exposure estimate for halohydantoins, and the chronic DWLOCs. The chronic PAD and the chronic dietary (food) exposure for that subgroup were used to calculate the chronic DWLOC. Two methods were used to calculate dietary exposure, and calculations are presented using both methods. Based on the use of the PDM4 model the chronic maximum EEC for dihalodialkylhydantoin in surface water was calculated as 313 ppb, or 313 ug/L. As shown in Table 14, the chronic DWLOCs are greater than the EEC, indicating that aggregate food and drinking water exposure do not exceed the Agency's level of concern.

**Table 14. Chronic Aggregate Exposure and Risk**

| Population Subgroup | cPAD mg/kg/day | Chronic Food Exp[1] mg/kg/day | Max Chronic Water Exp[2] mg/kg/day | Surface Water EEC[3] mg/L | Chronic DWLOC[4] mg/L |
|---|---|---|---|---|---|
| General Population | 3.0 | $3.94 \times 10^{-4}$ | 2.999 | 0.3 | 104986 |
| General Population (alternate FDA method) | | 0.0137 | 2.986 | | 104520 |
| Females 13-50 years | 1.0 | $4.60 \times 10^{-4}$ | 0.999 | | 29986 |
| Females 13-50 years (alternate FDA method) | | 0.016 | 0.984 | | 29520 |

[1] Chronic food exposure = estimated daily intake (mg/person/day) / body weight (70 kg [M]; 60kg[F])

[2] Maximum chronic water exposure (mg/kg/day) = [(cPAD (mg/kg/day) - chronic food exposure (mg/kg/day)]

[3] Based on PDM4 model.

[4] Chronic DWLOC(µg/L) = $\frac{\text{[maximum chronic water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/µg]}}$

### 8. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of halohydantoins products use them in a variety of industrial applications, including recirculating cooling water, once-through cooling tower water, pulp and paper process water, photo processing water, and transportation cleaning systems. Concentrations of halohydantoin in these products range from 90% to 98%, and are generally formulated as tablets, pellets, briquettes, or granules. The remaining formulations are gels, powders, or ready-to-use solutions, and all may be considered as solid (as opposed to liquid) formulations.

Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of halohydantoins, MOEs greater than 100 are not of concern to the Agency. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

For more information on the assumptions and calculations of potential risk of halohydantoins to workers, see the Occupational Exposure Assessment (Section 6) in the *Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).*

### a. Occupational Toxicity

The toxicological endpoints used in the occupational assessment can be found in Table 7 above.

### b. Occupational Handler Exposure

EPA has assessed the exposures and risks to occupational workers that handle and apply halohydantoin in the Occupational Exposure Assessment in the *Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).* This section summarizes the results of the occupational exposure/risk assessment. The following handler exposure scenarios were assessed and represent high-end exposures to industrial uses of the formulated product:

- Placing the halohydantoin tablets/pellets into cooling and process water systems, and
- Pouring halohydantoin granules/powders into a feeder for cooling and process water systems.

These two types of exposure scenarios were assessed for each of the water systems in question. The methods for applying gels, briquettes, and ready-to-use solutions are nearly identical to at least one of the two methods described above, based on the directions on the label. Therefore, although the two exposure scenarios considered include only products that are tablets, pellets, granules, or powders, these scenarios should be sufficient to describe the risks associated with all formulations.

#### i. Industrial Process (Handlers)

Occupational handler risk estimates have been assessed for halohydantoins using surrogate unit exposure data from the Chemical Manufacturers Association (CMA) database, application rates from labels, and EPA estimates of daily amount handled. The handlers were identified as those individuals who use dihalodialkylhydantoin in industrial/commercial water systems (recirculating cooling water, once-through cooling tower water, pulp and paper process water, photo processing water, and transportation cleaning systems) to limit microbial growth. The application rates were assumed to be the maximum rates listed on the product labels. The amounts of pesticide handled were based on a report containing use information for selected

scenarios related to antimicrobials (Dang, 1996).

For industrial use, the short- and intermediate-term dermal and inhalation MOEs for the primary were determined. Dermal MOEs range from a high of 151,000 for solid pour in photo processing water systems, to 76 for solid place in once-through cooling tower water systems. Except for once-through cooling tower water systems, all MOEs are above the target margin of exposure (100). For more information, see the Revised Halohydantoins Risk Assessment, dated December 15, 2004, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).

*Material Preservatives and Commercial/Institutional/Industrial Premises and Equipment and Swimming Pools*

Use of dihalodialkylhydantoin in a commercial setting is similar in purpose to industrial use; used to prevent slime formation in water systems. In addition, it is used as a material preservative in paints. Six scenarios have been identified to represent potential high-end exposures for these uses.:

- Liquid pour of product into paint during manufacturing as a material preservative;
- Solid place of product in air conditioner / humidifier drip pans;,
- Solid place of product in ornamental fountains;,
- Solid place of product for use in transportation cleaning water systems;,
- Commercial painters (brush/airless sprayer); and
- Solid place/pour of product in commercial swimming pools and spas.

The occupational material preservative use assessed for paints is believed to be representative of the other preservative uses on the labels such as detergents, fabric softeners, household cleaning products, surfactants, etc. Therefore, a separate commercial use of household cleaning products has not been conducted.

Very little data are available at this time regarding typical amounts of product handled by workers. For ~~a~~ workers performing air conditioning maintenance in a large institution, it has been assumed that 3 air-conditioner units were maintained one day. A large ornamental fountain was assumed to be the same size as an average residential swimming pool. Assumptions for the in-bay car wash are based on information from the International Carwash Association and from anecdotal evidence. The EPA calculated the exposures for workers at a commercial/public swimming pool, using the assumption that a large commercial/public swimming pool size is 200,000 gallons, and that a large commercial spa's volume is approximately 1000 gallons.

For commercial uses, the short- and intermediate term dermal MOEs for the handlers wearing PPE range from 140 to 151,000. An MOE lower than the target MOE was found for only one scenario; placing tablets into public swimming pools ungloved (MOE=46). However, the product labels state that gloves should be worn when placing tablets into swimming pools. When gloves are used risks are mitigated for the placing of tablets (MOE = 7,500). For more information, see the Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).

*Metal Working Fluids*

Potential inhalation and dermal exposures to occupational handlers may exist when using treated metal working fluid. The Agency conducted the screening level assessment for metal working fluids using the Chemical Engineering Branch (CEB) model (U.S. EPA, 1991). Exposure assumptions used in the model are presented in Dang, 1997. The CEB model uses measured and/or assumed airborne oil mist concentrations for metal working operations. Since no measured concentrations are available for halohydantoins, the high-end oil mist concentration is based on the OSHA's Permissible Exposure Limit (PEL) of 5 $mg/m^3$ (NIOSH, 1998). The label indicates that 0.45% (i.e., 0.0045) of the product is added to metal working fluids and of that, only 52.4% is the active ingredient. Therefore, the upper bound air concentration of halohydantoins that a worker is exposed to is 5 $mg/m^3$ x 0.0045 x 0.524 or an air concentration of 0.012 $mg/m^3$. Additionally, the following assumptions were made in the assessment: the inhalation rate for adults is 1.25 $m^3$ /hr; the exposure duration is 8 hours; and body weight is 70 kg. Using these assumptions, the long-term dose was calculated to be 0.0017 mg/kg/day, resulting in a long-term MOE of 59,000. Therefore, the calculated MOE indicates that the inhalation risks do not exceed the Agency's level of concern for a machinist exposure to metal working fluid that is treated with halohydantoins.

A screening-level long-term dermal exposure estimate was derived from the 2-Hand Dermal Immersion in Liquid Model in ChemSTEER (EPA/OPPT). The model is available at www.epa.gov/opptintr/exposure/docs/chemsteer.htm . The weight fraction of halohydantoin in metal working fluids is 0.0024 (0.0045 formulated product added to oil x 0.524 ai in formulated product = 0.0024). Based on the model for emersion of hands in metal working fluids, the long-term dermal dose is estimated at 0.3 mg/kg/day. The long-term dermal MOE is 1,300 (i.e., dermal NOAEL of 390 mg/kg/day / potential dose of 0.3 mg/kg/day). The dermal MOE is above the target MOE of 100, and therefore, the risk is not of concern. For more information, see the Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).

### ii. Agricultural Premises and Aquatic Area Uses (Handlers)

For occupational handlers, one agricultural premise use and one aquatic area use have been identified.

- Solid pour/place of product into chemigation systems,
- Solid pour of product into vehicle and foot baths at greenhouse entrances.

Use of halohydantoin in chemigation systems is via loading of a brominator feed system, through which the product is dispensed via dissolution as feed water is passed through the tank. The amount of halohydantoin that will be used in the irrigation systems will depend greatly on the size of the greenhouse/nursery and the amount of irrigation necessary for the particular crop/climatic conditions. The amount of footbaths that should be used for the assessment is also in question. From anecdotal evidence, 1 gallon of water is used for each footbath, and 1" of water use for irrigation can be assumed. It has also been assumed that, for chemigation, the product

will be used on 10 acres of crop. From these assumptions, the total amount of water applied for chemigation is 270,000 gallons. This scenario is not representative of the available exposure data and the uncertainty level is deemed high. The exposures maybe overestimated because of the extrapolation to such a high amount of water applied. All MOEs calculated are of concern (i.e., MOEs less than the target MOE of 100). No postapplication exposures were considered. For more information, see the Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).

### c. Postapplication Exposure (All Occupational Uses)

Postapplication inhalation exposures may occur in the industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational postapplication dermal and inhalation exposures to halohydantoins are likely to be minimal compared to handler exposure because of dilution during processing. No postapplication exposures were evaluated for the agricultural premise use and aquatic area use as this exposure is anticipated to be negligible. No postapplication exposure data have been submitted to the agency to determine the extent of postapplication exposures in the industrial settings. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of dihalodialkylhydantoin is low.

### d. Human Incident Data

Halohydantoins are active ingredients used in a variety of products (e.g. for treatment of swimming pools, spas and hot tubs, and toilet bowl water). The purpose of this chapter is to review the evidence of health effects in humans resulting from exposure to Halohydantoins.

Two approaches are used in this section:

- The potential health effects of halohydantoins in humans, reported as incident reports from different sources, are summarized.
- A literature search of chronic health effects associated with halohydantoin exposure, including results of epidemiological studies, is summarized.

There are many incidences that have been reported associated with exposure to end-use products containing halohydantoins. Dermal, ocular, and inhalation are the primary routes of exposure. Most of the incidences are related to irritation and/or allergic type reaction. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash, itching, skin discoloration/redness, blistering, allergic type reactions including hives/welts, allergic contact dermatitis, and bleeding also have been reported. The most common symptoms reported for cases of ocular exposure were eye irritation/burning. Eye pain and swelling of eyes also has been reported in some incidences.

The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms, and headache. Seizure and heart palpitation also have been

reported.

Although oral exposure is considered a minor route of exposure for halohydantoin use, irritation to mouth/throat/nose, vomiting/nausea/abdominal pain have been reported in the cases of ingestion.

## B. Environmental Risk Assessment

The following environmental risk characterization is intended to describe the magnitude of the estimated environmental risks associated with halohydantoins use. For more information, see the Revised Halohydantoins Risk Assessment, dated June 25, 2007, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).
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### 1. Environmental Fate and Transport

The Agency does not have a complete database for environmental fate studies on dihalodialkylhydantoin. However, hydrolysis appears to be the major route for dissipation. Dihalodialkylhydantoin has been shown to hydrolyze relatively rapidly. It also degrades rapidly in an anaerobic aquatic environment with an observed half-life of less than 4 hours; there are indications that this short half-life appeared to be independent of aerobic or anaerobic conditions. The rapid hydrolysis, under abiotic conditions, show half-lives of less than 30 days in pH 5, pH 7, and pH 9 (in buffered solutions), which indicated that hydrolysis is an early step in the degradation process. However, the major degradate, dimethylhydantoin (DMH), was hydrolytically stable at pH 5, 7, and 9, and may possibly leach in the soil profile or move with surface water runoff and may pose environmental concerns. An aqueous photolytic study on dimethylhydantoin, conducted at pH 7 and at 25±1°C in the presence of xenon arc as light source, yielded a first order rate constant of $7.89 \times 10^{-4}$/day which translates into a half life of 878 days. Aqueous photolytic stability means that surface water runoff of DMH can be a source of concern for drinking water contamination. The Agency lacks any data on halohydantoins as far as mobility (soil column leaching) is concerned, as well as binding constants to soils to indicate if dihalodialklhydantoins will be persistent in soils. Because of lack of data, the Agency cannot assess if halohydantoins are bioaccumulative and if these can be potentially a source of concern for the aquatic organisms.

Dihalodialkylhydantoin degrades relatively rapidly in water under abiotic conditions. However, there is environmental concern for soil or surface water contamination from the major degradate DMH, as DMH is hydrolytically and photolytically stable. DMH is also stable under aerobic conditions and shows a moderate tendency toward binding with soils (Kd's). If present in the environment, it may cause a concern for ground- and surface water contamination.

### 2. Ecological Risk

Most of the halohydantoins uses are considered indoor uses. However, there is potential environmental exposure from the once-through cooling tower use. Halogenated halohydantoins show varying toxicity, depending on the number of halogens (bromine or chlorine) on the molecule. The halogens dissociate from the DMH core upon exposure to water; therefore, DMH was considered to be the moiety of concern for environmental exposure and ecological toxicity. A summary of ecotoxicological endpoints for DMH is provided in the Table 15. As indicated in the table, DMH demonstrates low toxicity to terrestrial and aquatic animals.

**Table 15: Summary of Ecotoxicity Endpoints**

| Test type | Species | % a.i. | Endpoint | EPA MRID # | Toxicity Category |
|---|---|---|---|---|---|
| Avian acute oral (71-1/850.2100) | Northern bobwhite (*Colinus virginianus* | 96 | LD50 = 1839mg/kg<br>NOEL = 1350 mg/kg | 147319 | Slightly toxic |
| Avian dietary (71-2/850.2200) | Northern bobwhite (*Colinus virginianus*) | 96 | LC50 > 5620 ppm | 147321 | Practically non-toxic |
| Avian dietary (71-2/850.2200) | Mallard (*Anas platyrhynchos*) | 97.2 | >5000 ppm<br>NOEC = 5000 ppm | 432899-03 | Practically non-toxic |
| Freshwater fish acute (72-1/850.1075) | Rainbow trout (*Oncorhynchus mykiss*) | 97.1 | LC50 >972 mg/L<br>NOEC = 972 mg/L | 423736-01 | Practically non-toxic |
| Freshwater fish acute (72-1/850.1075) | Bluegill (*Lepomis macrochirus*) | 97.1 | LC50 > 1,017 mg/L<br>NOEC = 1,017 mg/L | 423685-01 | Practically non-toxic |
| Fish early life-stage (72-4/850.1300) | Fathead minnow (*Pimephales promelas)* | 99.9 | NOEC = 14 mg/L(dry weight)<br>LOEC = 29 mg/L | 427217-02 | (chronic endpoints are not assigned a toxicity category) |
| Freshwater invertebrate acute (72-2/850.1010) | *Daphnia magna* | 97.1 | EC50 > 1070 mg/L<br>NOEC = 1070 mg/L | 423736-03 | Practically non-toxic |
| Marine/estuarine fish acute (72-3a/850.1075) | Sheepshead minnow *(Cyprinodon variegatus)* | 97.1 | LC50 > 1006 mg/L<br>NOEC = 1006 mg/L | 423747-01 | Practically non-toxic |
| Marine/estuarine invertebrate acute (72-3c/850.1045) | Mysid (*Mysidopsis bahia*) | 97.1 | LC50 > 921mg/L (limit test) | 423736-02 | Practically non-toxic |
| Marine/estuarine bivalve acute (72-3b/850.1025) | Eastern oyster *(Crassostrea virginica)* shell deposition | 97.2 | EC50 > 125 mg/L<br>NOEC = 125 mg/L | 432899-02 | Practically non-toxic |

## 3. Environmental Exposure Modeling

The PDM4 Model was used to estimate exposure from once-through cooling tower uses. A low-flow power plant (100 ± 10 million gallons per day) was used as the scenario providing the maximum concentrations of DMH in the receiving water, e.g., the "worst case" scenario. Actual concentrations in receiving waters are likely lower, and will likely not show the increasing trend indicated in Table 16, due to higher flow rates and possible degradation/dissipation of DMH by mechanisms other than hydrolysis. Based on the modeling, a summary of the estimated environmental concentrations (EECs) over time is provided below:

**Table 16: Summary of Estimated Environmental Concentrations of DMH in Rivers Receiving Outfall from Low-Flow Power Plants Using Once-through cooling tower Systems**

| Time Period Modeled | Peak Concentration of DMH (EEC) | Duration of Peak Concentration |
|---|---|---|
| 4 days | 36.0 ppb | 24 hours |
| 30 days | 210 ppb | 24 hours |
| 60 days | 313 ppb | 24 hours |

The model was also used to determine the percent of days per year various "concentrations of concern" were exceeded for several power plant scenarios. For more information, see the Revised Halohydantoins Risk Assessment, dated December 15, 2004, available at http://www.regulations.gov (EPA-HQ-OPP-2004-0303).

### a. Terrestrial Organisms:

No model is available to estimate exposure and risk to birds and mammals from discharge of once-through cooling tower system effluents into surface waters. The low EECs, coupled with the generally low toxicity of DMH to birds and mammals, indicate that risks to these organisms are unlikely. There are no data available to assess the phytotoxicity of DMH at this time; therefore, the risk to terrestrial/semi-aquatic plants cannot currently be assessed.

### b. Aquatic Organisms:

Using the worst-case scenario of a low-flow power plant using halohydantoins for once-through cooling tower system treatment, the following risk quotients (RQ) were calculated for aquatic organisms in Table 17.

**Table 17: Aquatic Organism Risk Quotients for DMH Used in Once-through cooling tower of Low-Flow Power Plants**

| Endpoint Type | Species | Value | EEC (from Table 16) | RQ (EEC/LC50) |
|---|---|---|---|---|
| Freshwater Fish Acute | Rainbow trout (*Oncorhynchus mykiss*) | LC50 >972 mg/L (MRID - 423736-01) | 36.0 ppb (0.036 mg/L) | 0.000037 |
| Freshwater Invertebrate Acute | *Daphnia magna* | EC50 > 1070 mg/L NOEC = 1070 mg/L (MRID 423736-03) | 36.0 ppb (0.036 mg/L) | 0.000034 |
| Freshwater Fish Chronic | Fathead minnow (*Pimephales promelas)* | NOEC = 14 mg/L LOEC = 29 mg/L (MRID - 427217-02) | 313 ppb (0.313 mg/L) | 0.022 |

Using the very conservative EECs provided by modeling the once-through cooling tower, no LOCs are exceeded. Expressed as number of days exceedance, using the most sensitive parameter of 14.0 mg/L (14000 ppb) (freshwater fish chronic NOEC) as the "concentration of concern" and the exceedance curve generated by modeling, the chance of this concentration being exceeded by any of the once-through plant scenarios is extremely low, less than once every two years. Other uses of halohydantoin products are indoor or contained (e.g., swimming pool) uses, and should not result in appreciable environmental exposure when products are used as labeled. As indicated in Table 16 above, risks to freshwater fish and aquatic invertebrates are not anticipated from the use of halohydantoins in once-through cooling tower systems as the RQs do not exceed the Agency's level of concern. Marine/estuarine fish are generally less sensitive than freshwater fish to halohydantoins, and marine/estuarine invertebrates are comparably as sensitive to DMH as freshwater invertebrates. Therefore, the freshwater RQs are presumed to be protective of marine/estuarine species. Risks to aquatic plants cannot be assessed due to the lack of phytotoxicity data.

## 4. Listed Species Consideration

### a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a) (2), the Environmental Protection Agency, Office of Pesticide Programs has established procedures to valuate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section II B, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. Based on low toxicity and the use of halohydantoins products low exposure, risk to endangered birds and mammals is not anticipated. Calculated RQs for fish and aquatic invertebrates from the once-through cooling tower use are well below LOCs for Endangered species; other uses of halohydantoin products are indoor or contained (e.g., swimming pool) uses, and should not result in appreciable environmental exposure when products are used as labeled. Therefore, risk to Endangered fish and aquatic invertebrate species is not anticipated from the use of halohydantoin products. Risk to Endangered plants cannot be addressed due to the lack of phytotoxicity data.

# IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

## A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing halohydantoins as 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 supported products containing halohydantoins.

The Agency has completed its assessment of the dietary, occupational, drinking water and ecological risks associated with the use of pesticide products containing the active ingredient halohydantoins. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient halohydantoin, the Agency has sufficient information on the human health and ecological effects of halohydantoins to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing halohydantoins are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of halohydantoins that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of halohydantoins and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of halohydantoins, the Agency has determined that halohydantoins products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of halohydantoins. If all changes outlined in this document are incorporated into the product labels, then all current risks for halohydantoins will be substantially mitigated for the purposes of this determination.

## B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for halohydantoins. During the public comment period on the risk assessments, which closed on September 29, 2004, the Agency received comments from the ACC Brominated Biocides Panel and other interested parties. These comments in their entirety are available in the public docket; http://www.regulations.gov (EPA-HQ-OPP-2004-0303). The Agency's responses to these comments are incorporated into the revised risk assessment, which is also available in the public docket.

## C. Regulatory Position

### 1. Food Quality Protection Act (FQPA) Considerations

#### a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has concluded that the tolerance exemption for halohydantoins meets the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures from food and residential use. The Agency has determined that the human health risks from these combined exposures are within acceptable levels provided that the mitigation contained in this document is implemented. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, water and residential exposures.

#### b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with halohydantoins. The Agency has determined that, the established tolerance exemptions for halohydantoins with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of halohydantoins. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of halohydantoins. As discussed in Section III, the acute and chronic dietary (food and drinking water) risks from halohydantoins are below the Agency's level of concern.

#### c. Determination of Safety to Infants and Children

EPA has determined that the tolerance exemptions for halohydantoins meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of halohydantoins in this population subgroup.

In determining whether infants and children are particularly susceptible to toxic effects from exposure to residues of halohydantoins, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA safety factor has been reduced

to 1X for halohydantoins. The rational for the decisions are based on: the developmental endpoint is sufficiently protective of effects that may occur in infants and children from exposure to dimethylhydantoin. Even though, there is quantitative evidence of increased sensitivity of neonatal rabbits, the Agency considered this effect not indicative of susceptibility, based upon: (1) the very high dose level at which the effect occurred; (2) the minimal nature of the effect and (3) the likelihood that the effect was due to a greater dose received by pups from ingestion of both milk and feed during the lactation period.

### d. Endocrine Disruptor Effects

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, halohydantoins may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

### e. Cumulative Risks

Risks summarized in this document are those that result only from the use of halohydantoins. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for halohydantoins. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common

mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

### 2. Tolerance Summary

No pesticide tolerances have been established for the halohydantoins. The Agency has determined that, the established tolerance exemptions for halohydantoins with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of halohydantoins.

### 3. Codex Harmonization

No CODEX maximum residue levels (MRLs) have been established for halohydantoins.

## D. Regulatory Rationale

The Agency has determined that the halohydantoins are eligible for reregistration provided that additional required data confirm this decision, the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of halohydantoins. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

### 1. Human Health Risk Management

#### a. Dietary (Food) Risk Mitigation

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. For all supported uses, acute and chronic dietary risk estimates are not of concern. Therefore, no risk mitigation measures are required.

#### b. Drinking Water Risk Mitigation

Based on modeling, the once-through cooling tower use of the halohydantoins is not likely to result in risks to drinking water. Therefore, no risk mitigation is required.

#### c. Residential Risk Mitigation

Residential risks for handlers were calculated for short- and intermediate-term dermal and inhalation exposures. For all supported uses, residential exposure risk estimates are not of

concern. However, as formaldehyde is a metabolite of dihalodialkylhydantoins, there may be risk associated with this exposure, particularly for use of products that produce a greater chance of inhalation exposure to formaldehyde, such as air fresheners. Risks associated with the exposure to formaldehyde via the hydroxymethylhydantoins will be addressed when registration review is conducted on hydroxymethylhydantoin. Therefore, no risk mitigation measures are necessary.

### d. Occupational Risk Mitigation

#### i. Handler Mitigation

Dermal and Inhalation Risk for Agricultural Premises

Dermal and inhalation risk concerns have been identified for occupational handlers treating agricultural premises. All MOEs calculated are of concern (i.e. scenarios are of concern with MOEs less than the target MOE of 100). No postapplication exposures were considered.

To reduce occupational exposure, the following label language will be required:

- For irrigation/chemigation rates that are greater than 35,000 gallons per day, applicators must use "solid pour." For smaller applications less than 35,000 gallons per day, applicators can "place" the solids.
- Confirmatory exposure data will be required

Dermal Risk for Swimming Pools

Occupational risks of concern were identified for handlers placing tablets into public swimming pools ungloved (MOE=46). However, the product labels state that gloves should be worn when placing tablets into swimming pools. When gloves are used for the placing of tablets the MOE is not of concern (MOE = 7,500). The risk will be mitigated by requiring the use of gloves.

Once-through Cooling Tower

Occupational risks of concern were identified for handlers applying halohydantoins to once-through cooling towers. To reduce exposure and mitigate risks, handlers will be required to use gloves when applying these products to once-through cooling towers.

#### ii. Post-Application Risk Mitigation

Post-application inhalation exposures may occur in the industrial settings around the water systems via inhalation. Dermal exposures may occur while maintaining industrial equipment. However, occupational postapplication dermal and inhalation exposures to dihalodialkylhydantoin are likely to be minimal compared to handler exposure because of dilution

during application. No exposure data has been submitted to the Agency to determine the extent of post-application exposures in the industrial settings. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of dihalodialkylhydantoin is low. The Agency does not believe that any mitigation is necessary at this time.

### 2. Environmental Risk Management

Most of the halohydantoins uses are considered indoor uses. However, there is potential environmental exposure from the once-through cooling tower use. Risks to freshwater fish and aquatic invertebrates are not anticipated from the use of halohydantoins in once-through cooling tower systems as the RQs do not exceed the Agency's level of concern. Marine/estuarine fish are generally less sensitive than freshwater fish to halohydantoins, and marine/estuarine invertebrates are comparably as sensitive to DMH as freshwater invertebrates. No risk mitigation is required.

### 3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing halohydantoins. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

### 4. Listed Species Considerations

#### a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species" (50 C.F.R. ' 402.02).

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify

if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The current active ingredient uses of halohydantoins fall into this category. Risks to endangered birds and mammals are not anticipated from the use of hydantoin products due to low exposure and low toxicity. Calculated RQ's for fish and aquatic invertebrates from the once-through cooling tower use are well below LOCs for endangered species; other use of hydantoin products are indoor or contained (e.g., swimming pool) uses, and should not result in appreciable environmental exposure when products are used as labeled. Therefore, risk to endangered fish and aquatic invertebrate species is not anticipated from the use of hydantoin products. Risk to endangered plants cannot be addressed due to the lack of phytotoxicity data.

## V. What Registrants Need to Do

The Agency has determined that halohydantoins are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 17). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For halohydantoins technical grade active ingredient products, the registrant needs to submit the following items:

**Within 90 days from receipt of the generic data call in (DCI):**

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:**

1. cite any existing generic data, which address data requirements or submit new generic data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/AD)
(DCI/AD)
ShaRon Carlisle
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk

ShaRon Carlisle
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive
Arlington, VA 22202

For end use products containing the active ingredient halohydantoins, the registrant needs to submit the following items for each product.

**Within 90 days from the receipt of the product-specific data call-in (PDCI)**:

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:**

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and

5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. the product-specific data responding to the PDCI.

Please contact Emily Mitchell at (703) 308-8583 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PM-32)
Emily Mitchell
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PM-32)
Emily Mitchell
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive
Arlington, VA 22202

## A. Manufacturing Use Products

### 1. Additional Generic Data Requirements

The generic database supporting the reregistration of halohydantoins has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and included in the generic DCI for this RED.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

The following ecological effects data are required to support the once through cooling tower system uses for halohydantoin products:

- 72-4/850.1400 Aquatic invertebrate life-cycle test with DMH

In addition, the following phytotoxicity studies are needed to address the Endangered Species Act identified by the Agency:

- 122-1 Seedling emergence/vegetative vigor in rice (at 1 ppm DMH, mixed in the soil and applied to the foliage in the same test)
- 122-2 Tier I Aquatic plant toxicity using *Lemna* sp. (at 1 ppm DMH)
- 122-2 Tier 1 Algal toxicity using the green alga *Selenastrum capricornutum* (at 1 ppm DMH)

Reserved data requirements **(pending the results of the plant tests described above):**

- 123-1/850.4225 and 850.4250 Tier II (dose-response) seedling emergence/vegetative vigor with rice
- 123-2/850.4400 Tier II (dose-response) aquatic plant toxicity using *Lemn*a sp.
- 123-2/850.5400 Tier II (dose-response) algal toxicity, 4 species (green alga, freshwater diatom, marine diatom, and blue-green cyanobacteria)

**Table 18. Confirmatory Data Requirements for Reregistration**

| Guideline Study Name | New OPPTS Guideline No. | Old Guideline No. |
|---|---|---|
| Dermal Indoor Exposure | 875.1200, 875.1600 | 233 and 236 |
| Inhalation Indoor Exposure | 875.1400, 875.1600 | 234 and 236 |
| Descriptions of Human Activity | 875.2800 | 133-1 |
| Aquatic invertebrate life-cycle test with DMH | 850.1400 | 72-4 |
| Seedling emergence/vegetative vigor in rice (at 1 ppm DMH, mixed in the soil and applied to the foliage in the same test) | | 122-1 |
| Tier I Aquatic plant toxicity using *Lemna* sp. (at 1 ppm DMH) | | 122-2 |
| Tier 1 Algal toxicity using the green alga *Selenastrum capricornutum* (at 1 ppm DMH) | | 122-2 |
| **Studies Held in Reserve** | | |
| Tier II (dose-response) seedling emergence/vegetative vigor with rice | 850.4225 and 850.4250 | 123-1 |
| Tier II (dose-response) aquatic plant toxicity using *Lemn*a sp. | 850.4400 | 123-2 |
| Tier II (dose-response) algal toxicity, 4 species (green alga, freshwater diatom, marine diatom, and blue-green cyanobacteria) | 850.5400 | 123-2 |

### 2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 19, Label Changes Summary Table.

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, will follow this

RED.be sent to the registrants at a later date. The PDCI will be based upon current efficacy-related requirements for antimicrobial pesticide products, claims, or use patterns.

### 2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 19.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in 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.

### a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

**Table 19. Labeling Changes Summary Table**

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| **Manufacturing Use Product** | | |
| Supported Use Sites | "Only for formulation into antimicrobial products for use in: agricultural/farm premises, structures, buildings, and equipment; dairy farm milk handling facilities, equipment, storage rooms, houses, and sheds; food processing plants, food handling, food distribution equipment and premises; eating establishments premises and equipment; commercial, institutional, and industrial premises and equipment (floors, walls, storage areas); domestic dwellings, food handling areas, indoor premises; and medical institutional critical care and non-critical care premises, human water systems, swimming pools and industrial processes and water systems."<br><br>For Formulation into antimicrobial products for use in: animal transport$_{\text{vehicles}}$, carpets, fountains/water displays/decorative ponds/, once- through and recirculating$_{\text{industrial}}$ commercial cooling water systems, pulp/paper mill water systems, and swimming pools, mushroom facilities/premises and equipment, egg handling equipment and rooms, egg washing treatment, chick room, poultry houses chiller water/carcass spray, food processing plants/equipment, dairies/breweries and bottling plants/equipment, fruit and vegetable rinse/process water and tank lines, potable drinking water, water storage systems (aircrafts boats, RVs, off-shore oil rigs), water filtration systems, ventilation systems. | Directions for Use |
| **End Use Products Intended for Occupational Use** | | |

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| Application Restrictions-For Occupational Handler -Dermal (*Tablets into public swimming pools*) | "Must wear chemical resistant gloves while placing the tablet in the swimming$_{pool}$" | Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls |
| Application Restrictions-For Occupational Handler -Dermal (*Once through cooling tower – "solid place"*) | "Must wear chemical resistant gloves while placing the tablet in the once through cooling tower system" | Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls |
| Application Restrictions-For Residential Handler -Dermal *(Tablets into public swimmingpools)* | "Must wear chemical resistant gloves while placing the tablet in the swimming$_{pool/spas}$" | Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls |

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| Application Restrictions-For Occupational Handler (*Greenhouse Irrigation*) | 1) Must have label language that states for application rates greater than 35, 000 gallons per day applicators must use "solid pour" and for smaller applications less than 35,000 gallons per day, applicators can must "place solids" into a metered feeding system<br><br>2) "Occupational handler must wear chemical resistant gloves while placing granules and tablets in nursery and greenhouse irrigation systems" | Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls |

# VI. APPENDICES

## Halohydantoins Appendix A

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| **Residential and public access premises** | | | | |
| Hard non-porous non-food contact surfaces, such as bathrooms, flooring, walls, garbage cans. Etc. | 6836-324 (soluble solid) | Spray, brush, mop or sponge | 1gram of product per 7.8 gallons of water. Preclean areas. 10 minute contact time. | Avoid breathing spray. |
| Kennels | 6836-324 (soluble solid) | Spray, brush, mop or sponge | 1gram of product per 7.8 gallons of water. Preclean areas. 10 minute contact time. | Avoid breathing spray. |
| In- Tank- Sanitizer | 777-106<br>777-107<br>5185-446<br>5185-469<br>5813-65<br>5813-66<br>6836-255<br>6836-256<br>6836-263<br>6836-264<br>6836-265<br>6836-272<br>6836-273<br>6836-274<br>6836-275<br>6836-279 | Place tablet in tank | Clean toilet bowl thoroughly and flush the toilet. When water level is low and valve closed, place tablet into the right corner of the tank. When tablet dissolved replace it with a new tablet. Tablets should be used in toilets flushed daily. | Do not touch tablet directly. Wash hands thoroughly if there is any skin contact. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 6836-287<br>6836-288<br>6836-291<br>6836-299<br>6836-300<br>(Tablet) | | | |
| In Tank Sanitizer/Necktie | 5813-84<br>(Tablet) | Place tablet in tank | Clean toilet bowl thoroughly including under rim. Flush toilet and remove toilet tank lid. Hang unit(s) on toilet tank wall with tablet holder on inside of tank and fragrance gel (holder) on the outside of the tank. | Immediately wash your hands after handling unit. |
| **Industrial Process and Water Systems** | | | | |
| Air Gas Scrubber Systems | 3377-62<br>3377-71<br>(Ready to Use) | Open Pour/Ready to Use | Initial Dose: When system is noticeably fouled add product to achieve a residual bromine level of 0.5-5ppm or as needed to maintain control. Repeat until control is achieved.<br><br>Subsequent Dose: When | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | microbial control is evident apply product to achieve a residual bromine level of 0.5-5ppm or as needed to maintain control. | |
| Pulp and Paper Systems | 1448-356<br>1448-428<br>5785-63<br>6836-282<br>63838-4<br>75361-1<br>83451-4<br>(Tablet) | Place tablet in the system at a point where sufficient mixing can occur | When system is noticeably fouled add at a of 12 to 20 ppm<br>When biological control is evident: 12 to 90 ppm.<br>0.5-2.0 lbs of product per ton. | Do not exceed 2.2lbs of this product per dry metric ton fiber when this product is used in the manufacture of paper and paperboard products that contain food. |
| Pulp and Paper Systems | 6836-297<br>(Tablet) | Place tablet in the system at a point where sufficient mixing can occur | 0.5-2.0 lbs of product per ton. To produce 0.1-1.0 ppm of available halogen as chlorine. | May be used in the manufacture of food contact paper and paperboard products. |
| | 1448-420<br>3377-62<br>3377-63<br>3377-71<br>5785-57 | Open Pour/ready to use | When system is noticeably fouled add at a rate of 0.5 to 120ppm. When biological control is evident add at a rate of 12 | Do not exceed 1.0 kilograms per 1,000kg per dry metric ton fiber in paper and paperboard components that contact food. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | (Ready to Use) | | to 90 ppm. | |
| | 8622-29<br>83451-3<br>5785-65<br>(Granular) | Open Pour/Granules | When system is noticeably fouled add 12 to 20 ppm. When biological control is evident add 12 to 90 ppm. | Used in the manufacture of paper and paperboard products that does not contact food. |
| | 8622-28 (wettable powder) | Open Pour/Powder | When system is noticeably fouled add 12 to 20 ppm. When biological control is evident add 12 to 90 ppm. | Used in the manufacture of paper and paperboard products that do not contact food |
| | 83451-10 (Soluble Concentrate) | Open Pour/Soluble Concentrate | When system is noticeably fouled add 28.8 to 288ppm. When biological control is evident add 28.8 to 216 ppm. | Used in the manufacture of paper and paperboard products that does not contact food. |
| | 83451-11 (Gel) | Open Pour/Gel | When system is noticeably fouled add 32.9 to 329ppm. When biological control is | Used in the manufacture of paper and paperboard products that contact food. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | evident add 32.9 to 247 ppm | |
| Paper and Paperboard Process Water (Continued) | 6836-113<br>6836-115<br>6836-314<br>(Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled apply 0.5 to 2.0 lbs per ton of paper produced to achieve 0.1- 1.0 ppm total available halogen as chlorine. Repeat treatment until residual is achieved.<br><br>Subsequent Dose: When microbial control is evident apply 0.5-2.0 lbs per ton of paper produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat periodically as needed to maintain control. | None listed |
| | 6836-317<br>(Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled apply 0.1-10lbs of tablets to 1,000 gallons (0.1 to 1.0 lbs of tablets per dry metric ton of paper produced) Repeat treatment until residual of up to 5 ppm bromine is achieved. | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Paper and Paperboard Process Water (Continued) | | | Subsequent Dose: When microbial control is evident apply 0.1 to 0.75 lbs of this product to 1,000 gallons of water. (0.1 to 0.75 lbs of tablets per dry metric ton of paper produced). Repeat treatment until achieve 0.1-1.0 $ppm_{total\ available}$. Repeat treatment until residual of up to 1 ppm is achieved. | |
| | 83451-10 (Soluble Concentrate) | Open Pour/Soluble Concentrate | Initial Dose: When system is noticeably fouled add 0.0238 to 0.238 gallons to 1,000 gallons of water in the system.<br><br>Subsequent Dose: When biological control is evident add 0.0238 to 0.179 gallons to 1,000 gallons of water in the system. | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | | |
| Paper and Paperboard Process Water (Continued) | 6836-237<br>6836-280<br>6836-281<br>6836-296<br>(Granular) | Open Pour/Granules | Initial Dose: When system is noticeably fouled apply 0.5-2.0lbs per ton of paper produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat treatment until residual is achieved.<br><br>Subsequent Dose: When microbial control is evident apply 0.5-2.0 lbs per ton of paper produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat periodically as needed to maintain control. | None listed. |
| | 6836-312<br>6836-315<br>6836-319 | Open Pour/ Powder | Initial Dose: When system is noticeably fouled apply 0.1-2.0lbs per ton of paper | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | (Wettable Powder) | | produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat treatment until residual is achieved.<br><br>Subsequent Dose: When microbial control is evident apply 0.1-2.0 lbs per ton of paper produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat periodically as needed to maintain control. | |
| Pasteurizer, Can Warmer, Cannery, Retort Water Systems | 1448-356<br>1448-428<br>5185-420<br>69681-16<br>83451-4<br>(Tablet) | Place tablet in system | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Pasteurizer, Can Warmer, Cannery, Retort Water Systems (Continued) | | | gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 1448-420 (Ready to Use) | Open Pour/Ready to Use | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | None listed |
| | 83451-3 (Granular) | Open Pour/Granules | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| Pasteurizer, Can Warmer, Cannery, Retort Water Systems (Continued) | 83451-10 (Soluble Concentrate) | Open Pour/ Soluble Concentrate | Initial Dose: When the system is noticeably fouled add 0.0477 to 0.143 gallons /1,000 gallons of water. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.0238 to 0.072 gallons /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 83451-12 (Ready to Use) | Open Pour/ Ready to Use | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | None listed. |
| | 83451-11 (Gel) | Open Pour/Ready to Use | Initial Dose: When the system is noticeably fouled add 0.0545 to 0.1634 gallons /1,000 gallons of water. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.0272 to 0.0823 gallons /1,000 gallons of water. | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| Evaporative Cooler<br><br>Evaporative Cooler (Continued) | 1448-356<br>1448-428<br>5785-63<br>5785-100<br>5185-420<br>69681-16<br>75361-1<br>83451-4<br>(Tablet) | Place tablet in system | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | None listed. |
| | 1448-420<br>83451-12<br>(Ready to Use) | Open Pour/Ready to Use | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| | 83451-12 (Wettable Powder) | Open Pour/Powder | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm $bromine_{residual}$ is established for at least 4 hours.<br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| Evaporative Cooler (Continued) | 83451-10 (Ready to Use) | Open Pour/Ready to Use | Initial Dose: When system is noticeably fouled add 0.0477 to 0.143 gallons/1,000 gallons of water in the system. Repeat initial dose until 1 to 3 ppm bromine residual is established for at least 4 | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | hours.<br>Subsequent Dose: When microbial control is evident add 0.0238 to 0.072 gallons/1,000 gallons of water in the system. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 75361-1 (Tablet) | Place tablet in the system | Place tablets into condensate line dispenser or floatation device into reservoir. Maintain 1 to 4 ppm active$_{bro}$ mine. | Do not place tablet on metal surfaces. |
| | 83451-3 (Granular) | Open Pour/Granules | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 83451-11 (Gel) | Open Pour/Gel | Initial Dose: When the system is noticeably fouled add 0.0545 to 0.1634 gallons /1,000 gallons of water. Repeat in 1 to3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.0272 to 0.0823 gallons /1,000 gallons of water. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | None listed. |
| Recirculating Cooling Water | 1448-356<br>1448-428<br>5185-420 | Place tablet in system. | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds | None listed |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 5185-421<br>5785-63<br>5785-100<br>63838-4<br>6836-314<br>6836-315<br>6836-317<br>69681-16<br>83451-4<br>(Tablet) | | /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| | 8622-77<br>63838-7<br>(powder) | | Initial Dose: When the system is noticeably fouled add 1.7 to 6.0 pounds /10,000 gallons. Repeat until 1 ppm bromine residual is established for at least 4 hours.<br>Subsequent Dose: When control is evident add 0.8 to 3.0 pounds /10,000 gallons. Repeat as needed to maintain 1-3 ppm bromine residual for at least 4 hours | |
| | 1448-420<br>(Ready to Use) | Open Pour/Ready to Use | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Recirculating Cooling Water (Continued) | | | /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| | 8622-30 (Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled, add 0.75 to 6.0 lbs/1000 gallons of water. Repeat in dosage until one ppm halogen residual, measured as free chlorine for at least 4 hours.<br><br>Subsequent Dose: When system is noticeably fouled, add 0.1 to 3.0 lbs/1000 gallons of water. Repeat as needed to maintain one ppm halogen | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | residual, measured as free chlorine for at least 4 hours. | |
| Recirculating Cooling Water (Continued) | 5785-62<br>66397-1<br>75361-1<br>8622-73<br>(Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled, add 0.75 to 6.0 lbs/1000 gallons of water. Repeat in dosage until one ppm halogen residual, measured as free chlorine for at least 4 hours.<br><br>Subsequent Dose: When system is noticeably fouled, add 0.1 to 3.0 lbs/1000 gallons of water. Repeat as needed to maintain one ppm halogen residual, measured as free chlorine for at least 4 hours. | None listed. |
| | 5785-69 | Place tablet in | Initial Dose: When system | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | (Tablet) | system. | is noticeably fouled use 1 to 2 tablets for each 100 gallons of water. Add additional tablets until a residual of 10 to 35 ppm bromine is established. Maintain treatment until system is free from microbial fouling.<br><br>Subsequent Dose: Use tabs as needed to maintain a residual of 5 to 15 ppm bromine. | |
| Recirculating Cooling Water (Continued) | 5785-65<br>6836-315<br>6836-316<br>83451-3<br>(Granular) | Open Pour/Granules | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm $bromine_{residual}$ is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | least 4 hours | |
| | 6836-237<br>6836-280<br>6836-324<br>(Granular) | Open Pour/Granules | Initial Dose: When system is noticeably fouled add 0.1 to 1.0 lbs to 1,000 gallons of water. Repeat until control is achieved.<br><br>Subsequent Dose: When microbial control is evident add 0.1 to 0.75 lbs to 1,000 gallons of water every 3 days or as needed to maintain control. | None listed. |
| | 83451-12<br>(Wettable Powder) | Open Pour/Powder | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Recirculating Cooling Water (Continued) | | | bromine residual for at least 4 hours. | |
| | 1448-420<br>3876-150<br>5785-57<br>6836-113<br>6836-115<br>6836-116<br>6836-120<br>6836-121<br>6836-122<br>6836-123<br>6836-124<br>6836-210<br>(Ready to Use Solution) | Intermittent, slug or continuous feed method. | Initial Dose: When system is noticeably fouled add 0.1 to 1.0 lbs to 1,000 gallons of water. Repeat until control is achieved.<br><br>Subsequent Dose: When microbial control is evident add 0.1 to 0.75 lbs to 1,000 gallons of water every 3 days or as needed to maintain control. | None listed. |
| | 5785-70 (Granular) | Open Pour/Granules | Initial Dose: Use 1oz per 100 gallons of water. Add additional granules until residual of 1 to 35 ppm is established.<br><br>Subsequent Dose: Use as needed to maintain residual 5 to 15 ppm bromine. | Do not mix granules with pesticide or fertilizer concentrates. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 3377-62<br>3377-71<br>(Ready to Use) | Intermittent, slug or continuous method. | Initial Dose: When system is noticeably fouled add 0.5 to 5ppm as needed to maintain control. Applying ½ ounce to 1,000 gallons of water yields theoretical average 4 ppm available bromine. Repeat as until control is evident.<br>Subsequent Dose: When microbial control is evident add 05 to 5 ppm as needed to maintain control. | None listed. |
| | 83451-10<br>(Soluble Concentrate) | Open Pour/Soluble Concentrate | Initial Dose: When system is noticeably fouled add 0.0477 to 0.143 gallons /1000 gallons of water. Repeat initial dose until bromine residual is established for at least 4 hours.<br>Subsequent Dose: When microbial control is evident add 0.0238 to 0.072 gallons/1,000 gallons of water. Repeat as needed to maintain 1 to 3 ppm bromine residual for at | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | least 4 hours. | |
| | 83451-11 (Gel) | Open Pour/Gel | Initial Dose: add 0.0545 to 0.1634 gallons/ 1000 gallons of water. Repeat initial dosage until 1 to 3 ppm bromine residual is established for at least 4 hours.<br>Subsequent Dose: add 0.0272 to 0.0823 gallons/ 1000 galloons of water. Repeat as needed until 1 to 3 ppm bromine residual is established for at least 4 hours. | None listed. |
| Once Through Cooling Water System | 1448-356<br>1448-428<br>5785-63<br>63838-4<br>6836-115<br>69681-16<br>83451-4<br>8622-30<br>(Tablet) | Place tablet in system | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | to maintain 1 to 3 ppm bromine. | |
| | 5785-62 (Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled, add 0.75 to 2.255lbs/1000 gallons of water. Repeat in dosage until one ppm halogen residual, measured as free chlorine for at least 4 hours<br>Subsequent Dose: When system is noticeably fouled, add 0.4$_{\text{to 1.25}}$ lbs/1000 gallons of water. Repeat as needed to maintain one ppm halogen residual, measured as free chlorine for at least 4 hours. | None listed. |
| Once Through Cooling Water System (Continued) | 63838-4<br>75361-1<br>8622-73 (Tablet) | Place tablet in system | Initial Dose: When noticeably fouled add 2-6 lbs per 10,000$_{\text{gallons of}}$ water. Repeat initial dosage until at least one ppm of active residual bromine is established for at least 4 hours.<br>Subsequent Dose: When | None listed.<br><br>None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | microbial control is evident add 1 to 3lbs per 10,000 gallons of water. Repeat as needed to maintain one ppm of active residual bromine for at least 4 hours. | |
| | 1448-420<br>3876-150<br>5785-57<br>6836-210<br>6836-113<br>6836-317<br>(Ready to Use) | Open Pour/Ready to Use | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | None listed. |
| | 5785-65<br>6836-237<br>6836-280<br>6836-315<br>83451-3<br>(Granular) | Open Pour/Granules | Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Once Through Cooling Water System (Continued) | | | hours.<br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours | |
| | 8622-29 (Granular) | Open Pour/Granules | Initial Dose: When noticeably fouled add 2-6 lbs per 10,000 gallons of water. Repeat initial dosage until at least one ppm of active residual bromine is established for at least 4 hours.<br><br>Subsequent Dose: When microbial control is evident add 1 to 3lbs per 10,000 gallons of water. Repeat as needed to maintain one ppm of active residual bromine for at least 4 hours. | None listed. |
| | 6836-316 83451-12 (Wettable | Open Pour/Powder | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | Powder) | | /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1to 3 ppm bromine | |
| Once Through Cooling Water System (Continued) | 8622-28 (Wettable Powder) | Open Pour/Powder | Initial Dose: When noticeably fouledadd 2-6 lbs per 10,000 gallons of water. Repeat initial dosage until at least one ppm of active residual bromine is established for at least 4 hours.<br>Subsequent Dose: When microbial control is evident add 1 to 3lbs per 10,000 gallons of water. Repeat as needed to maintain one ppm of active residual bromine for at least 4 hours. | None listed. |
| | 83451-10 (Soluble | Open Pour/Soluble | Initial Dose: When system is noticeably fouled add | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | Concentrate) | Concentrate | 0.0477 to 0.143 gallons /1000 gallons of water. Repeat initial dose until bromine residual is established for at least 4 hours.<br>Subsequent Dose: When microbial control is evident add 0.0238 to 0.072 gallons/1000 gallons of water. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 83451-11 (Gel) | Open Pour/Gel | Initial Dose: When system is noticeably fouled add 0.0545 to 0.1634 gallons/ 1000 gallons of water. Repeat initial dosage until 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When microbial control is evident add 0.0272 to 0.0823 gallons/1000 gallons of water. Repeat as needed to | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| Auxiliary Water and Waste Water System | 1448-356<br>5185-420<br>5785-63<br>6836-314<br>6836-317<br>69681-16<br>83451-4<br>(Tablet) | Place tablet in system | Add 0.1 to 0.6 lbs /1,000 gallons of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection point in the disinfection contact chamber. Adjust this product's dosage to achieve disinfection and minimize the halogen concentration at the exit of the contact chamber. | Do not use treated wastewater to irrigate crops. |
| Auxiliary Water and Waste Water System (Continued) | 5785-65<br>(Granular) | Open Pour/Granules | Add 0.1 to 0.6 lbs /1,000 gallons of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection point in the disinfection contact chamber. Adjust this product's dosage to achieve disinfection and minimize the halogen concentration at the exit of the contact chamber. | Do not use treated wastewater to irrigate crops. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 1448-420 5785-57 (Ready to Use) | Open Pour/Ready to Use | Add 0.1 to 0.6l bs /1,000 gallons of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection point in the disinfection contact chamber. Adjust this product's dosage to achieve disinfection and minimize the halogen concentration at the exit of the contact chamber. | Do not use treated wastewater to irrigate crops. |
| | 3377-62 3377-71 (Ready to Use) | Open Pour/Ready to Use | The quantity required varies with degree of fouling. Add sufficient amount to achieve residual bromine levels 0.5 -5ppm. Applying ½ounce to 1,000 gallons of water yields a theoretical average of 4 ppm of available bromine. Higher dosages may be necessary depending upon the system. | None listed |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Auxiliary Water and Waste Water System (Continued) | 83451-10 (Soluble Concentrate) | Open Pour/Soluble Concentrate | Add 0.0238 to 0.143 gallons of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection point in the contact chamber. Adjust this product's dosage to achieve sanitization and minimize the halogen concentration at the exit of the contact chamber. | Do not use treated wastewater to irrigate crops. |
| | 6836-316 (Wettable Powder) | Open Pour/Powder | Add 0.1 to 0.6 lbs /1,000 gallons of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection of water treated to maintain 0.5 to 5.0 ppm bromine residual at the injection point in the contact chamber. | Do not use treated wastewater to irrigate crops. |
| | 83451-11 (Gel) | Open Pour/Gel | Add 0.0272 to 0.1634 gallons /1,000 gallons of water treated to maintain | Do not use treated wastewater to irrigate crops |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | 0.5 to 5.0 ppm bromine residual at the injection point in the contact chamber. Adjust this product's dosage to achieve sanitization and minimize the halogen concentration at the exit of the contact chamber. | |
| Industrial air washer systems | 6836-113<br>6836-115<br>6836-210<br>6836-314<br>6836-316<br>(Tablet) | Place tablet in system | Initial Dose: When system is noticeably fouled add to airwasher sump or chill water sump to insure uniform mixing. Add 0.1 to 1.0 lbs per 1,000 gallons of water.<br><br>Subsequent Dose: When microbial control is evident add 0.1 to 0.6 lbs per 1,000 gallons of water. | None listed. |
| Industrial air washer systems | 6836-314<br>6836-316 | Place tablet in system | Initial Dose: When the system is noticeably fouled | Badly fouled systems should be cleaned before treatment is done. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| (Continued) | (Tablet) | | add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 6836-237<br>6836-280<br>6836-324<br>(Granular) | Open Pour/Granules | Initial Dose: When system is noticeably fouled add to airwasher sump or chill water sump to insure uniform mixing. Add 0.1 to 1.0 lbs per 1,000 gallons of water.<br><br>Subsequent Dose: When microbial control is evident add 0.1 to 0.6 lbs per 1,000 gallons of water. | Badly fouled systems should be cleaned before treatment is done. |
| | 6836-315 (Granular) | Open Pour/Granules | ~~Initial Dose~~ : When the system is noticeably fouled | Badly fouled systems should be cleaned before treatment is done. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Industrial air washer systems (Continued) | | | ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at least 4 hours. | |
| | 6836-316 (Wettable Powder | Open Pour/Powder | Initial Dose: When the system is noticeably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours.<br><br>Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residual for at | Badly fouled systems should be cleaned before treatment is done. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | least 4 hours | |
| | 3377-62<br>3377-63<br>3377-71<br>(Ready to Use) | Open Pour/Ready to Use | Initial Dose: When system is noticeably fouled add sufficient amount to achieve a residual bromine level of 0.5 -5ppm or as needed to maintain control. Apply ½ ounce to 1,000 gallons of water. Yields a theoretical average 4ppm available bromine. Repeat until control is achieved.<br><br>Subsequent Dose: When microbial control is evident apply sufficient amount to achieve area residual bromine level 0.5 to 5ppm or as needed to maintain control. | None listed. |
| Photo Processing Water | 6836-115 | Place in system | Place tabs with the | Do not use water from this line to mix |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 6836-317<br>6836-314<br>69681-16<br>83451-4<br>(Tablet) | | regulating valve at a low setting. If biological growth is observed increase the flow in small increments until growth is controlled. 1.0 to 3.0 ppm of residual bromine should be introduced into water supply line. Three to (3) to 9 grams of tabs will introduce 1.0 to 3.0 ppm residual bromine in 1,000 gallons of water. | chemicals. |
| | 6836-237<br>6836-315<br>6836-324<br>(Granular) | Open Pour/Granules | It is intended that 0.5 to 3.0 ppm of residual bromine should be introduced into water supply line. Three to (3) to 12 grams of tabs will introduce 1.0 to 3.0 ppm residual bromine in 1,000 gallons of water. | Do not use water from this line to mix chemicals. |
| | 6836-316<br>(Wettable Powder) | Open Pour/Powder | Adjust pH between 7.2 to 7.6 when using other products as outlined in directions for other products. A bromine or | Do not use water from this line to mix chemicals. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | chlorine residual of 1-2 ppm must first be established in the water. When bromine residual reaches 1-2 ppm adjust feeder accordingly. To maintain bromine residual adjust the feeder feed rate to assure constant treatment level of 1-3 ppm. | |
| Automobile wash water systems | 6836-210 (Tablet) | Place tablet in system | Initial Dose: If a heavily fouled system exists and physical cleaning is not possible add 0.05 to 0.2 lbs per 1,000 gallons of water for two weeks. Then reduce maintenance levels.<br><br>Maintenance Dose: Effective control under normal circumstances is maintained by adding 0.025 to 0.1 pounds per 1,000 gallons of water. | None listed. |
| **Commercial, Institutional and Industrial Premises and Equipment** | | | | |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Air Conditioner/Humidifier Drip Pans | 1448-356<br>5785-63<br>5785-100<br>5185-420<br>69681-16<br>83451-3<br>(Granular) | Open Pour/Granules | Place this product in the basin or drip pan close to the outlet drain. Use one or more tablets as necessary to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | Do not place tablets directly onto metal surfaces. |
| Air Conditioner/Humidifier Drip Pans (Continued) | 75361-1<br>(Tablet) | Place tablet in system | Place tablet into condensate line dispenser or floatation device into reservoir. Maintain 1-4 ppm active bromine. Check once every month or more often as required. The life of the tablet will vary depending on atmospheric conditions and temperature requirements. | Do not place tablets directly onto metal surfaces |
| | 83451-4<br>8622-30<br>(Tablet) | Place tablet in system | Place this product in the basin or drip pan close to the outlet drain. Use one or more tablets as necessary | None listed |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | |
| | 1448-420 8622-30 (Ready to Use) | Open Pour/ Ready to Use | Place this product in the basin or drip pan close to the outlet drain. Use one or more tablets as necessary to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | None listed. |
| | 83451-3 (Granular) | Open Pour/Granules | Place this product in the basin or drip pan close to the outlet drain. Use one or more tablets as necessary to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | None listed. |
| | 8622-29 (Granular) | Open Pour/Granules | Place this product in the basin or drip pan close to | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Air Conditioner/Humidifier Drip Pans (Continued) | | | the outlet drain. Use one or more tablets as necessary to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | |
| | 8622-29 (Granular) | Open Pour/Granules | Place this product in the basin or drip pan close to the outlet drain. Use one or more tablets as necessary to maintain cleanliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume. | None listed. |
| **Swimming Pools, Spas, Hot Tubs** | | | | |
| Swimming Pools | 1448-428<br>3377-72<br>57787-24<br>63838-4<br>66397-1<br>66397-2<br>67262-23 | Place tablet into system | Initial Application: Adjust ph to 7.2-7.8. A djust the feeder flow of water according to the manufacturer's directions to maintain bromine residual between 1-4 ppm | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 6836-116<br>6836-118<br>6836-197<br>6836-211<br>6836-314<br>6836-317<br>69681-16<br>7124-102<br>7124-104<br>75361-1<br>(Tablet) | | in the pool per 1,000 gallons.<br><br><u>Continued Application:</u><br>Check feeder periodically a refill with additional product. Adjust feeder flow water according to manufacturer's directions to maintain bromine levels between 1-4 $ppm_{in\ pool}$. | |
| Swimming Pools (Continued) | 8622-41<br>8622-70<br>8622-73<br>(Tablet) | Place tablet into system | Newly Filled Pools: Establish an effective active bromine residual of between 2-3 ppm.<br><br>Residential: Add 17 tablets per 10,000 gallons every 5-7 days as needed to maintain a bromine residual of 2-3 ppm at all times.<br><br>Commercial: Add 31 | Keep pH between 7.2-7.6 and never allow it to fall below 7.0. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | tablets per 10,000 gallons every 5-7 days or as needed to maintain and achieve bromine residual between 3-5 ppm at all times. | |
| Swimming Pools (Continued) | 3377-61 6836-211 (Soluble Concentrate) | Open Pour/Soluble Concentrate | Initial Application: Chemically balance calcium hardness to 200 ppm and total alkalinity to 100 to 150 ppm. Adjust pH to 7.2-7.8 Adjust the flow of water into feeder according to manufacturer's directions to maintain active bromine residual between 1-4 ppm.<br><br>Continued Application: Check the feeder weekly and refill with additional product. Adjust the flow of water into feeder according to manufacturer's directions to maintain an active bromine level | Do not mix this product in concentrated form w any other chemicals. Do not add other chemicals to the feeding device when using this product. A violent reaction leading to fire and explosion could result. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | between 1-4 ppm. | |
| | 42177-74<br>6836-123<br>(Ready to Use) | Open Pour/Ready to Use | Balance calcium and alkalinity and then adjust pH to between 7.2-7.6. Superoxidate to 1020ppm bromine. Water is safe when bromine is below 5 ppm. If bromine residual content is below 1-3 ppm, add 0.2-2.0 oz per 1000 as needed to maintain | Do not mix with other chemicals. Always add product to large quantities of water. |
| | 6836-316<br>(Wettable Powder) | Open Pour/Powder | Adjust pH between 7.2-7.6. A bromine or chlorine residual of 1 to 3 ppm must first be established in the pool. To maintain bromine residual adjust feeder feed rate to assure a constant treatment level. | None listed |
| | 6836-250<br>6836-251<br>5185-490<br>(Granular) | Open Pour/Granules | Add product to maintain 1-3 ppm as bromine. Use a reliable test kit to monitor for bromine regularly. Maintain the pool water pH between 7.2-7.8. | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Spas and Hot Tubs | 1448-428<br>3377-72<br>5185-420<br>5185-421<br>63838-4<br>66397-1<br>66397-2<br>6836-116<br>6836-196<br>6826-211<br>6836-242<br>6836-243<br>(Tablet) | Place tablet in system | Adjust the feeder according to manufacturer's directions to maintain a bromine level between 1-4 ppm in residential spas and 3-6 ppm in commercial spas. Check feeder regularly and add additional product as needed. | Do not heat above manufacturer's recommended temperature. |
| Spas and Hot Tubs (Continued) | 6836-314<br>6836-317<br>69681-16<br>7124-102<br>7124-103<br>7124-104<br>71654-13<br>75361-1<br>75562-1<br>(Tablet) | Place tablet in system | Adjust the feeder according to manufacturer's directions to maintain a bromine level between 1-4 ppm in residential spas and 3-6 ppm in commercial spas. Check feeder regularly and add additional product as needed. | Do not heat above manufacturer's recommended temperature. |
| | 6836-316 (Wettable Powder) | Open Pour/Powder | Adjust the feeder according to manufacturer's directions to maintain a bromine level between 1-4 ppm in residential spas and | Do not heat above manufacturer's recommended temperature. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Spas and Hot Tubs (Continued) | | | 3-6 ppm in commercial spas. Check feeder regularly and add additional product as needed. | |
| | 57787-24<br>8622-41<br>8622-70<br>(Tablet) | Place tablet in system | Introduce 3 tablets per 300 gallons of spa water with the use of floating tablet feeder or automatic brominator. Adjust tablet feeder or brominator to obtain an active bromine residual of at least 2 ppm. Maintain spa by adding 3 tablets per 300 gallons every 5-7 days or as needed to maintain an active bromine residual of 2ppm at all times. | Keep pH between 7.2-7.6 and never allow it to fall below 7.0. |
| | 5185-490<br>6836-251<br>(Granular) | Open Pour/Granules | Adjust the feeder according to manufacturer's directions to maintain a bromine level between 2-4 ppm in residential spas and 3-6 ppm in commercial spas. Check feeder regularly and add | Do not heat above manufacturer's recommended temperature. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | additional product as needed. | |
| | 3377-61<br>6836-211<br>(Soluble Concentrate) | Open Pour/ Soluble Concentrate | Adjust the feeder according to manufacturer's directions to maintain a bromine level between 1-4 ppm in residential spas and 3-6 ppm in commercial spas. Check feeder regularly and add additional product as needed. | Do not mix this product in concentrated form w any other chemicals. Do not add other chemicals to the feeding device when using this product. A violent reaction leading to fire and explosion could result. |
| Spas and Hot Tubs (Continued) | 5185-433<br>(Soluble Concentrate) | Open Pour/Soluble Concentrate | Use one dispenser per 350 gallons of spa or hot tub water. Under heavy bather loading or reduced water circulation, additional dispensers may be used to maintain constant active bromine residuals of 2 to 4 ppm in residential spas. | None listed. |
| | 42177-75<br>67262-23<br>6836-123 | Open Pour/ Ready to Use | Adjust the feeder according to manufacturer's directions to maintain a | Do not heat above manufacturer's recommended temperature. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | (Ready to use) | | bromine level between 1-4 ppm in residential spas and 3-6 ppm in commercial spas. Check feeder regularly and add additional product as needed. | |
| | 53735-10 (Ready to use) | Open Pour/Ready to Use | Use one dispenser per 350 gallons of spa or hot tub water. Under heavy bather loading or reduced water circulation, additional dispensers may be used to maintain constant active bromine residuals of 2 to 4 ppm in residential spas. | None listed |
| | 5185-480 (cartridge) | Install Cartridge in Spa feeder | Adjust pH to between 7.2-7.6. Place this product in spa feeder. To Install insert canister into opening lining up canister tabs with key ways. While pushing canister rotate counter clockwise, pull to remove from opening. | This product can only be used in conjunction with polaris precis spa feeder. |
| Foot Spas | 3377-61 | Place tablet in | Add one tablet to the foot | None listed. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | 75562-1 (Tablet) | system | spa water and agitate to dissolve. One tablet in 1-1.25 gallons of spa water will provide an active bromine concentration of 40 ppm. | |
| **Aquatic Areas** | | | | |
| Chemigation | 5785-69 (Tablet) | Open Pour/Tablet | Maintain residual between 5-15 ppm bromine in the water. To insure even distribution of tablets, it is important to level treated mats. If microbial growth develops add additional tablets until bromine residual reaches 10-35 ppm. Continue until fouling is eliminated, then resume treatment between 5-15ppm bromine. | Do not mix with pesticide or fertilizer concentrates |
| Chemigation (continued) | 5785-70 (Granular) | Open Pour/Granules | Maintain residual between 5-15 ppm bromine in the water. To insure even distribution of granules, it is important to level treated mats. If microbial growth develops add additional | Do not mix with pesticide or fertilizer concentrates |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | | | granules until bromine residual reaches 10-35 ppm. Continue until fouling is eliminated, then resume treatment$_{bet}$ ween 5-15ppm bromine. | |
| Ornamental Fountains | 1448-356<br>1448-428<br>3377-71<br>3377-72<br>5185-420<br>63838-4<br>6836-115<br>83451-4<br>(Tablet) | Place tablet in system | Adjust pH to 7.2-7.6. A bromine residual of 1-2 ppm must be established in the water. To maintain a bromine residual adjust the brominator feed rate to assure a constant$_{trea}$ tment of 1-3ppm. | None listed. |
| | 63838-4<br>6836-115<br>(Tablet) | Place tablet in system | Initial Dose: Add 0.1 to 6lbs per 10,000 gallons of water. Repeat initial dose until control is achieved. Subsequent Dose: $_{A}$ dd 0.1 to 3lbs per 10,000 gallons daily or as needed to maintain control. | None listed. |
| | 3377-72<br>(Tablet) | Place tablet in system | Add sufficient amount to achieve and maintain a bromine residual 0.5-5ppm or as needed to control the system. If using a | Do not mix this product in concentrated form w any other chemicals. Do not add other chemicals to the feeding device when using this product. A violent reaction leading to fire and explosion could result. |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Ornamental Fountains (Continued) | | | dispensing device adjust the device feed rate to assure a constant treatment between 0.5-5ppm residual bromine. | |
| | 5785-70 (Granular) | Open Pour/Granules | Maintain residual between 5-15 ppm bromine in the water. To insure even distribution of granules, it is important to level treated mats. If microbial growth develops add additional granules until bromine residual reaches 10-35 ppm. Continue until fouling is eliminated, then resume treatment between 5-15ppm bromine. | Do not mix with pesticide or fertilizer concentrates. |
| | 5185-490 (Granular) | Open Pour/Granules | A bromine or chlorine residual of 1-2ppm must be established. To maintain bromine residual, adjust brominator feed rate to assure a constant treatment level of 1-3 ppm. | None listed. |
| | 3377-61 3377-62 | Open Pour/ Soluble | Add sufficient amount to achieve and maintain a | Do not mix this product in concentrated form with any other chemicals. Do not add other |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| Ornamental Fountains (Continued) | (Soluble Concentrate) | Concentrate | bromine residual 0.5-5ppm or as needed to control the system. If using a dispensing device adjust the device feed rate to assure a constant treatment between 0.5-5ppm residual bromine. | chemicals to the feeding device when using this product. A violent reaction leading to fire and explosion could result |
| | 83451-10 (Soluble Concentrate) | Open Pour/Soluble Concentrate | A bromine or chlorine residual of 1-2ppm must be established. To maintain bromine residual, adjust brominator feed rate to assure a constant treatment level of 1-3 ppm. | None listed. |
| | 1448-420 (Ready to Use) | Open Pour/Ready to Use | A bromine or chlorine residual of 1-2ppm must be established. To maintain bromine residual, adjust brominator feed rate to assure a constant treatment level of 1-3 ppm. | None listed |
| | 3377-71 (Ready to | Open Pour/Ready to | Add sufficient amount to achieve and maintain a | Do not mix this product in concentrated form w any other chemicals. Do not add other |

| Use Site | Reg. no./ Formulation | Method of Application | Application Rate/ No. of applications | Use Limitations |
|---|---|---|---|---|
| | Use) | Use | bromine residual 0.5-5ppm or as needed to control the system. If using a dispensing device adjust the device feed$_{rate}$ to assure a constant treatment between 0.5-5ppm residual bromine. | chemicals to the feeding device when using this product. A violent reaction leading to fire and explosion could result |

**APPENDIX B: Dihalodialkylhydantoins (case 3055)**

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of dihalodialkylhydantoins. These requirements apply to dihalodialkylhydantoins in all products, including data requirements for which a technical grade active ingredient is the test$_S$ ubstance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

IV.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   **(1) Agricultural premises and equipment**
   **(3) Commercial, institutional and industrial premises and equipment**
   **(4) Residential and public access premises**
   **(7) Materials preservatives**
   **(8) Industrial processes and water systems**
   **(11) Swimming pools**
   **(12) Aquatic areas**

3.**Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

| DATA REQUIREMENT | CITATION(S) |
|---|---|

| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
|---|---|---|---|---|
| **TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY** | | | | |
| 830.1550 | 61-1 | Product Identity and Composition | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.1600<br>830.1620<br>830.1650 | 61-2 A | Starting Materials and Manufacturing Process | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.1670 | 61-2 B | Formation of Impurities | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.1700 | 62-1 | Preliminary Analysis | 1,3,4,7,8,11,12 | MRID# 41952701<br>MRID# 41952801<br>MRID# 42478501 |
| 830.1750 | 62-2 | Certification of Limits | 1,3,4,7,8,11,12 | MRID# 43315902 |
| 830.1800 | 62-3 | Analytical Method | 1,3,4,7,8,11,12 | MRID# 41952701<br>MRID# 41952801 |
| 830.6302 | 63-2 | Color | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6303 | 63-3 | Physical State | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6304 | 63-4 | Odor | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.7200 | 63-5 | Melting Point | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.7220 | 63-6 | Boiling Point | 1,3,4,7,8,11,12 | N/A |
| 830.7300 | 63-7 | Density | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.7840<br>830.7860 | 63-8 | Solubility | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.7950 | 63-9 | Vapor Pressure | 1,3,4,7,8,11,12 | N/A |
| 830.7370 | 63-10 | Dissociation Constant in Water | 1,3,4,7,8,11,12 | N/A |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 830.7550<br>830.7560<br>830.7570 | 63-11 | Partition Coefficient (Octanol/Water) | 1,3,4,7,8,11,12 | Data Gap |
| 830.7000 | 63-12 | pH | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6313 | 63-13 | Stability | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6314 | 63-14 | Oxidizing/Reducing Action | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6316 | 63-16 | Explodability | 1,3,4,7,8,11,12 | N/A |
| 830.6317 | 63-17 | Storage Stability | 1,3,4,7,8,11,12 | MRID# 35011701 |
| 830.6320 | 63-20 | Corrosion Characteristics | 1,3,4,7,8,11,12 | MRID# 35011701 |
| **ECOLOGICAL EFFECTS** | | | | |
| 850.2100 | 71-1 A | Avian Acute Oral Toxicity Test - Quail/duck | 1,3,4,7,8,11,12 | Acc# 253966<br>Acc# 253972<br>Acc# 253071<br>Acc# 253073<br>Acc# 252719<br>Acc# 137088<br>Acc# 147319<br>MRID# 43289905 |
| 850.2200 | 71-2 A | Avian Acute Dietary - Quail | 1,3,4,7,8,11,12 | Acc# 147321<br>Acc# 253071<br>MRID# 43289904 |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 850.2200 | 71-2 B | Avian Acute Dietary – Duck | 1,3,4,7,8,11,12 | Acc# 147321<br>Acc# 253071<br>Acc# 253073<br>Acc# 253966<br>Acc# 253972<br>MRID# 43289903 |
| 850.1075 | 72-1 A | Fish Acute Toxicity - Bluegill | 1,3,4,7,8,11,12 | Acc# 145356<br>Acc# 147322<br>Acc# 252719<br>Acc# 253071<br>Acc# 253072<br>Acc# 253074<br>MRID# 42368501<br>MRID# 42373601<br>MRID# 42374702<br>MRID# 43179706 |
| 850.1075 | 72-1 B | Fish Acute Toxicity - Minnow | 1,3,4,7,8,11,12 | MRID# 46053<br>MRID# 42374702 |
| 850.1075 | 72-1 C | Fish Acute Toxicity - Rainbow Trout | 1,3,4,7,8,11,12 | Acc# 145358<br>Acc# 147322<br>Acc# 147323<br>Acc# 252719<br>Acc# 253071<br>Acc# 253072<br>Acc# 253074<br>MRID# 46053<br>MRID# 42373601<br>MRID# 43179705 |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 850.1010 | 72-2 A | Acute Aquatic Invertebrate Toxicity | 1,3,4,7,8,11,12 | Acc# 252719<br>Acc# 253071<br>Acc# 253072<br>Acc# 253074<br>Acc# 147324<br>Acc# 145357<br>MRID# 46053<br>MRID# 42373603<br>MRID# 43179707 |
| 850.1025 | 72-3 A | Estu/Mari tox. Fish | 1,3,4,7,8,11,12 | MRID# 40993103<br>MRID# 42076102<br>MRID# 42374701<br>MRID# 43687301 |
| 850.1035? | 72-3 B | Estu/Mari tox. Mollusk | 1,3,4,7,8,11,12 | MRID# 40993101<br>MRID# 42076101<br>MRID# 43289902<br>MRID# 43687302 |
| 850.1045? | 72-3 C | Estu/Mari tox. Shrimp | 1,3,4,7,8,11,12 | MRID# 40993101<br>MRID# 42076103<br>MRID# 43687303<br>MRID# 42373602 |
| 850.1300 | 72-4 A | Early Life Stage Fish | 1,3,4,7,8,11,12 | MRID# 42721702 |
| 850.1400 | 72-4 B | Life Cycle Invertebrate | 1,3,4,7,8,11,12 | Data Gap |
| 850.4225 | 123-1 | Seedling emergence dose-response in rice | 1,3,4,7,8,11,12 | Data Gap |
| 850.4250 | 123-1 | Vegetative vigor dose-response in rice | 1,3,4,7,8,11,12 | Data Gap |
| 850.4400 | 123-2 | Aquatic vascular plant dose-response toxicity- *Lemna* sp. | 1,3,4,7,8,11,12 | Data Gap |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 850.5400 | 123-2 | Acute algal dose-response toxicity- 4 species | 1,3,4,7,8,11,12 | Data Gap |
| **TOXICOLOGY** | | | | |
| 870.1100 | 81-1 | Acute Oral – Rat, Mouse | 1,3,4,7,8,11,12 | MRID# 45738401<br>MRID# 93074006<br>MRID# 93076011<br>MRID# 93077008 |
| 870.1200 | 81-2 | Acute Dermal - Rabbit | 1,3,4,7,8,11,12 | MRID# 93076013<br>MRID# 93076025 |
| 870.1300 | 81-3 | Acute Inhalation – Rat | 1,3,4,7,8,11,12 | MRID# 43654101 |
| 870.2400 | 81-4 | Acute Eye Irritation - Rabbit | 1,3,4,7,8,11,12 | N/A |
| 870.2500 | 81-5 | Acute Skin Irritation - Rabbit | 1,3,4,7,8,11,12 | MRID# 93076017<br>MRID# 93074011<br>MRID# 93075014<br>MRID# 93077009 |
| 870.2600 | 81-6 | Dermal Sensitization | 1,3,4,7,8,11,12 | MRID# 41670001 |
| 870.3050 | | 28-Day Oral Toxicity - Mouse | 1,3,4,7,8,11,12 | MRID# 45738402 |
| 870.3100 | 82-1 A | 90-Day feeding-Rodent | 1,3,4,7,8,11,12 | MRID# 42009201 |
| 870.3150 | 82-1 B | 90-Day feeding-Non-rodent/dog | 1,3,4,7,8,11,12 | No study is available. However, a chronic toxicity study is available |
| 870.3200 | 82-2 | 21/28-Day Dermal Toxicity – Rat | 1,3,4,7,8,11,12 | No study is available. However, a 90-day dermal toxicity study is available. |
| 870.3250 | 82-3 | 90 Day Dermal-Rodent | 1,3,4,7,8,11,12 | MRID # 43173901 |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 870.3465 | 82-4 | 90-Day Inhalation – Rat | 1,3,4,7,8,11,12 | Study required to assess risks from formaldehyde exposure, will be assessed in the RED assessment for formaldehyde. |
| 870.4100 | 83-1 A | Chronic Toxicity-Rodent | 1,3,4,7,8,11,12 | MRID# 43397702<br>MRID# 44095901 |
| 870.4100 | 83-1 B | Chronic Toxicity-Non-rodent/dog | 1,3,4,7,8,11,12 | MRID# 43553101<br>MRID# 43813301 |
| 870.4200 | 83-2 A | Oncogenicity-Rat | 1,3,4,7,8,11,12 | MRID# 43397702<br>MRID# 44095901 |
| 870.4200 | 83-2 B | Oncogenicity-Mouse | 1,3,4,7,8,11,12 | MRID# 43397701<br>MRID# 44063901 |
| 870.3700 | 83-3 A | Prenatal Developmental Toxicity -Rat | 1,3,4,7,8,11,12 | MRID# 42432701 |
| 870.3700 | 83-3 B | Prenatal Developmental Toxicity – Rabbit | 1,3,4,7,8,11,12 | MRID# 42413101<br>MRID# 42205401 |
| 870.3800 | 83-4 | Reproduction and fertility effects - Rat | 1,3,4,7,8,11,12 | MRID# 42462502 |
| 870.4300 | 83-5 | Combined Chronic toxicity/carcinogenicity | 1,3,4,7,8,11,12 | MRID# 43397702 |
| 870.5100 | 84-2 A | Bacterial Reverse Mutation Test - Ames | 1,3,4,7,8,11,12 | Acc# 137100<br>Acc#164036<br>MRID# 265457<br>TRID# 433401118 |
| 870.5300 | 84-2 B | Gene Mutation In vitro Mammalian Cell Assay | 1,3,4,7,8,11,12 | Acc# 132165<br>Acc# 137089<br>TRID# 433401121<br>TRID# 433401127 |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 870.5375 | 84-2 C | In Vitro Mammalian Chromosome Aberration Test | 1,3,4,7,8,11,12 | Acc# 137096<br>Acc# 137101<br>Acc# 164037<br>Acc# 265457<br>MRID# 40348201<br>TRID# 433401119<br>TRID# 433401125<br>TRID# 470264004 |
| 870.5550 | 84-4 | Unscheduled DNA Synthesis in Mammalian Cells in Culture | 1,3,4,7,8,11,12 | Acc# 132166<br>Acc# 137097<br>Acc# 164038<br>Acc# 265457<br>TRID# 433401120<br>TRID# 433401126<br>TRID# 470264005 |
| 870.7485 | 85-1 | General Metabolism | 1,3,4,7,8,11,12 | MRID# 42123802<br>MRID# 42173901 |
| **ENVIRONMENTAL FATE** | | | | |
| 835.2120 | 161-1 | Hydrolysis of Parent and Degradates | 1,3,4,7,8,11,12 | MRID# 43281801<br>MRID# 42466201 |
| 835.2240 | 161-2 | Photodegradation – Water | 1,3,4,7,8,11,12 | MRID# 42466202 |
| 835.4400 | 162-3 | Anaerobic Aquatic Metabolism | 1,3,4,7,8,11,12 | MRID# 42738401 |
| **REENTRY PROTECTION** | | | | |
| 875.1200<br>875.1600 | 233<br>236 | Dermal Indoor Exposure | 1,3,4,7,8,11,12 | Data Gap |
| 875.1400<br>875.1600 | 234<br>236 | Inhalation Indoor Exposure | 1,3,4,7,8,11,12 | Data Gap |

| DATA REQUIREMENT | | | | CITATION(S) |
|---|---|---|---|---|
| New Guideline Number | Old Guideline Number | Study Title | Use Pattern | MRID Number |
| 875.2800 | 133-1 | Descriptions of Human Activity | 1,3,4,7,8,11,12 | Data Gap |
| **RESIDUE CHEMISTRY** | | | | |
| 860.1100 | 171-2 | Chemical Identity | 1,3,4,7,8,11,12 | N/A |
| 860.1200 | 171-3 | Directions for Use | 1,3,4,7,8,11,12 | N/A |

# Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the September 10, 2004 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at www.regulations.gov

These documents include:

- Halohydantoins Preliminary Risk Assessment; Notice of Availability, 9/10/04.
- Halohydantoins Case Overview Reregistration Case Number 3055, 3/17/03

Preliminary Risk Assessment and Supporting Science Documents:

- Halohydantoins: Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 12/15/03.
- Product Chemistry Science Chapter on halohydantoins. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 9/21/00, Chris Jiang.
- Environmental Modeling for Halohydantoins PDM4 Model, PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 08/05/04.
- Dihalodialkylhydantoins: Ecological Hazard and Environmental Risk Assessment, PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 09/07/04, Kathryn Montague, M.S.
- Halohydantoins Toxicology Chapter. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 10/01/02.
- Dimethylhydantoin [Acute, Probabilistic, Chronic, Cancer] Dietary Exposure Assessment[s] for the [Section (3, 18) Reregistration Eligibility Decision, etc.]. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 05/08/03, A. Najm Shamim, Ph.D.
- Dihalodialkylhydantoin Occupational Residential Exposure Assessment. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, Timothy F. McMahon, Ph.D.
- Incident Reports Associated with Halohydantoins. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 7/27/04.

- Environmental Fate Assessment of hydantoins. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division Antimicrobials Division, 12/11/02, A. Najm Shamim, Ph.D.
- Comments from the Regional Water Quality Control Board, SF Bay Region. 9/23/04, Bill Johnson, Pesticicde TMDL Coordinator.
- Comments from the Sanitation Districts of LA County. 9/24/04, James F. Stahl, Industrial Waste Section.
- Comments from the Natural Resource Defense Council (NRDC). 9/24/04, Aaron Colangelo, staff attorney NRDC
- Comments from the California Regional Water Quality Control Board, SF Bay Region. 9/28/04, Bill Johnson, Pesticicde TMDL Coordinator.
- Comments from the ACC Brominated Biocides Panel. 9/29/04.
- Comments from the ACC Brominated Biocides Panel. 10/05/04.
- Comments from the California Regional Water Quality Board SF Bay Region. 10/12/04, Bill Johnson, Pesticicde TMDL Coordinator.

**Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)**

## 1. MRID Studies


| MRID # | Citation |
|---|---|
| 46053 | Horne, J.D.; Groover, R.D.; Afzal, M.; et al. (1980) 96-Hour Static Bioassays Using Two Great Lakes Chemical Corporation Compounds with Three Marine and Three Freshwater Species. (Unpublished study received Aug 1, 1980 under 1729-122; prepared by NUS Corp., submitted by Tesco, Inc., Marietta, Ga.; CDL:243015-B) |
| 132165 | Kirby, P.; Pizzarello, R.; Rogers-Back, A.; et al. (1983) L5178Y TK+/- Mouse Lymphoma Mutagenesis Assay: Test Article 447:34-2: Study No. T1803.701001. (Unpublished study received May 9, 1983 under 38906-5; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:250313-J) |
| 132166 | Thilagar, A.; Pant, K.; Kumaroo, P. (1982) Unscheduled DNA Synthe- sis in Primary Cultures of Rat Hepatocytes (by Autoradiography): Test Article 447:34-2: Study No. T1803.380002. (Unpublished study received May 9, 1983 under 38906-5; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL: 250313-K) |
| 137088 | Fink, R.; Beavers, J.; Joiner, G.; et al. (1981) Acute Oral LD50-- Bobwhite Quail: Dibromodimethylhydantoin: Project No. 178-106. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Wildlife International Ltd., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-B) |
| 137089 | Fink, R.; Beavers, J.; Brown, R.; et al. (1981) Eight-day Dietary LC50--Mallard Duck: Dibromodimethylhydantoin: Project No. 178- 105. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Wildlife International Ltd., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-C) |
| 137095 | Haworth, S.; Lawlor, T.; Gaudette, L.; et al. (1982) Salmonella/ Mammalian-microsome Preincubation Mutagenicity Assay (Ames Test): Study No. T1805.502. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:252095-D) |
| 137096 | Thilagar, A.; Gaudette, L.; Kumaroo, P. (1982) Cytogenicity Study-- Chinese Hamster Ovary (CHO) Cells in vitro: Ethylmethylhydantoin: Study No. |

T1805.338. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:252095-E)

137097 Thilagar, A.; Gaudette, L.; Pant, K. (1982) Unscheduled DNA Syn- thesis in Primary Cultures of Rat Hepatocytes (By Autoradio- graphy): Ethylmethlhydantoin: Study No. T1805.380002. (Unpub- blished study received Dec 27, 1983 under 38906-7; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:252095-F)

137100 Haworth, S.; Gaudette, L.; Lawlor, T.; et al. (1982) Salmonella/ Mammalian-microsome Preincubation Mutagenicity Assay (Ames Test): Dimethylhydantoin: Study No. T1803.502. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Micro- biological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL: 252095-J)

137101 Thilagar, A.; Gaudette, L.; Kumaroo, P.; et al. (1982) Cytogenicity Study--Chinese Hamster Ovary (CHO) Cells in vitro: Dimethylhy- dantoin: Study No. T1803.338. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:252095-K)

145356 Larkin, J. (1984) The Acute Toxicity of 1,3-Dichloro-5-ethyl-5- methylhydantoin to Bulegill Sunfish (Lepomis macrochirus): Project No. 84-E-042B. Unpublished study prepared by Biospherics Inc. 11 p.

145357 Larkin, J. (1984) The Acute Toxicity of 1,3-Dichloro-5-ethyl-5- methylhydantoin to Daphnia magna Straus: Project No. 84-E-042DM. Unpublished study prepared by Biospherics Inc. 11 p.

145358 Larkin, J. (1984) The Acute Toxicity of 1,3,-Dichloro-5-ethyl-5-methylhydantoin to Rainbow Trout (Salmo gairdneri): Project No. 84-E-042R. Unpublished study prepared by Biospherics, Inc. 11 p.

147319 Beavers, J. (1985) An Acute Oral Toxicity Study in the Bobwhite with Halobrom: Final Report: Project No. 191-106. Unpublished study prepared by Wildlife International Ltd. 16 p.

147321 Beavers, J. (1985) A Dietary LC50 Study in the Bobwhite with Halobrom: Final Report: Project No. 191-104. Unpublished study prepared by Wildlife International Ltd. 14 p.

147322 McAllister, W.; Cohle, P. (1984) Acute Toxicity of Halobrom to Bluegill Sunfish (Lepomis macrochirus): Static Acute Toxicity Report 3242 Unpublished study prepared by Analytical Bio- chemistry Laboratories, Inc. 52 p.

147323 McAllister, W; Cohle, P. (1984) Acute Toxicity of Halobrom to Rainbow Trout

(Salmo gairdneri): Static Acute Toxicity Report 32421.Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 53 p.

147324 Forbis, A.; Burgess, D.; Georgie, L. (1984) Acute Toxicity of Halobrom to Daphnia magna: Static Acute Toxicity Report 32422. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 38 p.

164036 Lawlor, T. (1986) Salmonella/Mammalian-microsome Plate Incorporation Mutagenicity Assay (Ames Test): [Using 5,5-Dimethylhydantoin]: Study No. T4638.501. Unpublished study prepared by Microbiological Associates, Inc. 34 p.

164037 Putman, D. (1986) Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells: [Using 5,5-Dimethylhydantoin]: Study No. T4638.337. Unpublished study prepared by Microbiological Associates, Inc. 18 p.

164038 Curren, R. (1986) Unscheduled DNA Synthesis in Rat Primary Hepatocytes: [Using 5,5-Dimethylhydantoin]: Study No. T4638.380. Un- published study prepared by Microbiological Associates, Inc. 26 p.

252719(1) Fink, R.; Beavers, J.; Joiner, G.; et al. (1981) Acute Oral LD50-- Bobwhite Quail: Dibromodimethylhydantoin: Project No. 178-106. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Wildlife International Ltd., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-B)

252719(2) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of Glybrom to the Bluegill Sunfish ...: Project No. 371-7. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Biospherics, Inc., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-E)

252719(3) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of Glybrom to Rainbow Trout ...: Project No. 371-4. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Biospherics, Inc., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-D)

252719(4) Graney, R.; Spare, W.; Hutchinson, C.; et al. (1981) The Acute Toxicity of Glybrom to Daphnia magna straus: Final Report: Pro- ject No. 371-1. Unpublished study prepared by Biospherics Inc. 14 p.

253071(1) Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Acute Oral LD50-- Bobwhite Quail: Project No. 178-103. (Unpub- lished study received Sep 24, 1981 under 38906-3; prepared by Wildlife International, Ltd., submitted by Glyco Chemicals, Inc., Greenwich, Conn.; CDL:245992-A)

253071(2) Graney, R.L.; Spare, W.C.; Hutchinson, C. (1981) The Acute Toxicity of

Glychlor to Rainbow Trout (?~Salmo gairdneri~?): Project No. 371-5. Final rept. (Unpublished study received Sep 24, 1981 under 38906-3; prepared by Biospherics, Inc., submitted by Glyco Chemicals, Inc., Greenwich, Conn.; CDL:245994-A)

253071(3) Graney, R.L.; Spare, W.C.; Hutchinson, C. (1981) The Acute Toxicity of Glychlor to~Daphnia magna~Straus: Project No. 371-2. Final rept. (Unpublished study received Sep 24, 1981 under 38906-3; prepared by Biospherics, Inc., submitted by Glyco Chemicals, Inc., Greenwich, Conn.; CDL:245995-A)

253071(4) Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Eight-day Dietary LCI50^--Bobwhite Quail: Project No. 178-101. (Unpublished study received Sep 24, 1981 under 38906-3; prepared by Wildlife International, Ltd. and Washington College, submit- ted by Glyco Chemicals, Inc., Greenwich, Conn.; CDL:245997-A)

253071(5) Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Eight-day Dietary LCI50^--Mallard Duck: Project No. 178-102. (Unpublished study received Sep 24, 1981 under 38906-3; prepared by Wildlife International, Ltd. and Washington College, sub- mitted by Glyco Chemicals, Inc., Greenwich, Conn.; CDL:245996-A).

253071(6) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of Glychlor to the Bluegill Sunfish ...: Project No. 371-8. Unpub- lished study prepared by Biospherics, Inc. 19 p.

253072(1) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of GSD-550 to Rainbow Trout ...: Project No. 371-6. Final rept. (Unpublished study received Nov 24, 1981 under 38906-1; prepared by Biospherics, Inc., submitted by Glyco, Inc., Green- wich, CT; CDL:250024-J)

253072(2) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of GSD-550 to the Bluegill Sunfish ...: Project No. 371-9. (Unpublished study received Nov 24, 1981 under 38906-1; prepared by Biospherics, Inc., submitted by Glyco, Inc., Greenwich, CT; CDL:250024-K)

253072(3) Graney, R.; Spare, W.; Hutchinson, C. (1981) The Acute Toxicity of GSD-550 to Daphnia magna Straus: Project No. 371-3. Final rept. (Unpublished study received Nov 24, 1981 under 38906-1; prepared by Biospherics, Inc., submitted by Glyco, Inc., Green- wich, CT; CDL:250024-L)

253073(1) Fink, R.; Beavers, J.; Joiner, G.; et al. (1981) Acute Oral LD50-- Bobwhite Quail: Dibromodimethylhydantoin: Project No. 178-106. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Wildlife International Ltd., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-B)

253073(2) Fink, R.; Beavers, J.; Brown, R.; et al. (1981) Eight-day Dietary LC50--Mallard Duck: Dibromodimethylhydantoin: Project No. 178- 105. Final rept. (Unpublished study received Dec 27, 1983 under 38906-7; prepared by Wildlife International Ltd., sub- mitted by Glyco, Inc., Greenwich, CT; CDL:252094-C)

253074(1) Spare, W. (1982) DantoBrom Acute Toxicity of GSD-560 to Rainbow Trout (Salmo gairdneri): Project No. 82-E-1812R. Unpublished study prepared by Biospherics Inc. 12 p.

253074(2) Spare, W. (1982) DantoBrom The Acute Toxicity of GSD-560 to the Bluegill Sunfish (Lepomis macrochirus): Project No. 82-E-1812B. Unpublished study prepared by Biospherics Inc. 13 p.

253074(3) Spare, W. (1982) DantoBrom The Acute Toxicity of GSD-J60 to Daphnia magna Straus: Project No. 82-E-1812D. Unpublished study pre- pared by Biospheric Inc. 13 p.

253966 Beavers, J. (1984) An Acute Oral Toxicity Study in the Bobwhite with 1,3-Dichloro-5-ethyl-5-methyl Hydantoin: Final Report: Pro- ject No. 198-103. Unpublished study prepared by Wildlife Inter- national Ltd. 15 p.

253972(1) Beavers, J. (1984) An Acute Oral Toxicity Study in the Bobwhite with 1,3-Dichloro-5-ethyl-5-methyl Hydantoin: Final Report: Pro- ject No. 198-103. Unpublished study prepared by Wildlife Inter- national Ltd. 15 p.

253972(2) Beavers, J. (1984) A Dietary LC50 Study in the Mallard with 1,3-Di- chloro-5-ethyl-5-methylhydantoin: Final Report: Project No. 198- 102. Unpublished study prepared by Wildlife International Ltd. 14 p.

265457(1) Lawlor, T.E., B. Head, V.O. Wagner, B.E. Carter, S.M. Olewine, and R.J. Plunkett (1986). Salmonella/mammalian microsome plate incorporation mutagenicity assay on 5,5-dimethylhydantoin. Microbiological Associates Inc. Bethesda, MD. Study No. T4638.501. April 1, 1986. Unpublished.

265457(2) Putman, D.L., M.J. Zito, L.J. Belinsky, D.O. Azorsa, and F.K. Garvert (1986). Chromosome aberration assay in Chinese Hamster ovary (CHO) cells. Microbiological Associates Inc. Bethesda, MD. Study No. T4638.337. May 1, 1986. Unpublished.

265457(3) Curren, R.D., L. Dunn, M. Ernst, N. Durvasula, and V. Portner (1986). Unscheduled DNA Synthesis in rat primary hepatocytes. Microbiological Associates Inc. Bethesda, MD. Study No. T3638.380. May 5, 1986. Unpublished.

35011701 Unknown Author. (Unknown) "Product chemistry data requirements".

40348201 Putman, D. (1987) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: 1,3-Dichloro-5,5-ethylmethylhydantoin: Laboratory Study No.: T5344.337. Unpublished study prepared by Microbiological Associates, Inc. 27 p.

40993101 Surprenant, D. (1988) Acute Toxicity of Dantobrom RW to Eastern Oysters (Crassostrea virginica) Under Flow-through Conditions: SLS Rept. #88-8-2794; Study #11696.0388.6105.504. Unpublished study prepared by Springborn Life Sciences, Inc. 36 p.

40993103 Surprenant, D. (1988) Acute Toxicity of Dantobrom RW to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-through Conditions: SLS Rept. #88- 8-2795; Study #11696.0388.6105.505. Unpublished study prepared by Springborn Life Sciences, Inc. 35p.

41670001 Marom, M. (1990) Halobrom: Delayed Contact Hypersensitivity Study in the Guinea Pig: Final Report: Lab Project Number: DSB/132/ HAL. Unpublished study prepared by Life Science Research Israel Ltd. 5 p.

41952701 Katstra, H. (1991) DantoBrom: Reregistration Phase III Requirements Analysis and Certification of Product Ingredients: Lab Project Number: R-90-16A. Unpublished study prepared by LONZA Inc. 33 p.

41952801 Katstra, H. (1991) Glychlor: Phase III Reregistration Requirements Analysis and Certification of Product Ingredients: Lab Project Number: R-90-16D. Unpublished study prepared by LONZA Inc. 24 p.

41953001 Katstra, H. (1991) Dantochlor: Phase III Reregistration Require- ments: Analysis and Certification of Product Ingredients: Lab Project Number: R-90-16B.

Unpublished study prepared by Lonza, Inc. 35 p.

42009201 Federici, T.M. (1991). A 90 Day Subchronic Oral Toxicity Study in Rats with DMH. Exxon Biomedical Sciences, Inc. East Millstone, N.J. Lab study No. 169070. July 25, 1991.

42076101 Dionne, E. (1991) Halobrom (BCDMH,N,N1,Bromochlorodimethyl hydantoin): Acute Toxicity to Eastern Oysters (Crassostrea vir- ginica) under Flow-through Conditions: Final Report: Lab Project Number 91-6-3802: 11192.0590.6113.504. Unpublished study prepared by Springborn Labs, Inc. 55 p.

42076102 Sousa, J. (1991) Halobrom (BCDMH, N, N1 Bromochlorodimethylhydan- toin) Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus under Flow-Thru Conditions: Final Report. Lab Project Number: 91-5-3773; 11192.0590.6113.505. Unpublished study prepared by Springborn Labs, Inc. 60 p.

42076103 Sousa, J. (1991) Halobrom (BCDMH, N, N1Bromochlorodimethylhydantoin) Acute Toxicity to Mysid Shrimp (Mysidopsis bahia) under Flow-through Conditions: Final Report: Lab Project Number: 11192.0590.6113.515: 91-6-3795.Unpublished study prepared by Springborn Labs, Inc. 58 p.

42123802 Selim, S. (1991). Absorption, Distribution, Metabolism and Excretion (ADME) Studies of 5 Ethyl, 5-Methylhydantoin in the Rat. Lonza, Inc. Fair Lawn, N.J. Study No. PO2000. November 15, 1991.

42173901 Selim, S. (1991). Absorption, Distribution, Metabolism and Excretion (ADME) Studies of 5,5-Dimethylhydantoin in the Rat. Lonza Inc. Fair Lawn, N.J. Lab study No. P01982. November 17, 1991.

42205401 Beyer, B.K. (1992). Developmental Toxicity Study in Rabbits with 5-Ethyl-5-Methylhydantoin (MEH). Exxon Biomedical Sciences, Inc., Toxicology Laboratory, East Millstone, NJ 08875-2350. February 3, 1992. Laboratory Project ID. 166834RB. MRID 42205401. Unpublished.

42368501 Murphy, D. and G. Smith. 1992. DMH: A 96-Hour Static Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*) - Final Report. Wildlife International Ltd. (Easton, MD). Project No. 298A-105, June 17, 1992.

42373601 Murphy, D.; Smith, G. (1992) DMH: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorrynchus mykiss): Final Report: Lab Project Number: 298A-102. Unpublished study prepared by Wildlife Intl. Ltd. 56p.

42373602 Murphy, D.; Smith, G. (1992) DMH: A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia): Final Report: Lab Project Number: 298A-106. Unpublished study prepared by Wildlife Intl. Ltd. 55p.

42373603 Holmes, C. and G. Smith. 1992. DMH: A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*) - Final Report. Wildlife International Ltd. (Easton, MD). Project No. 298A-101, March 24, 1992.

42374701 Murphy, D.; Smith, G. (1992) DMH: A 96-Hour Static Acute Toxicity Test with the Sheepshead Minnow (Cyprinodon Variegatus): Final Report: Lab Project Number: 298A-104. Unpublished study prepared by Wildlife International Ltd. 56 p.

42374702 Murphy, D.; Smith, G. (1992) DMH: A 96 Hour Static Acute Toxicity Test with the Fathead Minnow (Pimephales Promelas): Final Report: Lab Project Number: 298A-103. Unpublished study prepared by Wildlife International Ltd. 57 p.

42413101 Nemec, M.D. (1992). A Developmental Toxicity study of Dimethylhydantoin in Rabbits. WIL Research Laboratories, Inc. Ashland, OH. Lab study No. WIL-12174. July 23, 1992.

42432701 Driscoll, C.D. and T.L. Neeper-Bradley (1992). Developmental toxicity Evaluation of 5,5-Dimethylhydantoin (DMH) Administered by Gavage to CD Rats. Bushy Run Research Center. Export, PA. Study No. 91N0048. July 30, 1992.

42462502 Nemec, M.D. (1992). Two-generation Reproduction Study of Dimethylhydantoin Administered Orally in Rats. WIL Research Laboratories, Inc. Ashland, OH. Study No. WIL-12153 August 25, 1992.

42466201 Schmidt, J.; Stansbrey, W. (1992) Hydrolysis of Dimethylhydantoin as a Function of pH at 25 degrees celsius: Lab Project Number: 39508. Unpublished study prepared by ABC Labs, Inc. 784 p.

42466202 Schmidt, J.; Stansbrey, W. (1992) Determination of the Aqueous Photolysis Rate of Dimethylhydantoin: Lab Project Number: 39509. Unpublished study prepared by ABC Labs, Inc. 493 p.

42478501 Severs, L. (1992) Preliminary Analysis of 1-Bromo-3-chloro-5,5-

Dimethylhydantoin (BCDMH): Final Report: Lab Project Number: WIL-12275. Unpublished study prepared by WIL Research Laboratories Inc. 50p

42721702 Holmes, C.; Swigert, J. (1993) An Early Life-Stage Toxicity Test with 5,5-Dimethylhydantoin in the Fathead Minnow (Pimephales promelas): Final Report: Lab Project Number: 289A-111. Unpublished study prepared by Wildlife International Ltd. 144 p.

42738401 Fackler, P. (1993) Bromo, Chloro-5,5-Dimethylhydantoin-- Determination of the Anaerobic Aquatic Metabolism: Final Report: Lab Project Number: 91-12-4047: 11192-0590-6115-755. Unpublished study prepared by Springborn Laboratories, Inc. 52 p.

42865603 Schoenig, G. (1993) Upgrade Information for Summary MRID No. 93076004 (Old MRID No. 00137089): Eight Day Dietary LC50 Mallard Duck (with) Dibromodimethylhydantoin. Unpublished study prepared by Wildlife International, Ltd. 9 p.

43173901 Chun, J.S. and K.A. Loughran (1994). Ninety-Day Dermal Toxicity Study with 5,5-Dimethylhydantoin (DMH) in CD Rats. Bushy Run Research Center, Union Carbide Corp. 6702 Mellon Road, Export, PA. Study No. 92N1016. March 10, 1994 .

43179705 Sword, M.; Thompson, K.; Williams, M. (1993) A 96-Hour Flow- Through Aquatic Toxicity Study wiht DANTOBROM BTB in the Rainbow Trout (Oncorhynchus mykiss): Final Report: Lab Project Number: 40592: 40861. Unpublished study prepared by ABC Lab., Inc. 94 p.

43179706 Sword, M.; Thompson, K.; Williams, M. (1993) A 96-Hour Flow- Through Aquatic Toxicity Study wiht DANTOBROM BTB in the Bluegill (Lepomis macrochirus): Final Report: Lab Project Number: 40594: 40861. Unpublished study prepared by ABC Lab., Inc. 91 p.

43179707 Blasberg, J.; Hicks, S.; Williams, M. (1993) Acute Toxicity DANTOBROM BTB to Daphnia magna under Flow-Through Conditions: Final Report: Lab Project Number: 40593: 40861. Unpublished study prepared by ABC Lab., Inc. 88 p.

43281801 Mao, J. (1994) Halobrom (Bromo,Chloro-5,5-Dimethylhydantoin): Hydrolysis Study: Final Report: Lab Project Number: 94-2-5160: 11192.0993.6118.715: 56-94-028. Unpublished study prepared by Springborn Labs, Inc. 101 p.

43289902 McElwee, C. (1993) (Inert ingredient): Acute Effect on New Shell Growth of the Eastern Oyster, Crassostrea virginica, under Flow-Through Conditions: Lab Project Number: J9207002B. Unpublished study prepared by Toxikon Environmental Science. 53 p.

43289903 Helsten, B. (1994) 8-Day Acute Dietary LC50 Study with (Inert ingredient) in Mallard Ducklings: Lab Project Number: 126/003/02. Unpublished study prepared by Bio-Life Associates, Ltd. 92 p.

43289904 Helsten, B. (1994) 8-Day Acute Dietary LC50 Study with (Inert ingredient) in Bobwhite Quail: Lab Project Number: 126/002/01. Unpublished study prepared by Bio-Life Associates, Ltd. 92 p.

43289905 Helsten, B. (1994) 14-Day Acute Oral LD50 Study with (Inert ingredient) in Bobwhite Quail: Lab Project Number: 126/004/03. Unpublished study prepared by Bio-Life Associates, Ltd. 40 p.

43290601 Neeper-Bradley, T. and M. Kubena (1994). Two-Generation Reproduction Study in CD Rats with (inert ingredient) Administered in the Diet. Bushy Run Research Center. Lab project No. 91N0094. Unpublished.

43315902 Sloan, R. (1994) Preliminary Analysis of Glychlor and Dantochlor: Lab Project Number: SP-94002-A: 94-042. Unpublished study prepared by Lonza Inc. 57 p.

43397701 Hermansky, S.J. and Loughran (1994). Chronic Dietary Oncogenicity Study with 5,5-Dimethylhydantoin (DMH). Bushy Run Research Center, Union Carbide Corp. 6702 Mellon Road, Export, PA. Lab study No. 91N0112. August 31, 1994.

43397702 Hermansky, S.J. and C.L. Benson (1994). Chronic Dietary Toxicity/Oncogenicity Study with 5,5-dimethylhydantoin (DMH) in Rats. Bushy Run Research Center, Union Carbide Corp. 6702 Mellon Road, Export, PA. Lab project No. 91N00113. August 31, 1994.

43553101 Goldenthal, Edwin I. (1995). Evaluation of Dimethylhydantoin (DMH) in a One-Year Chronic Dietary Toxicity Study in Dogs. Lonza Inc. 17-17 Route 208, Fair Lawn, NJ. Study No. 647-004.

43654101 Naas, D. (1995). An Acute Inhalation Toxicity Study of BCDMH in Albino Rats. WIL Research Labs, Inc. Lab project No. WIL-12358. Unpublished.

43654101 Naas, D. (1995). An Acute Inhalation Toxicity Study of BCDMH in Albino Rats. WIL Research Labs, Inc. Lab project No. WIL-12358. Unpublished.

43687301 Surprenant, D. (1995) Supplement to: Halobrom (BCDMH, N,N1-Bromochlorodimethylhydantoin)-Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-Through Conditions: Lab Project Number: 91-5-3773: 11192.0590.6113.505. Unpublished study prepared by Springborn Lab., Inc. 10 p.

43687302 Surprenant, D. (1995) Supplement to: Halobrom (BCDMH, N,N1-Bromochlorodimethylhydantoin)-Acute Toxicity to Eastern Oysters (Crassostrea virginica) Under Flow-Through Conditions: Lab Project Number: 91-6-3802: 11192.0590.6113.504. Unpublished study prepared by Springborn Lab., Inc. 7 p.

43687303 Surprenant, D. (1995) Supplement to: Halobrom (BCDMH, N,N1-Bromochlorodimethylhydantoin)-Acute Toxicity to Mysids (Mysidopsis bahia) Under Flow-Through Conditions: Lab Project Number: 91-6-3795: 11192.0590.6113.515. Unpublished study prepared by Springborn Lab., Inc. 10 p.

43813301 Chengelis, C. (1995) One-Year Oral Toxicity Study in Dogs with DMH: Final Report: Lab Project Number: WIL-12274. Unpublished study prepared by WIL Research Labs, Inc. 892 p.

44063901 Naas, D.J. (1996). 18-Month Dietary Oncogenicity Study in Mice with DMH. WIL Research Laboratories, Inc. Ashland, OH. Lab Study No. WIL-12257. May 23, 1996. Unpublished.

44095901 Naas, D. (1996). Combined 24-month toxicity/oncogenicity study in rats with DMH. WIL Research Laboratories, Inc. Ashland, Ohio. Lab study No. WIL-12258. July 30, 1996. Unpublished.

44243001 supplement to multi-generation reproduction.

45738401 Naas, D. (1989) Acute Oral Toxicity (LD50) Study in Albino Mice with DMH: Lab Project Number: WIL-12158. Unpublished study prepared by Wil Research Laboratories, Inc. 30 p. {OPPTS 870.1100}

45738402 Naas, D. (1991) 28-Day Dietary Study in Mice with DMH: Lab Project Number: WIL-12164. Unpublished study prepared by Wil Research Laboratories, Inc. 227 p.

93074006 Handy, R. (1990) Hydrotech Chemical Corporation Phase 3 Summary of MRID 00128244. Acute Oral Toxicity (LD50) Study in Albino Rats with Bromochlorodimethylhydantoin, #806-91-1: WIL Study No. WIL-12012. Prepared by WIL Research Laboratories. 22 p.

93074011 Handy, R. (1990) Hydrotech Chemical Corporation Phase 3 Summary of MRID

00128242. Primary Dermal Irritation Study in Albino Rabbits with Bromochlorodimethylhydantoin, #806-91-1: WIL Study No.: WIL-12015. Prepared by WIL Research Laboratories. 10 p.

93075014 Handy, R. (1990) Great Lakes Chem Corp Phase 3 Summary of MRID 00128242. Primary Dermal Irritation Study in Albino Rabbits with Bromochloro dimethylhydantoin, #806-91-1; WIL Study No.: WIL 12015. Prepared by WIL Research Laboratories. 10 p.

93076011 Ertefaie, S. (1990) Lonza Inc Phase 3 Summary of MRID 00137105. Acute Oral Toxicity Study in Rats-Dantoin DBDMH: Report No. 4741-77. Prepared by Biodynamics Inc. 13 p.

93076013 Ertefaie, S. (1990) Lonza Inc Phase 3 Summary of MRID 00084176. Acute Dermal Toxicity Study in Rabbits-Dantoin DCDMH: Project No. 4740-77. Prepared by Biodynamics, Inc. 7 p.

93076017 Ertefaie, S. (1990) Lonza Inc Phase 3 Summary of MRID 00137109. Primary Dermal Irritation Study in Rabbits-Dantoin DBDMH: Study No. 4743-77. Prepared by Biodynamics Inc. 8 p.

93076025 Fassuliotis, K. (1990) Lonza Inc Phase 3 Summary of MRID 00137110. Acute Dermal Toxicity Study in Rabbits [with] Dibromodimethylhydantoin: Project No. 4742-77. Prepared by Bio/dynamics Inc. 8 p.

93077008 Cohen, T. (1990) Ameribrom Inc. Phase 3 Summary of MRID 00147325. Halobrom- Acute Oral Toxicity in the Rat: Project No. DSB/057/HLB. Prepared by Life Science Research Israel Ltd. 8 p.

93077009 Cohen, T. (1990) Ameribrom Inc. Phase 3 Summary of MRID 00147326. Halobrom- Primary Dermal Irritation Study in Rabbits-Project No. DSB/049/DIH. Prepared by Life Science Research Israel Ltd. 9 p.

## Open Literature

### Citation

Brown, C. 2002. Water Use in the Professional Car Wash Industry. Published by International Carwash Association, Inc.

Clearon Corp. Material Safety Data Sheet for Halogene G. http://www.dsbg.com/Brome/brome.nsf/0a03dde88bb2d9c7422567760036799d/c1a588a37cc806a942256c2a003ea436/$FILE/8424GU_EN-MTR-CLRR.pdf, last accessed March, 2003.

Clements, JB. 2003. The In-Bay Automatic: An Additional Profit Center. http://www.wonderwash-wonderlube.com/aln_nov96.doc, last accessed February, 2003.

Cloete TE, Smith Z, Saayman G. A Cooling Water System as a Biofilm Reactor for the Treatment of Municipal Wastewater. Water SA Vol. 25 No. 3 July 1999. Available on website http://www.wrc.org.za.

Dang W, 1996. Antimicrobial Pesticides, Uses, Human Exposures, and Risk Assessments. March, 1996.

Dang, W. (1996) The Swimmer Exposure Assessment Model (SWIMODEL) and Its Use in Estimating Risks of Chemical Use In Swimming Pools.

DiToro, D. M. 1984. Probability Model of Stream Quality Due to Runoff. ASCE. Journal of Environmental Engineering. 110(3):607-628.

Gould, D.J. 1983. Dermatoses associated with brominated swimming pools. Br. Med. J. 287:913.

Loughney, L. And Harrison, J. 1998. Irritant contact dermatitis due to 1,bromo-3-chloro-5,5-dimethylhydantoin in a hydrotherapy Pool. Risk Assessment: the need for continuous evidence-based assessment. Occup. Med. 48:461-463

Malten K.E. and den Arend J.A. 1985. Irritant contact dermatitis. Traumiterative and cumulative impairment by cosmetics, climate, and other daily loads. Derm Beruf Umwelt 33(4):125-32.

Morgan, J.M. 1983. Dermatoses associated with brominated swimming pools. Br. Med. J. 287:913.

Penny, P.T. 1991. Hydrotherapy pools of the future - the avoidance of health problems. J. Hosp. Infect. 18:535-542.

Rycroft, R.J. and Penny, P.T. 1983. Dermatosis associated with brominated swimmingpools. Br. Med. J287:462.

## 2. Website References

Citation

EFAST Help, beta version, 2004.

USEPA, 2002. Pesticide Product Information System. http://www.epa.gov/opppmsd1/PPISdata/index.html, last accessed September 2002.

USEPA, 2002. ECOTOX User Guide: ECOTOXicology Database System. Version 3.0. Available: http://www.epa.gov/ecotox/

## 3. Other Supporting Documents

Citation

American Association of Textile Chemists and Colorists. 2003. Phone conversation with Tricia Day, Technical Assistant, July 2003.

Genest, Dan, Dominion Power. Telephone interview. June 14, 2004.

USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax, USEPA. Dated November 4, 1999. DP Barcode D247642.

USEPA. 2000a. Dihalodialkylhydantoin - 2nd Report of the Hazard Identification Assessment Review Committee. Dated August 28, 2000. HED Doc. No. 014298.

USEPA. 2000b. Residential SOPs. EPA Office of Pesticide Programs–Human Health Division. Dated April 5, 2000.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax, USEPA. Dated November 4, 1999. DP Barcode D247642.

USEPA, 2001. General Principles for Performing Aggregate Exposure and Risk Assessments. USEPA, Office of Pesticide Programs.

## Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date for Halohydantoins.
Case # 3055, PC code # 006315

## Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date for:

Halohydantoins  Case #3055  PC Code #006315

## Appendix G. Batching of Halohydantoin Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing any of the halohydantoins as an 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), and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar," since they may not have similar use patterns.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see partial list of 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. The Agency must approve any new or canceled formulations (that were presented to the Agency after the completion of the RED) before data derived from them can be used to cover other products in a batch. 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.

If a registrant would like to have the batching status of a product reconsidered, he/she needs to submit detailed information on the product, including a detailed rationale for the inclusion of the product into a batch. An MSDS for each "inert" ingredient should be included where possible. However, registrants and manufacturers should realize that the more unusual their formulation is, the less likely it is to be able to batch that product.

One hundred and five (105) products were found which contain one of the halohydantoins as an active ingredient. These products have been placed into ten batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Any product in a batch may cite new or previously submitted acute toxicity data (if it meets current Agency standards) from any other product in the same batch, except as specified below:

- In Batches 1, 4, 5, and 7, the highest-concentration products in the batch should **not** cite data from the lowest-concentration products in the batch: Reg. No. 5185-457 in Batch 1, Reg. No. 5185-469 in Batch 4, Reg. No. 5185-487 in Batch 5, and Reg. No. 6836-120 in Batch 7.

- In the No Batch category, each product must cite its own data.

| Batch 1 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 1448-356 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 1448-420 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 1448-428 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 3876-150 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-420 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-446 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-452 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 99% |
| | 5185-454 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97% |
| | 5185-455 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-456 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-457 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 94% |

| Batch 1 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 5185-480 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-489 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5185-490 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-57 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-63 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-65 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-69 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-70 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 5785-105 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 6836-314 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97.41% |
| | 6836-315 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97.7% |
| | 6836-316 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97.7% |
| | 6836-317 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97.7% |
| | 6836-318 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 97.7% |
| | 8622-25 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 98% |
| | 8622-28 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 8622-29 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 98% |
| | 8622-30 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 98% |
| | 8622-41 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 98% |
| | 8622-70 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 42177-74 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 42177-75 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 53735-10 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 67262-23 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |
| | 69681-16 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 96% |

| Batch 2 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 3377-61 | 1,3-Dibromo-5,5-dimethylhydantoin 99.4% |
| | 3377-62 | 1,3-Dibromo-5,5-dimethylhydantoin 99.4% |
| | 3377-63 | 1,3-Dibromo-5,5-dimethylhydantoin 99.4% |
| | 3377-71 | 1,3-Dibromo-5,5-dimethylhydantoin 96.4% |
| | 3377-72 | 1,3-Dibromo-5,5-dimethylhydantoin 96.4% |

| Batch 3 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-109 | 1,3-Dichloro-5,5-dimethylhydantoin 97% |
| | 6836-319 | 1,3-Dichloro-5,5-dimethylhydantoin 97% |

| Batch 4 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 5185-421 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 5185-433 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 93.5% |
| | 5185-469 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 88% |
| | 5785-100 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 89.5% |
| | 5785-106 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 93.5% |
| | 5785-107 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 93.5% |
| | 5785-108 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 7124-102 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 7124-103 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 7124-104 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 8622-26 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 8622-27 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |
| | 57787-24 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 92.5% |

| Batch 5 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 5185-483 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 40% |
| | 5185-487 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 35% |

| Batch 6 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-110 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 90%<br>1,3-Dibromo-5,5-dimethylhydantoin 9% |
| | 6836-124 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 88.7%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.8% |
| | 6836-211 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 90%<br>1,3-Dibromo-5,5-dimethylhydantoin 9% |
| | 6836-312 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 90%<br>1,3-Dibromo-5,5-dimethylhydantoin 9% |

| Batch 7 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-120 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 81.9%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.1% |
| | 6836-121 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 84.1%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.4% |
| | 6836-122 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 85.1%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.4% |
| | 6836-123 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 86.4%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.6% |
| | 66397-1 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 86.4%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.6% |
| | 66397-2 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 86.4%<br>1,3-Dibromo-5,5-dimethylhydantoin 8.6% |

| Batch 8 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-113 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-114 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-256 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-263 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-280 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-287 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-288 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-291 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-296 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |
| | 6836-297 | 1,3-Dichloro-5,5-dimethylhydantoin 81.1%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 16.1% |

| Batch 9 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-115 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-116 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-117 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-118 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4% |

| Batch 9 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | | 1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-196 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-197 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-210 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-237 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-242 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-243 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-250 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-251 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-255 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-272 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-273 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-274 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4% |

| Batch 9 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | | 1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-275 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-281 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-282 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-299 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |
| | 6836-300 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 60%<br>1,3-Dichloro-5,5-dimethylhydantoin 27.4%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6% |

| Batch 10 | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| | 6836-264 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 57%<br>1,3-Dichloro-5,5-dimethylhydantoin 26%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.1% |
| | 6836-265 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 57%<br>1,3-Dichloro-5,5-dimethylhydantoin 26%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.1% |

| No Batch | EPA Reg. No. | % Active Ingredient |
|---|---|---|
| Each “No Batch” product must cite its own data. | 5785-62 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 25.2% |
| | 5813-65 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 51%<br>1,3-Dichloro-5,5-dimethylhydantoin 23.3%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 9% |
| | 5813-66 | 1-Bromo-3-chloro-5,5-dimethylhydantoin 45%<br>1,3-Dichloro-5,5-dimethylhydantoin 20.6%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 8% |
| | 6836-279 | 1,3-Dichloro-5,5-dimethylhydantoin 52.7%<br>1,3-Dichloro-5-ethyl-5-methylhydantoin 10.5% |

# Appendix H. List of All Registrants Who Will Be Sent the Data Call-In

BUCKMAN LABORATORIES, INC.
1256 NORTH MCLEAN BLVD
MEMPHIS TN 38108
(901) 278-0330

GE BETZ, INC.
4636 SOMERTON ROAD
TREVOSE, PA 190536783
(215) 953-5588

BIO –LAB, INC
PO Box 300002
LAWRENCEVILLE GA, 300491002
(678) 502- 4149

GREAT LAKES CHEM CORP
PO Box 2200
WEST LAFAYETTE, IN 479962200
(765) 497-6391

CLOROX CO., THE
PO Box 493
PLEASANTON, CA 945660803
(925) 425-6842

LONZA INC.
90 BOROLINE ROAD
ALLENDALE, NJ 07401
(201) 785-9011

ALDEN LEEDS INC.
55 JACOBUS AVE
SOUTH KEARNY, NJ 07032
(973) 589-3544

AMERIBROM, INC.
95 MACCORKLE AVENUE, SOUTHWEST
SOUTH CHARLESTON WV 253031411
(304) 746-3101

ALLIANCE TRADING, INC.
109 NORTHPARK BLVD, 4$^{TH}$ FLOOR
COVINGTON LA 70433

KING TECHNOLOGY INC.
530 11$^{TH}$ AVENUE SOUTH
HOPKINS MN 55343
(952) 933- 6118

HAVILAND CONSUMER PRODUCTS, INC.
421 ANN STREET, NW
GRAND RAPIDS, MI 495042075
(616) 361-6691

ENVIRO TECH CHEMICAL SERVICES, INC.
500 WINMOORE WAY
MODESTO CA 95358
(209) 581-9576

MID-CONTINENT PACKAGING INC.
1200 N 54TH ST
ENID, OK 73701
(201) 589-3544

RECREATIONAL WATER PRODUCTS, INC.
PO Box 1449
BUFORD GA 305151449
(678) 502 4149

ALLCHEM PERFORMANCE PRODUCTS, LP
6010 NW FIRST PLACE
GAINESVILLE, FL 32607
(352) 333-7357

E.I. DUPONT DE NEMOURS AND COMPANY
PO Box 80402
WILMINGTON DE 198800402
(302) 695-2910

CONNECT CHEMICAL USA, LLC
107 COLONY PARK DRIVE, SUITE 100
CUMMINGS GA 30040
(678) 947-4410

SANI-CARE SALON PRODUCTS INC.
5295 WEBB PKWY
LILBURN GA 30047
(770) 279-7722

BWA WATER ADDITIVES US, LLC
1979 LAKESIDE PARKWAY, SUITE 925
TUCKER GA 30084
(678) 802-3024

ALBEMARLE
451 FLORIDA ST
BATON ROUGE LA 70801
(504) 388-7650