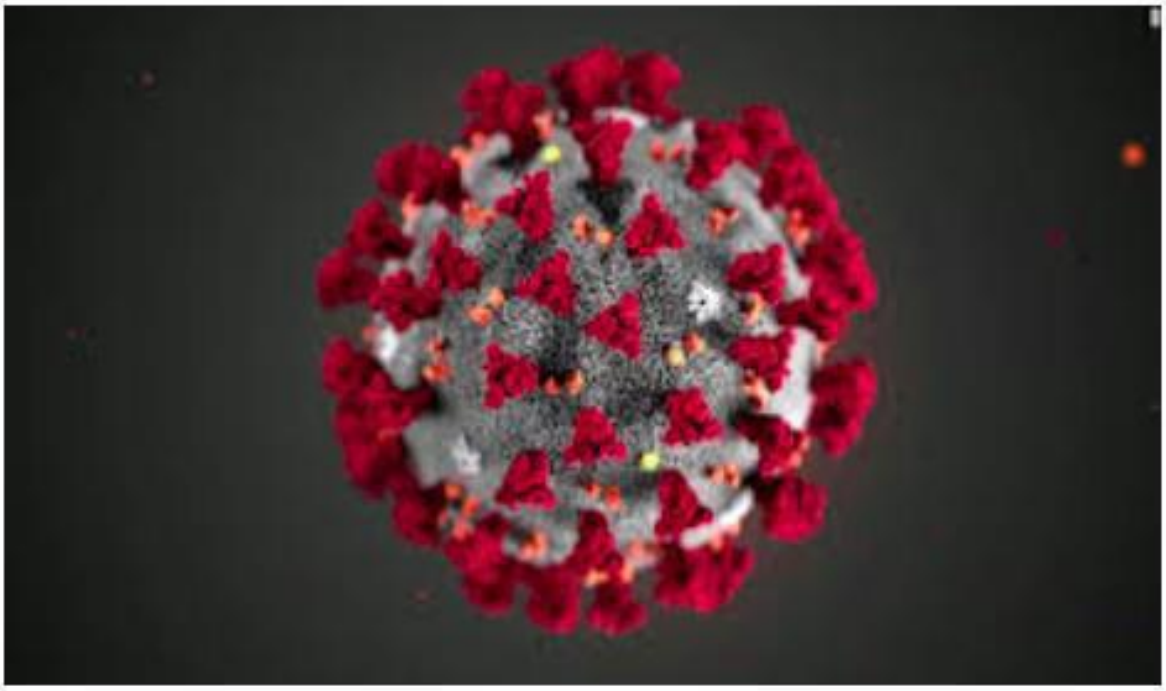

CORONACIDE™ REPORT

[redacted]

This report is comprised of a full EPA Registration Eligibility Decision for materials within the product, as well as a notarized letter certifying the EPA approval of the product. For any inquiries regarding any of the information contained in this report, please use the contact information listed below.

[redacted]

3/20/2020

Dr. Joe Eyring, Principal
HempBA, LLC
7831 W Country View Ln.
Herriman, UT 84096

RE: Reference CoronaStop28 and Strategia Microsure Products

Dear Dr. Eyring:

This letter is to certify that the ingredients for CoronaStop28 are EPA (Environmental Protection Agency) approved, except for the proprietary materials which are less than 1% by volume, creating the adherent. There are proprietary formulas within CoronaStop28 that create the adhesion of the chemicals to hard and soft surfaces that are considered proprietary information for the manufacturing of the product. We are currently selling CoronaStop28 worldwide based on approved EPA guidelines as represented by the manufacturer.

This letter is to also certify that our human skin sanitizer product, MicroSure, protects the skin for up to 8 hours. MicroSure has FDA approval with an issued NDC (National Drug Code) number 72513-100-04. The Microsure product originally started with approval through the FDA for a "wound care" product that included human implant coverage carrying the NDC number 72513-100-01. These products are 99.99% proficient in fighting COVID-19.

For further information please see the attached exhibits and labels for references to the above statements.

Sincerely,

JOHN D. LEVITAN
Chief Development Officer-Principal

I HEREBY CONFIRM that John D. Levitan, as Chief Development Officer-Manager of Medifll Specialties Group, LLC did personally appear before me and execute the above document on March 20, 2020.

Vivian Gilmore, Notary Public

VIVIAN K. GILMORE
MY COMMISSION # GG 112718
EXPIRES: June 7, 2021
Bonded Thru Notary Public Underwriters

Medical Specialties Group of Louisiana, LLC
815 South Palafox Street• Third Floor• Pensacola, FL 32502 USA
Telephone: +I (850) 4-34--6674-
www.msgofla.us

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)

TABLE OF CONTENTS

CHEMICAL TEAM

Science Team
Tim McMa hon
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Regulatory Team
ShaRon Carlisle
Heather Garvie
Diane Isbell

GLOSSARY OF TERMS AND ABBREVIATIONS

LD_{50}	
a.i.	
aPAD	
APHIS	LOAEC LOAEL
AR F T	LOC LOEC mg/kg/day
	MOE Active Ingredient
BCF	Acute Population Adjusted Dose
CDC	Animal and Plant Health Inspection Service
CDP R	Agricultural Re-entry Task Force Bioconcentration
CFR	Factor
ChEI	Centers for Disease Co ntrol
CMBS	California Department o f Pesticide Regulation
cPAD	Code of Federal Regulations Cholinesterase
	In hibition
CSFII	Carbamate Market Basket Survey
	Chronic Population Adjusted Do se
	USDA Continuing Surveys for Food Intake by Individuals Community
CWS	Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model Double
DL	layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Fo rmulation
EDSP	Endocrine Disruptor Screening Program
ED T S	Endocrine Disruptor Screening and Testing Advisory Committee
AC	Estimated Environmental Concentrati on. The estimated pesticide concentration in an environment,
EEC	such as a terrestrial ecosystem.
	End-Use Product
EP	U.S. Environmental Protection Agency
EPA	Tier II Surface Water Computer Model
EXAMS	Food and Drug Administration
FDA	Federal Food, Drug, and Cosmetic Act
FFDCA	Federal Insecticide , Fungicide, and Rodenticide Act
FIFRA	Functional Observation Battery
FOB	Food Quality Protection Act
FQ A P	Federal Register
FR	With gloves
GL	Global Positioning System
GPS	Hazard Identification Assessment Review Committee Incident
HIARC	Data System
ID S F	Insect Growth Regulator
	Integrated Pest Management
IGR	Reregistration Eligibility Decision Lifetime
IPM	A verage Daily Dose
RED	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause
LADD	death in 50% of test animals, usually expressed as the weight of substance per weight or volume of
LC_{50}	water, air or feed, e.g., mg/l, mg/kg or ppm. Lawn Care Operator
	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
LCO	unit weight of animal, e.g., mg/kg.

LOAEL 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
MRID MRL
N/A
NASS
NAWQA
NG
NMFS NOAEC NOAEL NPIC
NR
OP
OPP
OR T E F
PAD
PCA
PDCI PDP PF10
PF5 PHED
PHI ppb PPE PRZM RBC RED REI
RfD
RPA
RPM
RQ
RTU
RUP
SCI-GROW
SF
SL
SLN
STORET
TEP TGAI TRAC
UF
USDA USFWS USGS
WPS Halohydantoins RED Manufacturing-Use Product
Master Record Identification (number). EPA's system of recording and tracking studies submitted.
Maximum Residue Level
Not Applicable
National Agricultural Statistical Service
USGS National Water Quality A ssessment
No Gloves
National Marine Fisheries Service
No Observed A dverse Effect Concentration
No Observed Adverse Effect Level
National Pesticide Information Center
No respirator
Organophosphorus
EPA Office of Pestic ide Programs
Outdoor Residential Exposure Task Force
Population Adjusted Dose
Percent Crop Area

ections factor 10 respirator
Protection factor 5 respirator
Pesticide Handler's Exposure Data Pre-
harvest Interva l
Parts Per Billion
Personal Protective Equipment
Pesticide Root Zone Model
Red Blood Cell
Reregistration Eligibility D ecision
Restricted Entry Interval
Reference D ose
Reasonable and Prudent Alternatives
Reasonable and Prudent Measures
Risk Quotient
(Ready-to-use)
Restricted Use Pesticide
Tier I Ground Water Comput er Model
Safety Factor
Single layer clothing
Special Local Need (Registrations Under Section 24C of FIFRA)
Storage and Retrieval
Typical End-Use Product
Technical Grade Active Ingredient
Tolerance Reassessment Advisory Committee
Uncertainty Factor
United States Department of Agriculture
United States Fish and Wildlife Service
United States Geological Survey
Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has comp leted the human health and environmental risk assessments for halohydantoins and is issui ng 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 dock et. After considering the risks identified in the revised risk assessments, comments re ceived, 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 sup port 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 environmen tal effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" cri teria 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 tolera nce 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 req uire a safety finding in tolerance reassessment based on factors including consideration of cumu lative effects of chemicals with a common mechanism of toxicity. At this time, the Agency ha s 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 ha lohydantoins do not have a common mechanism of toxicity and will not perform a cumulative risk assessment as part of the tolerance reassessment for these pesticid al chemicals. This document presents the Agency's revised human health and ecological risk assessments and the reregis tration eligibility decision for the halohydantoins.

These antimicrobial chemicals are registered for use in indoor foo d 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 increa sed 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 effec t, and the likelihood that the effect was due to a greater dose received by pups from ingestio n of both milk and feed during the lactation period. Therefore, the Agency determined that the special hazardbased 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 eff ect 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 mech anism 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 pr oduced by other substances. For the purposes of this action, therefore, EPA has not assumed tha t the halohydantoins have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mech anism 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 rereg istration eligibility of the registered uses of halohydantoins. In an effort to simplif y the RED, the information presented herein is summarized from more detailed information, which can be found in th e 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 P ublic 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 regu latory history. Section III, Summary of Halohydantoins Risk Assessments, gives an overvie w 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 In secticide, 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 ethylmethylh ydantoin (EMH). The

primary reason for developing generic data on DMH and EMH rather than th e 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 chemi cal that could be administered t o 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 bas is 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-dimeth ylhydantoin, 1.3Dibromo-5,5-dimethylhydantoin, 1,3-Dichloro-5,5-dimethylhydantoin, and 1,3 -Dichloro-5-ethyl-5methylhydantoin. In addition, the Agency has determined that the 5,5-Dimethylhydantoin (DMH) and 5-Ethyl-5-methylhydantoin (EMH) metabolites of the halogenated hyd antoins are appropriate test substances for assessing the toxicity of this group. However, since the hydroxymethylhydantoins as listed above have the potential for releas e 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 hydroxymethylhyda ntoin.

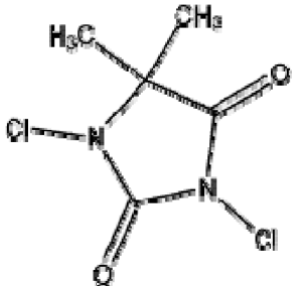
The common names, chemical names, empirical formu las, and CAS numb ers of the halohydantoins are presented in Table 1.

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

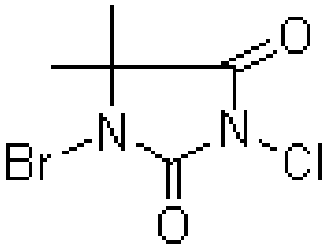
Common Name	Chemical Name	Empirical Formula	CAS No.
Dichlorodimethylhydantoin	1,3-dichloro-5,5dimethylhydantoin	$C_5H_6Cl_2N_2O_2$	118-52-5
Bromochlorodimethylhydantoin	1-Bromo-3-Chloro-5,5-Dimethylhydantoin	$C_5H_6BrClN_2O_2$	16079-88-2
Common Name	Chemical Name	Empirical Formula	CAS No.
Dichloroethylmethylh ydantoin	1,3-dichloro-5-ethyl-5methy lhydantoin	$C_6H_8Cl_2N_2O_2$	89415-87-2

Dibromodimethylhydantoin	1,3-dibrom o-5,5dimethylhy antoin d	$C_5H_6Br_2N_2O_2$	77-48-5
Bromochlorodimethylhydantoin	1-Bromo-3-chloro-5,5dimethylhydantoin	$C_5H_6BrClN_2O_2$	32718-18-6

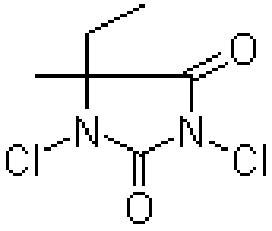
Structures of the halohydantoins considered in this document are below:



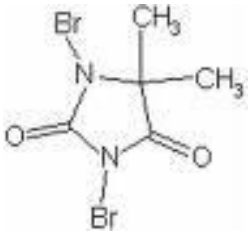
1,3 Dichloro-5,5-Dimethylhydantoin



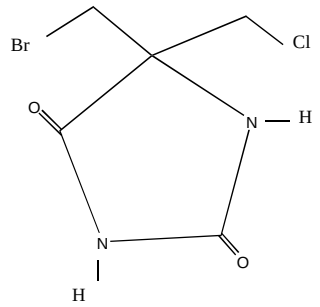
1-Bromo-3-Chloro-Dimethylhydantoin



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 decom poses exotherm ally at 180°C. It is attacked by strong alkali's, acids, and moisture.
Oxidation/Reduction	Oxidizer
pH of water solution, 1% slurry at 25 C_o	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 re lease chlorine and/or bromine and dimethylhydantoin (DMH) and, for certain products, ethylme thylhydantoin (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 hypobromo us acid.

a. Use Profile

The halohydantoins are used for microbial control in water and wa ter 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, wastewa ter 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 foodcontact 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 halohyd antoins 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

8 For ***toilet bowls and urinals***, 1 to 5 ppm of halohydantoins with 2 to 10 ppm of hal ogen 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 halohy dantoins with 1,125 ppm of halogen is used at a typical rate of 0.45 ou nces 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 g ranular form from end use packs that range from 20 to 50 pounds.

For ***residential and commercial spas***, 30 to 100 ppm of halohyda ntoins 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 briquet tes**,** tablets and granular formulations. The end-use pack size for gel products range fro m 22 oz to 400 pounds.

Aquatic Non-Food

For ***Decorative Waters*** without fish, 50 to 260 ppm of halohyda ntoins 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 halohydantoi ns 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 poun ds for all other formulations.

For ***once through cooling systems***, 5 to 35 ppm of halohydantoin s 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 gra nular, briquettes, tablet and gel form. End use product package sizes range from 22 oz to 4 00 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 pape r. 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 formu lations and 25 to 2,200 pounds for all other formulations.

For ***sewage and wastewater treatment systems***, 5 to 35 ppm of h alohydantoins 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. E nd 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 p pm 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 disp ense 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 swimm ing 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 fi nding and regulatory decision for halohydantoins. While the risk assessments and related a ddenda are not included in this document, they are available to the public in EPA's Pesticide D ocket EPA-HQOPP -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 hal ogenated compounds. This group of chemicals includes the following: 1-Bromo-3-chlor o-5,5dimethylhydantoin, 1.3-Dibromo-5,5-dimethylhydantoin, 1,3-Dichloro-5,5-d imethylhydantoin, 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) metabo lites of the halogenated hydantoins are appropriate test substances for assessing the toxicity of this group. However, since the hydroxymethy lhydantoins 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 hydroxy methylhydantoins 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 meta bolites for reregistration.

The Agency's use of human studies in the halohydantoins risk assessme nt is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Prot ections 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 presente d 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 (Tox icity 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 comp ounds. 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)-Mous e	45738401	LD_{50} (com bined) > 5,000 mg/kg	IV
1-Bromo-3-chloro-5,5-dimethylhydantoin			
870.1100 Acute oral toxic ity-Rat	9 3074006, 00128244 (42 26-010-01)	LD_{50}(ma les) = 1,35 0 mg/kg LD $_{50}$(fema les) = 1,520 mg/kg 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 L D_{50}(females) = 860 mg/kg L D_{50}(combined) = 929 mg/kg	III
870.1300 Acute inhalation toxicity-Rat	43654101	LC_{50}(males) = 0.157 mg/L LC_{50}(females) = 0.213 mg/L L C_{50}(combined) = 0.168 mg/L	II
870.2500 Acute dermal irritation-Rabb it	93074011, 9 3075014, 00128242 (422 5-014-10)	severe skin irritant	I
870.2500 Acute dermal irritation-Rabbit	93077009, 00147326 (4 600-950-22)	severe skin irritant	I

870.2600 Skin sensitization-Guinea pig	41670001	positive sens tiz i er	N/A
1,3-Dibromo-5,5-dimethylhydantoin			
870.1100 Acute oral toxicity-Rat	9 3076011, 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-Rab bit	93076017, 00137109 (4334-012-05)	severe skin irritant	I
870.2500 Primary dermal irritation-Rabbit	44988004	corrosive	I
870.2600 Dermal Sensitization - guine pa ig	44988005	non-sensitizer	N/A
1,3-Dichloro-5,5-dimethylhydantoin			
870.1200 Acute dermal toxicity -Rabbit	9 3076013, 00084176 (2402-448-05)	L D_{50} > 20,000 mg/kg	IV
870.2500 Acute dermal irritation-Rabbit	93076017, 00137109 (2402-448-01)	severe skin irritant	I

Table 4. SumToxicolog cal Dmary ofi ose and Endpoints for the Halohydantoins for Use in Human Risk Assessme nt

Exposure Scenario	**Dose Used in Risk Assessme nt, UF**	**FQPA SF and Endpoint for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietar y females 13 0-5 years of age	NOAEL = 100 mg/ kg/day UF = 1 00 Acute R fD = 1 mg/kg	FQPA SF = 1 aPAD = acute RfD / F QPA SF = 1 mg/kg/day	developmental toxic ity - rabbit developmental LOAE L = 500 mg/kg/day based on skeletal variations. (MRID 42413101)
Chronic Dietary[a] all populations	NOAEL= 300 mg/ kg/day UF = 10 0 Chronic fD R (gen Pop.) = 3 mg/kg/day	FQPA SF = 1 cPAD = chr RfD / FQPA SF = 3 mg/kg/day	chronic toxicity/carcinogenicity - rats LOAEL = 1000 mg/kg/day based on decr eased body weight/weight gain and lymph node hyperplasia. (MRID 43397702)

Chronic Dietary[a] females 13-50 years of age	NOAEL= 100 mg/kg/day UF = 100 Chronic RfD (females 13-50) = 1 mg/kg/day	FQPA SF = 1 cPAD = chr RfD / FQPA SF = 1 mg/kg/day	developmental toxicity - rabbit developmental LOAEL = 500 mg/kg/day based on skeletal variations. (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 = refer ence dose, MOE = margin of exposure

[a]The HIARC selected separate chronic RfDs for females, ages 13-50, and the general popu lation. 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 subc hronic, developmental, reproductive, and chronic toxicity testing) all show the presence of non-specific toxicity only at relatively high doses of the test chemical. Developmental an d 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 27th 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 27th presacral vertebrae is a common variation found in rabbit developmental toxicity studies and was not considered an adverse effect. In a p renatal developmental toxicity study conducted in rabbits with 5-ethyl-5-methylhydant oin, 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 re leasers. 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 hydrox ymethylhydantoin molecule will be addressed in the registration review of the hydroxymethylhyda ntoins.

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 like lihood that the effect was due to a greater dose received by pups from ingestion of both milk an d 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 stan dard 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 routeto-route extrapolation.

Carcinogenicity

Cancer studies in rats and mice indicated no systemic effects other than d ecreased 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 carcinog en 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 (FFDC A), 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 i s 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 fo r 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 r eproductive or developmental toxicity testing of 5,5-dimethylhydantoin is complete. Ba sed on the overall examination of the effects of DMH, the HIARC concluded that there was some evidence for incr asede susc ep tibility, because a developme ntal 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 esti mates (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 bot h 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 aPA D is 1 mg/kg/day. Uncertainty factors were included for inter-species extrapolation (10x) and intr a-species variation (10x).

b. Chronic PAD

Chronic dietary risk for halohydantoins was assessed by comparing chr onic dietary exposure estimates (in mg/kg/day) to the chronic Population Adj usted 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 th e manufacture of paper and paperboard. Acute and chronic dietary exposures were assessed fo r 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 foodcontact paper and paperboard. In this regard, the Food and Drug Administr ation (FDA) has developed guidelines to estimate the resid ues of pesticides used as slimicides on food contact paper and paperboard. The Agency has decided to use FDA methodology to estima te 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 assump tions 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 t he type of food that is being contained in the treated paper, and factors such as the quantity o f 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, hydroxymethylhydanto in 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 Ris k 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 estima tes 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 estima ting exposure.

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

Population Subgroup	EDI mg/day	Acute Dietary		Chronic Dietary	
		Di etary Exposure[a] (mg/kg/day)	% aPAD [b]	Dietary Exposure (mg/kg/day) [a]	% cPAD [b]
Adult Male	0.0276	--	--	3.94×10^{-4}	0.0131
Adult Female	0.0276	4.60×10^{-4}	0.046	4.60×10^{-4}	0.0153
Children	0.0138	--	--	1.38×10^{-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 Die tary		Chron ic 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 co ncentrations (PECs) of pesticides in surface water to estimate drinking water exposures t o 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 greates t 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 mod el was determined to be 313 ug/L.

6. Residential Exposure Assessment

The residential exposure assessment considers all potential pesticide exp osure, other than exposure due to residues in food or in drinking water. Residential exposure ma y 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 t o an appropriate No Observed Effect Level (NOAEL) dose.

a. Residential Toxicity

The toxicity endpoints and associated uncertainty factors used for assessing the nondietary risks for halohydantoins are listed in Table 7. Although the dermal endpoint represents short-, intermediate-, and long-term durations, the exposure duration of mo st 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 shor t-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.

T able 7. Toxicolog al ndpoints ic E

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Short-Te rm Oral (1-30 days) (Incidental)	oral study NOAEL= 500 mg/kg/day UF = 100	Residential, includes the 1x FQPA SF	developmen tal toxicity - rabbit maternal LOAEL = 1000 mg /kg/day based on decreased body weigh t gain in maternal rabbits. (MRID 4 2413101)
Intermediate-Term Oral (1 to 6 m onths) (Incidental)	oral study NOA EL= 3 00 mg/kg /day UF = 100	Residential, in clude s the 1x FQP A S F	sub chronic oral toxicity - rat LOAEL = 1 000 mg/kg/day based on decreased body weight an d liver weight. (M RID 42009201)
Dermal- all time periods Short-,(1-30 days), Intermediate -, (1 to 6 months), Lo ng-ter m (>6 months) (Occupat ional/ Residential)	derm al stud y NOAEL= 390 mg/kg/day (HDT) UF = 100 f or all populat ions	MOE = 100 (Occupational) R esiden tial, incl ude s the 1x FQPA S F	subchronic dermal toxicity - rats No systemic toxicity at the highest dose tested (MRID 4317 3901)
Short-Term Inhalation (1-30 days) (Occupational/ Residential)	Oral NOAEL= 100 mg/kg/day (inhalation absorption rate = 100%) UF = 100 for all populations	Residential, includes the 1x FQPA SF	developm ental toxicity - rabbit developm ental LOAEL = 500 mg/kg/day b ased on skeletal effects in offs pring. (MRID 42413 101)

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 disinfecta nts 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 p ools and spas.

Hydroxymethylhydantoins may be added as a material preservative to c ontrol 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 clean er	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 h andler 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 EPAHQ-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
	Mo pping	0.0053	73,000	0.00018	570 ,000
Toilet Bow l 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	5,4 00
Swimming Pools / Spas					
Sw imming Pools (Residential – backyard)	Solid Place	0.12	3200	0.000015	65 00000
	Solid Pour	0.85	460	0.00046	22 0000
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 cleane d/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 screeni ng-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 e xposed to residue in a swim ming 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 Halohydantoins RED 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, whi ch 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 f loors, 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, facilit ies 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 assu mptions is 0.07 mg/kg/day resulting in a hand-to-mouth MOE for toddlers of 7100 (short-term) a nd 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 pro cessing, it is unclear in what capacity the chemical is to be used. It has been assumed, for th is 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 (US EPA, 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 finger s used in the hand-tomouth 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 flu x rate of the chemical from clothing. It has been conservatively assumed that, o ver the course of a day, the amount of chemical transferred is the full quantity of chemi cal 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 tra nsferred. 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, avail able 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 de veloped 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 th e 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 fil e 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.

Halohydantoins RED

Table11. Margins of Exposure for Swimming Pool [a]

Age	Type of Swimmer	Dermal MOE	Inhalation MOE	Ingestion MOE
Adult	Competiti ve	3,100,000	47,000	190,000
Adult	Non-competiti ve	1,900,000	90,000	56,000
Child 7-10 y rs	Competiti ve	7,100,000	100,000	60,000
Child 7-10 yrs	Non-competitiv e	1,400,000	38,000	12,000
Child 7-10 yrs	Non-competitiv e	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, drin king 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 wate r exposures only. The acute dietary risk estimates from indirect food uses (i.e., use in food-contact p ackaging 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 leve l 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 Ex osure and Rpisk

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 D LOCW [4] mg/L	Potential Risk Concern
Females 13-50 years	1.0	4.6x10-4	0.999	0.036	29986	No
Fem ales 13-50 ye ars (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 expo sure (mg/kg/day)]** [3] **Based on PDM4 mod el.**

[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 u likely that all of the scenariosn 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 derma l 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 derma l scenario of floor contact, and the dietary exposure is aggregated separately with the single incid ental 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 chemi cal transferred is the full quantity of chemical pr esent 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 r es idential)[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	1470 00

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

2MOE 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)] Inhalati on 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 Wa er MOE = 1t ÷ [[(1 ÷ Target Aggregate MOE) - (1÷Aggregate MOE (food and residential)]]

7 Allowable water exposure = Short or Intermediate Term Oral NOAEL ÷ MOE water 8using PDM4 model

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

c. Chronic Dietary Aggregate Risk

Table 14 presents the total chronic dietary exposure estimate for h alohydantoins, and the chronic DWLOCs. The chronic PAD and the chronic dietary (food) exposu re for that subgroup were used to calculate the chronic DWLOC. Two methods were used to calcul ate 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	3.94×10^{-4}	2.999	0.3	104986
General Population (alternate FDA method)		0.0137	2.986		104520
Females 13-50 years	1.0	4.60×10^{-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 expos ure (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 come s 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-20040303).* This section summarizes the results of the occupational exposure/risk a ssessment. The following handler exposure scenarios were assessed and represent high-end exposures to i d n ustrial uses of the formulated product:

- ③ Placing the halohydantoin tablets/pellets into cooling and process water systems, and
- ③ Pouring halohydantoin granules/powders into a feeder for cooling an d 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 di rections 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 inhala tion MOEs for the primary were determined. Dermal MOEs range from a high of 151,000 for sol id 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 abov e 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 t o 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 commerc ial 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 Associ ation and from anecdotal evidence. The EPA calculated the exposures for workers at a comme rcial/public swimming pool, using the assumption that a large commercial/public swimmin g 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 handle rs 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. EP A, 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 op erations. 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 ass essment: 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 e xposure 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 longterm 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 informa tion, 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 a rea 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 w ater 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 Assessme nt, dated June 25, 2007, available at http w://w w.regulations.gov (EPA-HQ-OPP-2004-0303).

c. Postapplication Exposure (All Occupational Uses)

Postapplication inhalation exposures may occur in the industrial set tings around the water systems via inhalation, and dermal exposures may occur while mainta ining industrial equipment. However, occupational postapplication dermal and inhalation exposures to halohydantoins are likely to be minimal compared to handler exposure beca use 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 ha e been submitted to th v e 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 dihalodialk ylhydantoin 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 t oilet bowl water). The purpose of this chapter is to review the evidence of health effects in humans resulting from exposure to Hal ohydantoins.

Two approaches are used in this section:

③ The potential health effects of halohydantoins in humans, reported a s incident reports from different sources, are summarized.

③ 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 pr imary 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 irrita tion/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 intende d to describe the magnitude of the estimated environmental risks associate d 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 st udies on dihalodialkylhydantoin. However, hydrolysis appears to be the major route for d issipation. 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 a naerobic 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 7.89×10^{-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 halohydan toins as far as mobility (soil column leaching) is concerned, as well as binding constants to so ils 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 so urce 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 contaminatio n 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 (K d's). If present in the environment, it may cause a concern for ground- and surface water contami nation.

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)	Nort hern bobwhite (*C olinus vir ginianus*	96	LD50 = 1839mg/kg NOEL = 1350 m g/kg	147319	Slightly toxic
Avian dietary (71-2/850.2200)	Northern bobwhi te (*Colinu s virginia nu s*)	96	LC50 > 5620 ppm	147321	Practically non-toxic
Avian dietary (712/850.2200)	M allard (*Anas platyrhynchos*)	97.2	>5000 ppm NOEC = 5000 ppm	432899-03	Practically nontoxic
Freshwater fish acute (72-1/850. 1075)	Rainb ow trout (*Onco rhyn hus c mykiss*)	97.1	LC50 > 972 mg/L NOEC = 972 mg/L	423736-01	Practically nontoxic
Freshwater fish acute (72-1/850.1075)	Blu egill (*Lepomis macroch usir*)	97.1	LC5 0 > 1,017 mg/L NOEC = 1,017 mg /L	423685-01	Practically nontoxic
Fish early lifestage (72-4/850.13)00	Fathead m innow (*Pim ephal es pr omelas)*	99.9	NOEC = 14 mg/L (dry weight) LOEC = 29 mg/L	427217-02	(chronic endpoints are not assigned a toxicity category)
Freshwater invertebrate a cu te (72-2/850.10)10	*Daphnia magna*	97.1	EC50 > 1070 mg/L NOEC = 1070 mg/L	423736-03	Practically nontoxic
Marine/estuarine fish acute (72-3a/850.1 5) 07	Sheepsh ead minno w *(Cyprino don variegatus)*	97.1	LC5 0 > 1006 mg/L NOE C = 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 nontoxic
Marine/estuarine bivalve acute (72-3b/850.1025)	Eastern oyster *(Crassostrea virginica)* shell deposition	97.2	EC50 > 125 mg/L NOEC = 125 mg/L	432899-02	Practically non-toxic

3. **Environmental Exposure Modeling**

The PDM4 Model was used to estimate exposure from once-through coo ling tower uses. A low-flow power plant (100 ± 10 million gallons per day) was used as the sce nario 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 pos sible degradation/dissipation of DMH by mechanisms other than hydrolysis. Based on the modeling, a summary of the estimated environmental concentrations (EECs) over time iprovided below:s

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 o f 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 determi ne 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 oncethrough 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 Ty pe	Species	V alue	EEC (from Table 16)	RQ (EEC/LC50)
Freshwater Fish Acute	R ainbow trout (*Oncorhynchus mykiss*)	L C50 >972 mg/L (MRID 423 736-01)	36.0 ppb (0.036 mg/L)	0.000037
Freshwater Invertebrate Acute	*Daphnia magna*	EC 50 > 1070 mg/L NOEC = 1070 m g/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-throu gh cooling tower, no LOCs are exceeded. Expressed as number of days exceedance, using the mo st sensitive parameter of 14.0 mg/L (14000 ppb) (freshwater fish chronic NOEC) as the "co ncentration of concern" and the exceedance curve generated by modeling, the chance of this c oncentration 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., swimm ing 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), req uires 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 wild life 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 auth orize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result i n 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 specie s 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 estab lished procedures to valuate whether a proposed registration action may directly or indirectly reduce ap preciably the likelihood of both the survival and recovery of a listed species in the wild b y 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 Specie s LOC Criteria are ex ee c ded 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 asses sment is undertaken. The extent to which listed species may be at risk then determine s the need for the development of a more comprehensive consultation package as required by the End angered Species Act.

For certain use categories, the Agency assumes there will be minimal envi ronmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk A ssessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endang ered 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 sub mission 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-speci fic) 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 su pport reregistration of all supported products containing halohydantoins.

The Agency has completed its assessment of the dietary, occupational, d rinking 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 th e 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 p art of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing halohyda ntoins are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs a re addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these me asures. 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 determina tion 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 no t 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 ris k 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 docume nt 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 fo r halohydantoins meets the FQPA safety standards and that the risk from dietary (food sources o nly) exposure is within the "risk cup." An aggregate assessment was conducted for exposures fr om 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 consid ered 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 r isks associated with halohydantoins. The Agency has determined that, the established tolera nce 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 o r 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 FFDC A, that there is a reasonable certainty of no harm for infants and children. The safety determina tion for infants and children considers toxicity, use practices, and environmental behavior noted abo ve 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 child ren 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 du ring 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 si milar 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 Te sting 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 adopt ed 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 characteriz e 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 A gency consider "available information" concerning the cumulative effects of a particular pestic ide's residues and "other substances that have a common mechanism of toxicity." The rea son 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 webs ite 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 am endments and changes as specified in this document, meet the safety standards under the FQPA ame ndments 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 pro ided that additional required data confirm this decision, the risk mitigation measures outlined v in this document are adopted, and label amendme nts 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 no t 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 tha t 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 haloh ydantoins 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 det ermine 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 the y 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 p esticide 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 en vironmental exposure, and only a minimal toxicity data set is required (Overview of the Eco logical Risk Assessment Process in the Office of Pesticide Programs U.S. Environment al 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 screenin g-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 l ow 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 reregis tration 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 amend ments are made to reflect these measures. To implement the risk mitigation measures, the registr ants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summ ary 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 ex tension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite a y exi ing g neric data, which address data requirements or submit new generic nst e data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regardin g 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 f orm 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 compl eted 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 complianc e 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.

Pleas e co tact E n mily 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 include d in the generic DCI for this RED.

The risk assessment noted deficiencies in the surrogate dermal a nd 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 ba sed 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 emerge nce/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-respo nse) a al toxicity, 4 species (green alga, lg fres hwater 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 manufact uring 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 efficacyrelated 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 docume nt. 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 Se ction 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 pre mises, buildings, and equipment; dairy farm milk handling facilities, equipm ent, storage rooms, houses, plants, food handling, food distributi on equipment and premises; eating establishments premises and equipment; commercial, institutional, and industrial premises and equipment (floors, walls, storage areas); domestic dwel lings, food handling areas, indoor premises; and medical institutional critical care and non -critical care premises, human water systems, swimming pools and industrial processes an d water systems." For Formulation into antimicrobial products for use in: animal transport vehicles, carpets, fountains/water displays/decorative ponds/, once- through and recirculating industrial commercial cooling water systems, pulp/paper mill water systems, and swimmi ng pools, mushroom facilities/premises and equipment, egg handling equipm ent 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, wa ter storage systems (aircrafts boats, RVs, off-shore oil rigs), water filtration systems, ventilation systems.	Directions for Use structures, and sheds; food processing
End Use Products Intended for Occupational Use		

Amended Labeling Language	Placement on Label

resistant gloves while placing the tablet in the swimming pool”	Precautionary Statements under: Hazards to Humans and D omestic Animals (Immediately Following Engineering Controls
resistant gloves while placing the tablet in the once throu gh cooling tower	Precautionary Statements under: H azards to Humans and Domestic Animals (Immediately Following Engineering Controls
resistant gloves while placing the tablet in the swimming pool/spas”	Precautionary S tatements 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 ga llons per day applicators must use “solid pour” and for smaller application s less than 35,0 00 gallons per day, applicators can must “place solids” into a metered feeding system 2) “Occupational handler must wear chemical re sistant gloves while placing granu les and tablets in nursery and greenhouse irrigation systems”	Pre cautionary Statem ents under: Hazards to Humans and Domest ic Animals (Imme diately Following Engineering Controls

VI. APPENDICES

Use Site	Reg. no./ For mu latio n	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 spong e	1gram of product p er 7.8 gallons of water. Preclean areas. 10 minute c ontact 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 m inute cont act time.	Avoid breathing spray.
In- Tank- Sanitizer	777-106 777-107 5185-44 6 5185-469 5813-65 5813-66 6836-255 6836-256	Place tablet in tank	Clean toilet bowl thoroughly and flu sh the toilet. When wate r level is low and valve clos ed, place tablet into the right corner of the tank. Wh en tablet dissolved replace it with a new tablet. Tablets should	Do not touch tablet directly. Wash hands thoroughly if there is any skin contact.

	6836-263 6836-264 6836-265 6836-272 6836-273 6836-274 6836-275 6836-279		be used in toilets flushed daily.	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	6836-287 683 6-288 683 6-291 6836-299 6836-300 (T able t)			

In Tank Sanitizer/Necktie	5813-84 (Tablet)	Place tab let in tank	Clean toi let bowl thoroughly including under rim. Flush toil et and remove toilet tank lid. Hang unit(s) on toilet tank wall with ta blet 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 3377-71 (Ready to Use)	Open Pour/Re ady to Use	Initial Dose: When system is noticeably fouled add product to achieve a residual bro mine level of 0.5-5ppm or as needed to maintain control. Repeat until control is achieved. 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 a chieve a residual brom ine level of 0.5-5ppmor as needed to maintain control.	
Pulp and Paper Systems	1448-356 1448-428 5785-63 6836-282 63838-4 75361-1 83451-4 (Tablet)	Place tab let in the sys tem at a point wh ere sufficient mixing can occur	When system is notic eably fouled add at a of 1 2 to 20 ppm When biological control is evident: 12 to 90 ppm. 0.5-2.0 lbs of product per ton.	Do not exceed 2.2lbs of this product per dry me tric ton fiber when this product is used in the manufacture of paper and paperboard products that contain food.
Pulp and Paper Systems	6836-297 (Tablet)	Place tab let in the syste m at a poi nt where sufficient m ixing can occur	0.5-2.0 lbs of product per ton. To produce 0.1-1.0 ppm of available ha logen as chlorine.	May be used in the manufacture of food contact paper and paperboard products.
	1448-420 3377-62 3377-63 3377-71	Open Pour/ready to use	When system is noticeably fouled add at a rate of 0.5 to 120ppm. When biological control is	Do not exceed 1.0 kilograms per 1,000kg per dry metric ton fiber in paper and paperboard components that contact food.

	5785-57		evident add at a rate of 12	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(Ready to Use)		to 90 ppm.	
	8622-2 9 8345 1-3 5785-65 (Granular)	Open Pour/Granules	When system is noticeably fouled add 12 to 20 pp m. Wh en biological control is evident add 12 to 90 ppm.	Used in the ma nufacture 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 Concentr a te	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 6836-115 6836-314 (Tablet)	Plac e tablet in system	Initial Dose: Wh en system is noticeably fouled apply 0.5 to 2.0 lbs per ton of paper produced to ac hieve 0.1- 1.0 ppm total available halogen as chlorine. Repeat treatment until residual is achieved. 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 a va ilable halogen as chlorine . Repeat periodically as nee ded to maintain control.	None listed
	6836-317 (Tablet)	Place tablet in system	Initial Dose: When s ystem is noticeably fou led apply 0.1-10lbs of tab lets to 1,000 gallons (0. 1 to 1.0 lbs of tablets per dry m etric 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 contr ol is evident apply 0.1 to 0. 75 lbs of this product to 1,0 00 gallons of water. (0.1 to 0 .75 lbs of tablets per dry metric ton of paper pro duced). Repeat treatment until achieve 0.1-1.0 ppm total available. Repeat treatm en t 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 gallon s of water in the system . Subsequen t 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
	6836-237 6836-280 6836-281 6836-296	Open Pour/Granules	Initial Dose: When system is noticeabl y fouled apply 0.5-2.0lbs per ton of paper produced to achieve	None listed.

Paper and Paperboard Process Water (Continued)	(Granular)		0.1-1.0 ppm total a vailable halogen as chlorine. Repeat treatment until residual is achieved. 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.	
	6836-312 6836-315 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		produced to achieve 0.1-	

	Powder)		1.0 ppm total a vailable halogen as chlorine. Repeat treatment until residual is achieved. Subsequent Do se: When microbial cont rol is evident apply 0.1-2.0 l bs per ton of paper produced to achieve 0.1-1.0 ppm total available halogen as chlorine. Repeat periodically as needed to maintain c ontro l.	
Pasteurizer, Can Warme r, Cannery, Retort Water Systems	1448-356 1448-428 5185-420 69681-16 83451-4 (Tablet)	Place tab let in system	Initial Dose: W hen the system is notic eably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bro mine residual is established for at least 4 hours. 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 W armer, Cannery, Retort W ater System s (Continued)			gallons. Repeat as needed to maintain 1 to 3 ppm brom ine residual for at least 4 hours.	
	1448-420 (Ready to Use)	Open Pour/Ready to Use	Initial Dose: When the system is noticeabl y fouled add 0.2 to 0.6 poun ds /1 ,000 gallons. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours. Subsequent Dose: When control is eviden t add 0.1 to 0.3 po unds /1,000 gallons. Repeat as ne eded to maintain 1 to 3 p pm 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 brom ine residual is established for at least 4 hours. Subsequent Dose : When control is evid ent add 0.1 to 0.3 poun ds /1,000 gallons. Re peat as needed to maintai n 1 to 3 ppm bromine residu a l for at least 4 hours.	

Pasteurizer, Can W armer, Cannery, Retort Water Systems (Continued)	83451-10 (Soluble Concentrate)	Open Po ur/ Soluble Concent rate	Initial Dose: When the system is notice ably fouled add 0.04 77 to 0.143 gallons /1,000 gallons of water. Repeat in 1 to 3 ppm bromine resi dual is established f or at least 4 hours. Subsequent D ose : When control is evi dent 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 t he system is notic eably fouled add 0.2 to 0.6 poun ds /1,000 gallons. Rep eat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent Dose: When control is evident a dd 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 t o Use	Initial Dose: When t he system is noticeably fouled add 0.0545 to 0.1 634 gallons /1,000 ga llons of water. Repeat in 1 to 3 ppm bromine residual is established for at least 4 hours. 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 a s needed to ma intain 1 to 3 ppm bromine residual for at least 4 hours	
Evaporative Cooler Evaporative Cooler (Continued)	1448-356 144 8-428 578 5-63 578 5-100 518 5-420 696 81-16 75361-1 83451-4 (Tablet)	Place tab let in system	Initial Dose: W hen the system is notic eably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is establishe d for at least 4 hours. Subsequent D ose : When control is e vident add 0.1 to 0.3 poun ds /1,000 gallons. R epeat as needed to maintain 1 t o 3 ppm bromine residu al for at least 4 hours.	None listed.
	1448-420 83451-12 (Ready to	Open Pour/Ready to Use	Initial Dose: When the system is noticeably fouled add 0.2 to 0.6 pounds	None listed.

	Use)		/1,000 gallo ns. Repeat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent Dose: When	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			control is evid ent add 0.1 to 0.3 pounds /1,00 0 gallons. Repeat as needed to maintain 1 to 3 ppm bromine residua l for ta least 4 hours	
	83451-12 (Wettable	Open Pour/Powder	Initial Dose: When the system is noticeabl y fouled	

	Powder)		add 0.2 to 0.6 poun ds /1,000 gallons. Rep eat in 1 to 3 ppm bromine residual is established for a t least 4 hours. Subsequent Dose: When control is eviden t add 0.1 to 0.3 pounds /1 ,000 gallons. Repeat as n e eded to maintain 1 to 3 p pm 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. Subsequent Dose: When microbia l control is evident add 0.0238 to 0 .072 gallons/1,000 g allons of water in the sy stem. Repeat as nee ded to maintain 1 to 3 ppm bromine residual for at least 4 hou rs.	
	75361-1 (Tablet)	Place tablet in the system	Place tablets into condensate li ne 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 notic eably fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual is establishe d for at least 4 hours. 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 brom ine residual for at least 4 hours.	
	83451-11 (Gel)	Open Pour/Gel	Initial Dose: When th e system is noticeab ly ouled f add 0.0545 to 0.163 4 gallons /1,000 ga llon of s water. Repeat in 1 to3 ppm bromine residual is established for at least 4 hours. Subsequent Dose: When control is evid ent add 0.0272 to 0.082 3 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 1448-428 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
	5185-421 578 5-63 578 5-100 638 38-4 683 6-314 683 6-315 683 6-317 69681-16 83451-4 (T able t)		/1,000 gallons . Repeat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent D ose : When control is evid ent add 0.1 to 0.3 poun ds /1,000 gallons. Re peat as needed to m aintain 1 to 3 ppm bromine residu a for at l least 4 hours	

	8622-77 63838-7 (powder)		Initial Dose: When the system is noticeably fouled add 1.7 to 6.0 pounds /10,0 00 gallons. Repeat until 1 ppm b romine residual is est ablished for at least 4 hour s. Subsequent D ose : When control is e vident add 0.8 to 3.0 pounds /10,000 gallons. Re peat as needed to maintain 1-3 ppm brom ine 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	None listed.

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations

Recirculating Cooling Wa r (Continued) te			/1,000 gallons. Rep eat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent Dose: When control is evident a dd 0.1 to 0.3 pounds /1 ,000 gallons. Repeat as needed to maintain 1 to 3 p p m bromine residual fo r at least 4 hours	
	8622-30 (Tablet)	Place tablet in system	Initial Dose: When system is noticeably fo uled, add 0.75 to 6.0 lbs/1000 gallons of water. R epeat in dosage until one ppm halogen residual, measured as free chlorine for at least 4 hours. 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)	5785-62 663 97-1 75361-1 8622-73 (Tablet)	Place tab let in system	Initial Dose: When system is noticeably fo uled, add 0.75 to 6. 0 lbs/1000 gallons of wate r. Repeat in dosage until one ppm halogen residual, measured as free chlorine for at least 4 hours. Subsequent D ose : When system is notic eably fouled, add 0.1 to 3.0 lbs/1000 gall ons of water. Repeat as needed to maintain one ppm halogen residual, measured as free chlorine for at le ast 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 foul ed use 1 to 2 tablets for each 100 gallons of water. Add additional tablets until a residual of 10 to 35 ppm bromine is establ ished. Maintain tre atment until system is free from microbial fouling. Subsequent Dos e : Use tabs as needed to ma intai n a residual of 5 to 15 p p m bromine.	
	5785-65 6836-315 6836-316 83451-3	Open Pour/Granules	Initial Dose: When the system is noticeabl y fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1	None listed.

Recirculating Cooling Wa r te (Continued)	(Granular)		to 3 ppm bromine residual is established for a t least 4 hours. Subsequent Dos e : 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	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			least 4 hours	
	6836-2 37 6836-280 6836-324	Open Pour/Granules	Initial Dose: When system is noticeably fouled add 0.1 to 1.0 lbs to 1,000 gallons	None listed.

	(Granular)		of water. Repeat until control is ac hieved. Subsequent Do se : When mi crobial control is evident add 0.1 to 0.75 lbs to 1,000 gallons of water every 3 days or as needed to main tain control.	
	83451-12 (Wettable Powder)	Open Pour/Powder	Initial Dose: When the system is notic eably fouled ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bro mine residual is established for at least 4 hours. 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 Wa ter (Continued)			bromine residual for at least 4 hours.	
	1448-420 3876-150 5785-57 6836-113 6836-115 6836-116 6836-120 6836-121 6836-122 6836-123 683 6-124 6836-210 (Ready to Use Solution)	Intermittent, slug or contin uous fe ed method.	Initial Dose: When s ystem is noticeably foule d add 0.1 to 1.0 lbs to 1, 000 gallons of water. Repeat until control is achieved. Subsequent Dose: W hen microbial control is evident add 0.1 to 0.7 5 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 granule s until residual of 1 to 35 p pm is established. 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
	3377-6 2 3377 1-7 (Ready to Use)	Intermittent, slug or c ontinuo us method.	Initial Dose: W hen system is noticea bly fouled add 0.5 to 5ppm as nee ded to maintain cont rol. Applying ½ ounce to 1, 000 gallons of water yiel ds theoretical average 4 ppm available bromine. Re peat as until control is evide nt. Subsequent Do se : When microbial cont r ol is evident add 05 to 5 pp m as needed to maintain control.	None listed.

	83451-10 (Soluble Concentrate)	Open Pour/Sol uble Concent rate	Initial Dose: When system is noticeably fouled add 0.0477 to 0. 143 gallons /1000 gallons of water. Repeat initia l dose until bromine residu al is establish ed for at least 4 hours. Subsequent Do se : When microbial c ontrol 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./ Formulatio n	Method of Application	Application Rate/ No. of applications	Use Limitations
			least 4 hours.	
	83451-11	Open Pour/Gel	Initial Dose: add 0.0545 to	None listed.

	(Gel)		0.1634 gallons/ 10 00 gallons of water. Repeat initial dosage unt il 1 to 3 ppm bromine residual is established for at least 4 hours. Subsequent Dose: a dd 0.0272 to 0.0823 ga llons/ 1000 galloons of water. R epeat as needed until 1 to 3 ppm bromine residual is established for at least 4 hours.	
Once Through Cooling Wa te r System	1448-356 1448-428 5785-63 63838-4 6836-115 69681-16 83451-4 8622-30 (Tablet)	Place tablet in system	Initial Dose: When the system is noticeabl y fouled ass 0.2 to 0.6 pounds /1,000 gallons. Re peat in 1 to 3 ppm brom ine residual is established for a t least 4 hours. 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 fo uled, add 0.75 to 2.255lb s/1000 gallons of wate r. Repeat in dosage until o ne ppm halogen residual, measured as free chlori ne for at least 4 hours Subsequent D ose : When system is noti ceably fouled, add 0.4 to 1.25 lbs/1000 gallo ns of water. Repeat as needed to maintai n one pp m halogen residual, mea su red as free chlorine for a t l st 4 ea hours.	None listed.

Once Through Cooling Water System (Continued)	63838-4 75361-1 8622-73 (Tablet)	Place tab let in system	Initial Dose: W hen noticeably fouled add 2-6 lbs per 10,000 gallons of water. Repe at initial dosage until at least one ppm of active residual bromine is established for at least 4 hours. Subsequent Dose : When	None listed. 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 maint ain one ppm of active residual bromine for at least 4 hours.	
	1448-420 3876-150 5785-57 6836-210 6836-113	Open Pour/Ready to Use	Initial Dose: When the system is noticeabl y fouled add 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bromine residual	None listed.

	6836-317 (Ready to Use)		is established for at least 4 hours. Subsequent Dose: When control is eviden t add 0.1 to 0.3 pounds /1 ,000 gallons. Repeat as ne eded to maintain 1 to 3 p pm bromine residu al for at least 4 hours	
	5785-65 6836-237 6836-280 6836-315 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	None listed.

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations

Once Through Cooling Water System (Continued)			hours. Subsequent Dose: When control is evident add 0.1 to 0.3 pounds /1,000 gallons. Re peat as needed to ma intain 1 to 3 ppm bromine residua l for at least 4 hours	
	8622-29 (Granular)	Open Pour/Granules	Initial Dose: When noticeably f ouled add 2-6 lbs per 10,0 00 gallons of water. Repeat initial dosa ge until at least one ppm of active residual bromine is e stablished for at least 4 hours. Subsequent Do se : When microbial c ontrol is evident add 1 to 3 lbs per 10,000 gallons of water. Repeat as needed to m aint ain one ppm of active r esidual brom ine 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. Rep eat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent Dose: When control is evident a dd 0.1 to 0.3 pounds /1 ,000 gall ons. Repeat as needed to maintain 1 to 3 pp m bromine	
Once Through Cooling Water System (Continued)	8622-28 (Wettable	Open Pour/Powder	Initial Dose: Whe n noticeably fouled add 2-6	None listed.

	Powder)		lbs per 10,000 g allons of water. Repeat initi al dosage un til at least one ppm of active resid ual bromine is establish ed for at least 4 hours. Subsequent Dose: W hen microbial contr ol is evident add 1 to 3lbs p er 10,000 g allons of water. Repeat as needed to maintain o ne ppm of active residual bromine for at least 4 hours.	
	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 gallon s of water. Repeat i nitial dose until brom ine residual is established f or at least 4 hours. Subsequ ent Dose : When microbial c ontrol is evident add 0.0238 to 0.072 gallons/10 00 gallons of water. Rep eat as needed to maintain 1 to 3 ppm bromine resid ua l for at least 4 hours.	
	83451-11 (Gel)	Open Pour/Gel	Initial Dose: When system is noticeably f ouled add 0.0545 to 0.1 634 gallons/ 1000 gallons of water. Repeat initial dosage until 1 to 3 ppm b romine residual is estab lished for at least 4 hours. 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 Wa te r System	1448-356 5185-420 5785-63 6836-314 6836-317 69681-16 83451-4 (Tablet)	Plac e tablet in system	Add 0.1 to 0.6 lbs / 1, 000 gallons of water t reat d to e maintain 0.5 to 5.0 p m p bromine resid ual at t e h injection point in the disinfection c ontact chamber. Adjust t his product's dosage to achieve disinfectio n and minimize the halo ge n concentration at th e exit of the contact cham ber.	Do not use treated wastewater to irrigate crops.
	5785-65	Open	Add 0.1 to 0.6 l bs /1, 00 0	Do not use treated wastewater to irrigate

Auxiliary Water and Waste Water System (Continued)	(Granular)	Pour/Granules	gallons of wat er treated to maintain 0.5 t o 5.0 ppm bromine resid ual at the injection point in the disinfection co ntact chamber. Adjust thi s product's dosage to achieve disinfection and minimize the halogen concentration at the exit of the contact chamber.	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/Re ady to Use	Add 0.1 to 0.6 l bs /1,000 gallons of w ater t reated to maintain 0. 5 to 5. 0 ppm bromine r esidual at the injection point in the disinfecti on contact chamber. Ad just this product's dosage to achieve disinfe ction and minimi ze the halogen concentration at the exit of the contac t cha mber.	Do not use treated wastewater to irrigate crops.

	3377-62 3377-71 (Ready to Use)	Open Pour/Ready to Use	The quantity re quired varies with deg ree of fouling. Add su fficient amount to ac hieve residual bromine level s 0.5 -5ppm. Applying ½ ounce to 1,000 gallons of wat er 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
Au xiliary Water and Waste Wa ter System (Continued)	83451-10 (Soluble Concentrate)	Open Pour/Soluble Concentrate	Add 0.0238 to 0.14 3 gallons of water t reat d to e maintain 0.5 to 5.0 p m p bromine residual at the injection point in the contact chamber. Adjust this product's d osage to achieve sanitization and minimi ze the halogen concentration at the exit of the contact chamb er.	Do not use treated wastewater to irrigate crops.
	6836-316 (Wettable Powder)	Open Pour/Powder	Add 0.1 to 0.6 l bs /1, 00 0 gallons of water trea ted to maintain 0.5 to 5 .0 ppm bromine residua l at the injection of water treated to ma intain 0.5 to 5.0 ppm bromine residual at the injection point in the contact cham ber.	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 p pm bromine residual at the injection point in t he contact chamber. A djust this product's do sage to achieve sanitiz ation and minimize the halogen concentration at the exit of the contact chamber.	

Industrial air washer systems	6836-113 6836-115 6836-210 6836-314 6836-316 (Tablet)	Place tab let in system	Initial Dose: When system is noticeably fo uled add to airwasher sum p or chill water sump to insure uniform mixing. Add 0.1 to 1.0 lbs per 1, 000 gallons of water. 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 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 poun ds /1,000 gallons. Rep eat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subsequent Dose: When control is evident a dd 0.1 to 0.3 pounds /1 ,000 gallons. Repeat as needed to maintain 1 to 3 p p m bromine residual fo r at least 4 hours.	
	6836-237 6836-280 6836-324 (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 gal lons of water. Subsequent Dose : When microbial control is e vident 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 p ounds /1,000 gallons . Repeat in 1 to 3 ppm brom ine residual is established for at least 4 hours. Subseque nt Dose : When control is evid ent add 0.1 to 0.3 poun ds /1,000 gallons. Re peat as needed to m aintain 1 to 3 ppm bromine re sidua l for at least 4 hours.	
	6836-316 (Wettable	Open Pour/Powder	Initial Dose: When the system is noti ceably fouled	Badly fouled systems should be cleaned before treatment is done.

	Powder		ass 0.2 to 0.6 pounds /1,000 gallons. Repeat in 1 to 3 ppm bro mine residual is established for at least 4 hours. Subsequen t 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	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			least 4 hours	
	3377-62 3377-63 3377-71 (Ready to	Open Pour/Ready to Use	Initial Dose: Whe n system is noticeably fouled add sufficient amount to achieve a residual bromine	None listed.

	Use)		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 achie ved. Subsequent Dose: When microbial control i s evident app ly sufficient amount to achieve area residual bromine level 0.5 to 5ppm or as needed to maint ain control.	
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**

	6836-317 683 6-314 696 81-16 83451-4 (Tablet)		regulatin g valve at a low setting. If biological growth is obs erved increase the fl ow in small increments unt il growth is controlled. 1.0 to 3.0 ppm of residual bro mine should be introd uced into water supply line. Three to (3) to 9 grams of tabs will introduce 1.0 to 3.0 ppm residual bromin e in 1,000 gallons of wate r .	chemicals.
	6836-237 6836-315 6836-324 (Granular)	Open Pour/Granules	It is intended t hat 0.5 to 3.0 ppm of residua l bromine should be intr oduced into water supply line. Three to (3) to 12 grams of tabs will introduce 1.0 to 3.0 ppm residual b romin e in 1,000 gallons of water.	Do not use water from this line to mix chemicals.
	6836-316 (Wettable	Open Pour/Powder	Adjust pH between 7.2 to 7.6 when using other	Do not use water from this line to mix chemicals.

	Powder)		products as outlined in directions for other products. A bromine or	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			chlorine res idual of 1-2 ppm must first be established in th e water. When bromine r esidual reaches 1-2 ppm ad just feeder accordingly . To maintain brom ine residual adjust the feeder fee d 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 hea vily fouled system exist s and physical clean ing is not possible add 0.05 to 0.2 lbs per 1,000 gal lons of water for two weeks. T hen reduce maintenan ce levels. Maintenance Do se: Effective control under nor mal circumstances is ma intained 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/Humidi fier Drip Pans	1448-356 578 5-63 578 5-100 518 5-420 6968 1-16 83451-3 (Granular)	Open Pour/Gr anules	Place this pro du ct in the basin or drip p an close to the outlet dra in. Use one or more tablets a s necessary to maintain cle anliness of the system. Th e amount of tablets neede d will vary with temperature humidity, and condensate volume.	Do not place tablets directly onto metal surfaces.
Air Conditioner/Humidi fier Drip Pans (Continued)	75361-1 (Tablet)	Place tablet in system	Place tablet into condensate line dispenser or floatation d evice into reservoir. Mai ntain 1-4 ppm active br omine. Check once every mo nth or more often as require d. The life of the tablet will vary depending on atmospheric conditions a nd t emperature requirements.	Do not place tablets directly onto metal surfaces
	83451-4 8622-30 (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 cleanlin ess of the system. The am ount of tablets needed will v ary with temperature hum idity, and condensate vo lu me.	
	1448-420 8622-30 (Ready to Use)	Open Pour/ Ready to Use	Place this product in the basin or drip pan c lose to the outlet drain. U se one or more tablets as nec essary to maintain cleanlin ess of the system. The am ount of tablets needed will vary with temperature hu midity, and condensate vo lume.	None listed.
	83451-3	Open	Place this product in the	None listed.

	(Granular)	Pour/Granules	basin or drip pan cl ose to the outlet drain. Us e one or more tablets as nece ssary to maintain clean liness of the system. The amount of tablets needed will vary with temperature hu midity, and condensate volum e.	
	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 dra in. Use one or more tablets a s necessary to maintain cle anliness of the system. Th e amount of tablets needed will vary with temper atur e humidity, and condensa te volume.	
	8622-29	Open	Place this prod uct in the	None listed.

	(Granular)	Pour/Granules	basin or drip pan close to the outlet drai n. Use one or more tablets a s necessary to maintain cle anliness of the system. The amount of tablets needed will vary with temperature humidity, and condensate volume.	
Swimming Pools, Spas, Hot Tubs				
Swimming Pools	144 8-428 337 7-72 57787-24 63838-4 66397-1 66397-2 67262-23	Place tablet into system	Initial Applic ati n: o Adjust ph to 7.2-7.8. dj A ust 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 6836-118 6836-197 6836-211 6836-314 6836-317 69681-16 7124-102 7124-104 7 5361-1 (Tablet)		in t he pool per 1,000 gallons. <u>Continued Application :</u> Check feeder period i ally a c refill with additiona l product. Adjust fe eder flow water according to manufacturer's directions to maintain brom ine levels between 1-4 ppm in pool.	
Swimming Pools (Continued)	8622-41 8622-70 8622-73 (Tablet)	Place tablet into system	Newly Filled Pools: Establish an effectiv e active bromine resid ual of between 2-3 ppm. Residential: Add 1 7 tablets per 10,000 gallons every 5-7 days as need ed to maintain a brom ine residual of 2-3 ppm at all times. 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 pe r 10,000 gallons every 5-7 d ays or as needed to ma intain and achieve brom ine residual between 3-5 ppm at all times.	
	337 7-6 1 6836-211 (Soluble Concentrate)	Open Pour/Sol uble Concent rate	Initial Applic ation: Chemical ly balance calciu m hardness to 200 ppm an d total alkalinity to 100 to 150 ppm. Adjust p H to 7.2-7.8 Adjust the flow of water into feeder according to manufacturer's directions to maintain active bromine residual betw een 1-4 ppm.	Do not mix this product i n concentrated form w any other chem icals. Do not add other chem icals to the feeding device when using this product. A violent reaction leading to fire and explosion could result.

Swimming Pools (Continued)			Continued App lication: Check the feeder weekly and refill wit h additional product. Adjust the flow of water into feeder according to manufacturer's directions to maintain an active bromine level	

Use Site	Reg. no./ Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			between 1-4 ppm.	
	42177-74 6836-123 (Ready to Use)	Open Po ur/Ready t o Use	Balance calcium and alkalinity and then adjust pH to between 7.2 -7.6. Superoxidate to 10 20ppm bromine. Water i s safe when bromine is b elow 5 ppm. If bromine residual content is below 1-3 ppm, add 0.2-2.0 oz per 1 0 00 as needed to maintain	Do not mix with other chem icals. Always add product to large quantities of water.

	6836-316 (Wettable Powder)	Open Pour/Powder	Adjust pH betwee n 7.2-7.6. A bromine or chlori ne residual of 1 to 3 p pm must first be establishe d in the pool. To m aintain bromine residual adjust feed e r feed rate to assure a co nst nt a treatment level.	None listed
	6836-250 6836-251 5185-490 (Granular)	Open Pour/Granules	Add product to ma intain 13 ppm as brom ine. 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 Spas and Hot Tubs	1448-4 28 3377-7 2 5185-4 20 5185-4 21 63838-4 66397-1 66397-2 6836-116 6836-196 6826-211 6836-2 42 6836-2 43 (Tab let)	Place tab let in system	Adjust the feede r according to manufact urer's directions to m aintain a bromine level between 1-4 ppm in resi dential spas and 3-6 pp m in commercial spas. Che ck feeder regularly and add additional product as needed.	Do not hea t above manufacturer's recommended temperature.
(Continued)	6836-314 6836 -317 6968 1-16 7124 -102 7124 -103 712 4-104	Place tablet in system	Adjust the fee der according to manufacture r's directions t o maintain a bromin e level between 1-4 ppm in re sidential spas and 3-6 ppm in commercial	Do not heat above manufacturer's recommended temperature.

	7165 4-13 7536 1-1 75562-1 (Tablet)		spas. Check feeder regular ly and add additional p rodu t as c needed.	
	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
			3-6 ppm in c ommercial spas. Check feeder regularly and a dd additional product as needed.	
	57787-24 8622-41 8622-70	Place tablet in system	Introduce 3 tablet s per 300 gallons of spa water with the use of floating tablet	Keep pH between 7.2-7.6 and never allow it to fall below 7.0.

Spas and Hot Tubs (Continued)	(Tablet)		feeder or automat ic brominator. Adjust tablet feeder or brominat or to obtain an active bromine residual of at least 2 ppm. Maintain spa b y adding 3 tablets per 300 gall ons every 5-7 days or as needed to maintain a n active bromine r esid ual of 2ppm at all times.	
	5185-490 6836-251 (Granular)	Open Pour/Granules	Adjust the feeder ac cording to manufacturer' s directions to maintain a brom ine 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 6836-211 (Soluble Concentrate)	Open Po ur/ Soluble Concentrate	Adjust the f eeder according to manufacture ’s r directions to m intain a a bromine lev el between 1-4 ppm in residential spas and 3-6 ppm i n commercial spas. Check feeder regularly and ad d additional pr oduct as needed.	Do not mix this product i n concentrated form w any other chem icals. Do not add other chem icals 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 (Soluble Concentrate)	Open Pour/Soluble Concentrate	Use one disp enser per 350 gallons of spa or hot tub water. Unde r heavy bather loading or redu ced water circulation, additional dispensers may be used to maintain co nsta nt active brom ine residuals of 2 to 4 ppm in residential spas.	None listed.

	42177-75 67262-23 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 betwe en 1-4 ppm in residenti al spas and 3-6 ppm in c ommercial spas. Check fe eder regularly and a dd additional product as needed.	
	53735-10 (Ready to use)	Open Pour/Ready to Use	Use one dispenser per 350 gallons of spa or h ot tub water. Under heav y bather loading or reduce d water circulation, addition al dispensers may b e used to maintain constant ac tive bromine residuals o f 2 to 4 ppm in residential s pas.	None listed
	5185-480	Install Cartridge	Adjust pH to betwe en 7.2-	This product can only be used in conjunction

	(cartridge)	in Spa feeder	7.6. Place this product in spa feeder. To I nstall insert canister into openi ng lining up canister tabs w ith key ways. While pushing canister rotate counter clockwise, pull to remove from opening.	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 an d agitate to dissolve. One tablet in 11.25 gallo ns of spa water will provide an active bromine concentration of 40 ppm.	
Aquatic Areas				

Chemigation Chemigation (continued)	5785-69 (Tablet)	Open Pour/Tablet	Maintain r esidual between 5-15 ppm bro mine in the water. To ins ure even distribution o f tablets, it is important to level treated mats. If mi crobial growth develops add additional tablets until br omine residual reach es 10-35 ppm. Continue until fouling is elim i nated, then resume tre atment between 5-15ppm brom ine.	Do not mix with pesticide or fertilizer concentrates
	5785-70 (Granular)	Open Pour/Granules	Maintain residu al between 5-15 ppm bro mine 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 b romine residual reach es 10-35 ppm. Continue unti l fouling is elim inated, then resume treatment bet ween 5-15ppm bromin e.	
Ornamental Fountains	1448-356 1448-428 3377-71 3377-72 5185-42 0 63838-4 6836-115 83451-4 (Tablet)	Place tablet in system	Adjust pH to 7.2-7.6 . A bromine residual of 1-2 ppm must be establi shed in the water. To maint ain a bromine residual ad just the brom inator feed rate to assure a constant trea tment of 1-3ppm.	None listed.
	63838-4 6836-115 (Tablet)	Place tablet in system	Initial Dose: Add 0 .1 to 6lbs per 10,000 gallons of water. Repeat initi al dose until control i s achieved. Subsequent Dose: A dd 0.1 to 3lbs per 10,00 0 ga llons daily or as needed t o maintain control.	None listed.
	3377-72 (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 mi x 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
Orname ntal Fountains (Continued)			dispensing device adjust the device feed rate to assure a constant treatment between 0.5-5pp m residual bromine.	
	5785-70 (Granular)	Open Pour/Gr anules	Maintain res idu al between 5-15 ppm bro mine in the water. To insur e even distribution o f granules, it is important to level treated mats. If mi crobial growth develops a dd additional granules until bromine residual reach es 10-35 ppm. Co ntinue until fouling is elim inated, then resume treatme nt between 5-15ppm bro mine.	Do not mix with pesticide or fertilizer concentrates.

	5185-490 (Granular)	Open Pour/Granules	A bromine or chlorine residual of 1-2 ppm must be established. To maintain bromine residual, adjust brominator feed rate to assure a constant treatm ent 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
	(Soluble Concentrate)	Concentrate	bromine residual 0. 5-5 ppm or as neede d to contr ol the system. If using a dispensing device a djust the device feed rate to assure a constant tr eatment 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

Ornamental Fountains (Continued)	83451-10 (Soluble Concentrate)	Open Pour/Soluble Concentrate	A bromine or chl orine residual of 1-2pp m must be established. To mai ntain bromine re sidual, adjust brominator feed rate to assure a constant tre a tment level of 1-3 ppm.	None listed.
	1448-420 (Ready to Use)	Open Pour/Ready to Use	A bromine or chl orine residual of 1-2ppm must be established. To m aintain bromine residual, adjust brominator feed ra te to assure a constant treatm ent 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 resid ua l 0.5-5ppm or as n eeded to control the system. If us ing a dispensing dev ice adjust the device feed rate to assure a constant treatm ent between 0.5-5ppm residual bromine.	chemicals to the feeding de vice 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 dihalodialkylhydanto ins. These requirements apply to dihalodialkylhydantoins in all products, inc luding 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 EP A 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 use d 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 830.1620 830.1650	61-2 A	Starting Materia ls and Manufacturing Process	1,3,4,7,8,11,12	MRID# 35011701
830.1670	61-2 B	Formation of Impur ities	1,3,4,7,8,11,12	MRID# 35011701
830.1700	62-1	Preliminary Analysis	1,3,4,7,8,11,12	MRID# 41952701 MRID# 41952801 MRID# 42478501
830.1750	62-2	Certification of Limits	1,3,4,7,8,11,12	MRID# 43315902
830.1800	62-3	Analyt ical Method	1,3,4,7,8,11,12	MRID# 41952701 MRID# 41952801
830.6302	63-2	Color	1,3,4,7,8,11,12	MRID# 35011701
830.6303	63-3	Physic al 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	6 3-5	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 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 830.7560 830. 7570	63-11	Par tition Coefficient (Octanol/W ater)	1,3,4,7,8,11,12	Dat a Gap
830.7000	63-12	pH	1,3 ,7,8,11,12 ,4	MR ID# 35011701
830.6313	63-13	Stability	1,3,4,7,8,11,12	MRID# 35011701

830.6314	63-14	Oxidizing/Reducing Ac tion	1,3,4,7,8,11,12	MRID# 35011701
830. 6 316	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 Acc# 253972 Ac c# 253071 Acc# 253073 Acc# 252719 Acc # 137088 Acc# 147319 MRID# 43289905
850.2200	71-2 A	Avian Acute Dietary - Quail	1,3,4,7,8,11,12	Acc# 147321 Acc# 253071 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 Acc# 253071 Acc# 253073 Acc# 253966 Acc# 253972 MRID# 43289903
850.1075	72-1 A	Fish Acute Toxicity - Bluegill	1,3,4,7,8,11,12	Acc# 145356 Acc# 147322 Acc# 252719 Acc# 253071 Acc# 253072 Acc# 253074 MRID# 42368501 MRID# 42373601 MRID# 42374702 MRID# 43179706
850.1075	72-1 B	Fish Acute Toxicity - Minnow	1,3,4,7,8,11,12	MRID# 46053 MRID# 42374702
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout	1,3,4,7,8,11,12	Acc# 145358 Acc# 147322 Acc# 147323 Acc# 252719 Acc# 253071 Acc# 253072 Acc# 253074 MRID# 46053 MRID# 42373601 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 Acc# 253071 Acc# 253072 Acc# 253074 Acc# 147324 Acc # 145357 MR ID# 46053 MRI D# 42373603 MR ID# 43179707
850.1025	72-3 A	Estu/Mari tox. Fish	1,3 ,7,8,11,12 ,4	MR ID# 40993103 MRI D# 42076102 MR ID# 42374701 MR ID# 43687301
850.1035?	72-3 B	Estu/Mari tox. Moll usk	1,3 ,7,8,11,12 ,4	MR ID# 40993101 MR ID# 42076101 MR ID# 43289902 MR ID# 43687302
850.1045?	72-3 C	Estu/Mari tox. Shrimp	1,3,4,7,8,11,12	MRID# 40993101 MRID# 42076103 MRID# 43687303 MRID# 42373602
850.1300	72-4 A	Early Life Stage Fish	1,3,4,7,8,11,12	MRID# 42721702
850.1 400	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 – Ra t, Mouse	1,3,4,7,8,11,12	MRID# 45738401 MRID# 93074006 MRID# 93076011 MRID# 93077008
870.1200	81-2	Acute Dermal - Rabbit	1,3,4,7,8,11,12	MRID# 93076013 MRID# 93076025
870.1300	81-3	Acute Inhalation – Rat	1,3,4,7,8,11,12	MRID# 43654101
870.240 0	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 MRID# 93074011 MRID# 93075014 MRID# 93077009

870.2600	81-6	Dermal Sensitization	1,3,4,7,8,11,12	MRID# 41670001
870.305 0		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# 42 009201
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 – R at	1,3 ,7,8,11,12 ,4	Study require d to assess risks from formalde hyde exposure, will be assesse d in the RED ass e ssment for formaldehyde.
870.4100	83-1 A	Chronic Toxicity-Rodent	1,3,4,7,8,11,12	MRID# 43397702 MRID# 44095901
870.4100	83-1 B	Chronic Toxicity-Non-rodent/dog	1,3,4,7,8,11,12	MRID# 43553101 MRID# 43813301

870.4200	83-2 A	Oncogenicity-Rat	1,3,4,7,8,11,12	MR ID# 43397702 MRID# 44095901
870.4200	83-2 B	Oncogenicity-Mouse	1,3,4,7,8,11,12	MRI D# 43397701 MR ID# 44063901
870.3700	83-3 A	Prenatal Developmental Toxicity -Rat	1,3 ,4,7,8,11,12	MR ID# 42432701
870.3700	83-3 B	Prenatal Developmental Toxicity – Ra bbit	1,3, 4,7,8,11,12	MRID# 42413101 MRI D# 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/car cinogenicity	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 Acc# 164036 MRI D# 265457 TRID# 433401118
870.5300	84-2 B	Gene Mutation In vitro Mammalian Cell Assay	1,3,4,7,8,11,12	Acc# 132165 Acc# 137089 TRID# 433401121 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 Acc# 137101 Acc# 164037 Acc# 265457 MRID# 40348201 TRID# 433401119 TRID# 433401125 TRID# 470264004
870.5550	84-4	Unscheduled DNA Synthesis in Ma mma lian Cells in Culture	1,3,4,7,8,11,12	Acc# 132166 Acc# 137097 Acc# 164038 Acc# 265457 TRID# 433401120 TRID# 433401126 TRID# 470264005
870.7485	85-1	General Metabolism	1,3,4,7,8,11,12	MRID# 42123802 MRID# 42173901
ENVIRONMENTAL FATE				
835.2120	161 -1	Hydrolysis of Parent a nd Degradates	1,3,4,7,8,11,12	MRID# 43281801 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 875.1600	233 236	Dermal Indoor Exposure	1,3,4,7,8,11,12	Data Gap
875.1400 875.1600	234 236	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 th e 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 assessme nts (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 Availabil ity, 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 E ligibility Decision, PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobi als Division, 12/15/03.
- Product Chemistry Science Chapter on halohydantoins. PC Codes 006135, 006137, 028501, 128826, Case 3055, Antimicrobials Division, 9/21/00, Chris Jia ng.
- 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 As sessment, 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, Ch ronic, 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, J ames 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 Qual ity Control Board, SF Bay Region. 9/28/04, Bill Johnson, Pesticicde TMDL Coordinator.
- Comments from the ACC Brominat ed 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 Conside red to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

1. MRID Studies

MRID # Citation

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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 Synthesis in Primary Cultures of Rat Hepatocytes (by Autoradiograph y): 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)

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Wildlife International Ltd., submitted by Glyco, Inc., Greenwich, CT; CDL:252094-C)

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164037 Putman, D. (1986) Chromosome Aberration Assay in Chinese Ham ster Ovary (CHO) Cells: [Using 5,5-Dimethylhydantoin]: Study N o. T4638.337. Unpublished study prepared by Microbiological Associates, Inc. 18 p.

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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 pr ocess 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 ge nerate, 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 regi strants, 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 ba tch as the test material. If a registrant chooses to rely upon previously submitted acute toxic ity 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 RE D) 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 formu la (CSF) exists for a product, the registrant must indicate the formulation actually tested by id entifying the corresponding CSF.

In deciding how to meet the product specific data requirements, r egistrants must follow the directions given in the Data Call-In Notice and its attachments appended t o 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 Sha re (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 choos ing 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 ratio nale 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 rea lize 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 da ta (if it meets current Agency standards) from any other product in the same batch, exc ept 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
	1448-3 56	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	1448-4 20	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	144 8-428	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	3876-1 50	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	5185-420	1-Bromo-3-chloro-5,5-dimethylhydantoin 96%
	5185-4 46	1-Bromo-3-chloro-5,5-dimethyl hydantoin 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
	5185-4 80	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	5185-4 89	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	518 5-490	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	5785-5 7	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	5785-63	1-Bromo-3-chloro-5,5-dimethylhydantoin 96%
	5785-6 5	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	5785-6 9	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%
	578 5-70	1-Bromo-3-chloro-5,5-dimethylhyd antoin 96%
	5785-1 05	1-Bromo-3-chloro-5,5-dimethylhy dantoin 96%
	6836-314	1-Bromo-3-chloro-5,5-dimethylhydantoin 97.41%
	6836-3 15	1-Bromo-3-chloro-5,5-dimethylhy dantoin 97.7%
	6836-3 16	1-Bromo-3-chloro-5,5-dimethyl hydantoin 97.7%
	683 6-317	1-Bromo-3-chloro-5,5-dimethyl hydantoin 97.7%
	6836-3 18	1-Bromo-3-chloro-5,5-dimethyl hydantoin 97.7%
	8622-25	1-Bromo-3-chloro-5,5-dimethylhydantoin 98%
	8622-2 8	1-Bromo-3-chloro-5,5-dimethyl hydantoin 96%

	8622-2 9	1-Bromo-3-chloro-5,5-dimethyl hydantoin 98%
	8622-3 0	1-Bromo-3-chloro-5,5-dimethyl hydantoin 98%
	8622-4 1	1-Bromo-3-chloro-5,5-dimethyl hydantoin 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
	3377-6 1	1,3-Dibromo-5,5-dimethylhyd antoin 99.4%
	3377-6 2	1,3-Dibromo-5,5-dimethylhyd antoin 99.4%
	33 77-63	1,3-Dibromo-5,5-dimethylhy dantoin 99.4%
	3377-7 1	1,3-Dibromo-5,5-dimethylhy dantoin 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%
	683 6-319	1,3-Dichloro-5,5-dimethylhydanto in 97%

Batch 4	EPA Reg. No.	% Active Ingredient
	5185-421	1-Bromo-3-chloro-5,5-dimethylhy dantoin 92.5%
	5185-433	1-Bromo-3-chloro-5,5-dimethylhy dantoin 93.5%
	5185-469	1-Bromo-3-chloro-5,5-dimethylhy dantoin 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-dimethylhy dantoin 93.5%
	5785-108	1-Bromo-3-chloro-5,5-dimethylhy dantoin 92.5%
	7124-102	1-Bromo-3-chloro-5,5-dimethylhy dantoin 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-dimethyl hydantoin 40%
	5185-487	1-Bromo-3-chloro-5,5-dimethylhydantoin 35%

Batch 6	EPA Reg. No.	% Active Ingredient

	6836-1 10	1-Bromo-3-chloro-5,5-dimethylhy dantoin 90% 1,3-Dibromo-5,5-dimethylhy dantoin 9%
	6836-124	1-Bromo-3-chloro-5,5-dim ethyl hydantoin 88.7% 1,3-Dibromo-5,5-dimethylhydantoin 8.8%
	6836-211	1-Bromo-3-chloro-5,5-dim ethylhydantoin 90% 1,3-Dibromo-5,5-dimethylhydantoin 9%
	6836 12-3	1-Bro mo-3-chloro-5,5-d imethylhydantoin 90% 1,3-Dibromo-5,5-dimethylhydantoin 9%

Batch 7	EPA Reg. No.	% Active Ingredient
	683 6-120	1-Bromo-3-chloro-5,5-dimethylhy dantoin 81.9% 1,3-Dibromo-5,5-dimethylhy dantoin 8.1%
	6836-121	1-Bromo-3-chloro-5,5-dimethylhydantoin 84.1% 1,3-Dibromo-5,5-dimethylhydantoin 8.4%
	6836-1 22	1-Bromo-3-chloro-5,5-dime thylhydantoin 85.1% 1,3-Dibromo-5,5-dimethylhydanto in 8.4%
	6836-123	1-Bromo-3-chloro-5,5-dime thylhydantoin 86.4% 1,3-Dibromo-5,5-dimethylhydantoin 8.6%
	66397-1	1-Bromo-3-chloro-5,5-dimethylhydantoin 86.4% 1,3-Dibromo-5,5-dimethylhydantoin 8.6%
	66397-2	1-Bromo-3-chloro-5,5-dimethylhydantoin 86.4% 1,3-Dibromo-5,5-dimethylhydantoin 8.6%

Batch 8	EPA Reg. No.	
	6836-113	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-114	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-256	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-2 63	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-280	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-287	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-288	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-291	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-296	1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-297	1,3-Dichloro-5, 1,3-Dichloro-5-

Batch 9	EPA Reg. No.	
	683 6-115	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-

Batch 9	EPA Reg. No.	% Active Ingredient
		1,3-Dichloro-5-ethyl-5-methylhydantoin 10.6%
	6836-196	1-Bromo-3-chloro-5,5-dimethylh ydantoin 60% 1,3-Dichloro-5,5-dimethylhydantoin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	6836-197	1-Bromo-3-chloro-5,5-dimethylh ydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methy lhydantoin 10.6%
	6836-210	1-Bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	683 6-237	1-Bromo-3-chloro-5,5-dimethyl hydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	6836-2 42	1-Bromo-3-chloro-5,5-dimethyl hydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	6836-243	1-Bromo-3-chloro-5,5-dimethylh ydantoin 60% 1,3-Dichloro-5,5-dimethylhydantoin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	6836-250	1-Bromo-3-chloro-5,5-dimethylh ydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methy lhydantoin 10.6%
	6836-251	1-Bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-Dichloro-5,5-dimethylhydan toin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%
	683 6-255	1-Bromo-3-chloro-5,5-dimethyl hydantoin 60% 1,3-Dichloro-5,5-dimethylhyd antoin 27.4% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 10.6%

6836-116	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
6836-117	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
6836-118	1-Bromo-3-chlo 1,3-Dichloro-5,

	6836-2 72	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-273	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-274	1-Bromo-3-chlo 1,3-Dichloro-5,
Batch 9	EPA Reg. No.	
		1,3-Dichloro-5-
	6836-275	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-281	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-282	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	683 6-299	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-
	6836-300	1-Bromo-3-chlo 1,3-D ichloro-5 1,3-Dichloro-5-

Batch 10	EPA Reg. No.	
	6836-264	1-Bromo-3-chlo 1,3-Dichloro-5, 1,3-Dichloro-5-

	6836-265	1-Bromo-3-chloro-5,5-dimethylhydantoin 57% 1,3-Dichloro-5,5-dimethylhydantoin 26% 1,3-Dichloro-5-ethyl-5-methylhydantoin 10.1%

No Batch	EPA Reg. No.	% Active Ingredient
Each "N o Batch" p rod ct u must cite its own data.	5785-6 2	1-Bromo-3-chloro-5,5-dimethyl hydantoin 25.2%
	5813-65	1-Bromo-3-chloro-5,5-dimeth ylhydantoin 51% 1,3-Dichloro-5,5-dimethylhydan toin 23.3% 1,3-Dichloro-5-ethyl-5-methylhydantoin 9%
	5813-66	1-Bromo-3-chloro-5,5-dimethylhydantoin 45% 1,3-Dichloro-5,5-dimethylhydan toin 20.6% 1,3-Dichloro-5-ethyl-5-methylhy dantoin 8%
	6836-279	1,3-Dichloro-5,5-dimethylhydantoin 52.7% 1,3-Dichloro-5-ethyl-5-methylhydantoin 10.5%

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

BUCKMAN LAB ORATORIES, 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, 4TH FLOOR
COVINGTON LA 70433

KING TECHNOLOGY INC.

530 11TH 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

PILOT CHEMICAL COMPANY

We're going further

www.pilotchemical.com
2744 East Kemper Road • Cincinnati, OH 45241

CALFAX® DB-45

PRODUCT DATA SHEET

PRODUCT Calfax® **DESCRIPTION** oxide broad range of acids, sodium metasilicate.

DB-45 is a clear light amber aqueous solution of sodium dodecyl branched dipheny disulfonate. Calfax® DB-45 contains no halogenated solvents and is compatible with a alkalis, chlorine and peroxide bleaches and builders such as sodium carbonate and

INCI NAME Sodium

Dodecyl Diphenyl Oxide Disulfonate

CAS # 119345-04-9

TYPICAL Appearance @	25°C	Clear light amber liquid
PROPERTIES Odor		Mild
	Active (Wt. %)	45.0
Color (5% solution, #42 filter,	Klett) 30	
	Density (lbs/Gal) 9.6 pH (10% solution) 9.0	
Iron (ppm)		5.0 max
	Solubility In Water at 20ºC	Infinite
Surface Tension	(dynes/cm@1% actives, 25ºC	34 at pH=7.0; 35 at pH=12.5
Critical Micelle Conc.	(0.1M NaCl @25ºC, g/100g)	0.007
Foam	Height (Ross Miles, mm@1% actives, 25ºC, initial/5min)	140/130 at pH=7.0; 145/145 at pH=12.5

APPLICATIONS

Latex Emulsification

The high surface activity and the high electrolyte tolerance of Calfax® DB-45 make it the surfactant of choice for the manufacture of latex emulsions for adhesives and foam rubber. These properties allow the user to operate the emulsification process under conditions that would not be usable with conventional surface active agents, permitting greater control over latex's molecular weight and particle size. Calfax® DB-45 also aids in improving a latex emulsion's thermal and mechanical stability.

Agricultural Chemicals

High emulsification and excellent water solubility of Calfax® DB-45 can aid the formulator of agricultural emulsions by providing a broader blend of anionic to nonionic in hard to emulsify pesticides and herbicides.

Heavy Duty Cleaners

Calfax® DB-45 is uniquely effective as a solubilizer and detergent in acid, alkaline and bleach cleaner formulations where conventional detergents lack sufficient solubility and/or stability in the formula for necessary performance.

ADVANTAGES

Calfax® DB-45 is an excellent emulsifier and detergent compatible with a broad range of high electrolyte solutions such as brine, bleach, caustic and inorganic acids. The branched side chain of Calfax® DB-45 offers improved emulsification. Calfax® DB-45 is halogenated solvent free, CFR 21 and 40 approved.

HANDLING & Employ normal safety precautions (i.e. gloves and safety goggles) when handling.
STORAGE Prevent contact with skin and avoid contact with eyes. Wash thoroughly after handling material. Keep containers closed when not in use. Do not store Calfax® DB-45 at extremely low temperatures; store material at temperatures between 45°F to 100°F. Please refer to the Calfax® DB-45 MSDS before handling.

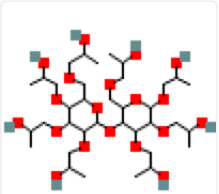
PACKAGING Calfax® DB-45 is available in 55-gallon polyethylene drums (net weight 500 lb/227kg); bulk quantities are available by tank car or tank truck.

See starting formulas and additional product information, at www.pilotchemical.com

PubChem

COMPOUND SUMMARY

Cellulose hydroxyethylate

PubChem CID:	4327536
Structure:	 2D Find Similar Structures
Molecular Formula:	$C_{36}H_{70}O_{19}$
Synonyms:	Cellulose hydroxyethylate Cellulose hydroxyethyl ether 2-Hydroxyethyl cellulose ether DB11602 ZINC000256097213 More...
Molecular Weight:	806.9 g/mol
Dates:	Modify: 2020-03-15 Create: 2005-09-14

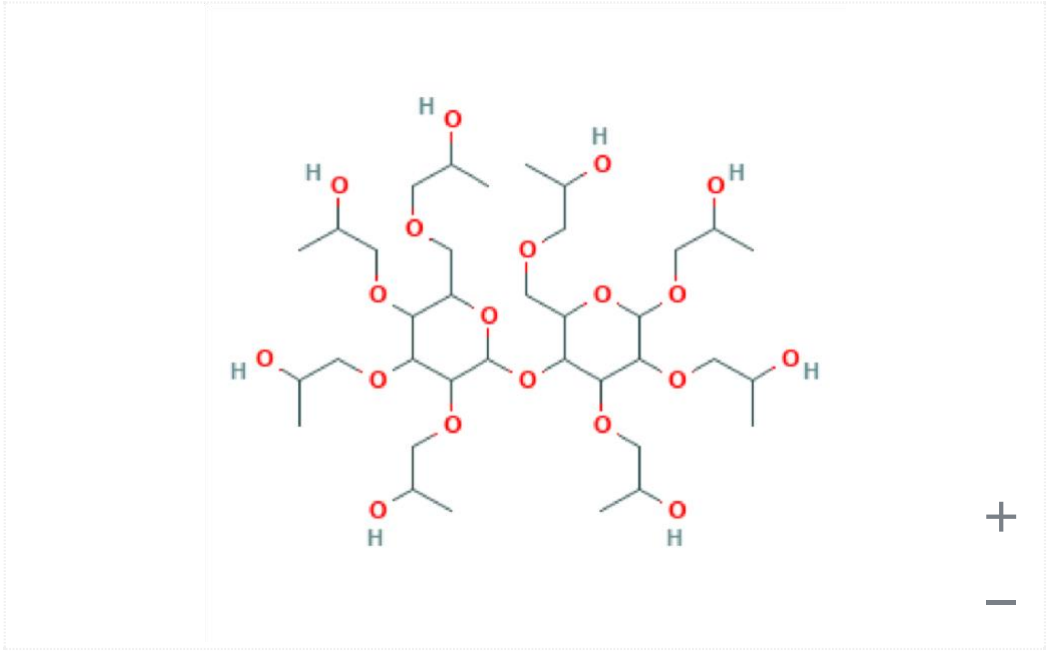
Hydroxyethyl cellulose is a polysaccharide derivative with gel thickening, emulsifying, bubble-forming, water-retaining and stabilizing properties. It is used as a key ingredient in many household cleaning products, lubricants and cosmetics due to its non-ionic and water-soluble nature. It is often used as an ingredient in ophthalmic pharmaceutical preparations such as artificial tear solutions and adjunct agent in topical drug formulations to facilitate the delivery of drugs with hydrophobic character.

▶ DrugBank

Structures

2D Structure

Chemical Structure Depiction



PubChem

1.2 3D Status

Conformer generation is disallowed since too many atoms, too flexible, too many undefined stereo centers

PubChem

2 Names and Identifiers

2.1 Computed Descriptors

2.1.1 IUPAC Name

1-[[3,4,5-tris(2-hydroxypropoxy)-6-[4,5,6-tris(2-hydroxypropoxy)-2-(2-hydroxypropoxymethyl)oxan-3-yl]oxyoxan2-yl]methoxy]propan-2-ol

Computed by LexiChem 2.6.6 (PubChem release 2019.06.18)

PubChem

2.1.2 InChI

InChI=1S/C36H70O19/c1-19(37)9-45-17-27-29(47-11-21(3)39)31(48-12-22(4)40)34(51-15-25(7)43)36(54-27)55-30-28(18-46-10-20(2)38)53-35(52-16-26(8)44)33(50-14-24(6)42)32(30)49-13-23(5)41/h19-44H,9-18H2,1-8H3 *Computed by InChI 1.0.5 (PubChem release 2019.06.18)*

PubChem

2.1.3 InChI Key

DFJVHKAPIXJTSC-UHFFFAOYSA-N

Computed by InChI 1.0.5 (PubChem release 2019.06.18)

PubChem

2.1.4 Canonical SMILES

CC(COCC1C(C(C(C(O1)OC2C(OC(C(C2OCC(C)O)OCC(C)O)OCC(C)O)COCC(C)O)OCC(C)O)OCC(C)O)OCC(C)O)O

Computed by OEChem 2.1.5 (PubChem release 2019.06.18)

PubChem

2.2 Molecular Formula

$C_{36}H_{70}O_{19}$

Computed by PubChem 2.1 (PubChem release 2019.06.18)

PubChem

2.3 Other Identifiers

2.3.1 CAS

9004-62-0

DrugBank

2.4 Synonyms

2.4.1 Depositor-Supplied Synonyms

Cellulose hydroxyethylate

Cellulose hydroxyethyl ether
2-Hydroxyethyl cellulose ether
DB11602
ZINC000256097213
1-{[3,4,5-tris(2-hydroxypropoxy)-6-{[4,5,6-tris(2-hydroxypropoxy)-2-[(2-hydroxypropoxy)methyl]oxan-3-yl]oxy}oxan-2yl]methoxy}propan-2-ol

PubChem

3 Chemical and Physical Properties 3.1 Computed Properties

Property Name	Property Value	Reference
Molecular Weight	806.9 g/mol	Computed by PubChem 2.1 (PubChem release 2019.06.18)
XLogP3-AA	-3	Computed by XLogP3 3.0 (PubChem release 2019.06.18)
Hydrogen Bond Donor Count	8	Computed by Cactvs 3.4.6.11 (PubChem release 2019.06.18)
Hydrogen Bond Acceptor Count	19	Computed by Cactvs 3.4.6.11 (PubChem release 2019.06.18)
Rotatable Bond Count	28	Computed by Cactvs 3.4.6.11 (PubChem release 2019.06.18)
Exact Mass	806.45113 g/mol	Computed by PubChem 2.1 (PubChem release 2019.06.18)
Monoisotopic Mass	806.45113 g/mol	Computed by PubChem 2.1 (PubChem release 2019.06.18)
Topological Polar Surface Area	263 Å²	Computed by Cactvs 3.4.6.11 (PubChem release 2019.06.18)
Heavy Atom Count	55	Computed by PubChem
Formal Charge	0	Computed by PubChem
Complexity	986	Computed by Cactvs 3.4.6.11 (PubChem release 2019.06.18)
Isotope Atom Count	0	Computed by PubChem
Defined Atom Stereocenter Count	0	Computed by PubChem
Undefined Atom Stereocenter Count	18	Computed by PubChem
Defined Bond Stereocenter Count	0	Computed by PubChem
Undefined Bond Stereocenter Count	0	Computed by PubChem
Covalently-Bonded Unit Count	1	Computed by PubChem
Compound Is Canonicalized	Yes	Computed by PubChem (release 2019.01.04)

PubChem

3.2 Experimental Propertie s

3.2.1 Melting Point

Decomposes at 205ºC as Cellosize

Cellosize product information

DrugBank

3.2.2 Solubility

Soluble

MSDS

DrugBank

4 Related Records

4.1 Related Compounds with Annotation

PubChem

4.2 Related Compounds

Same Connectivity	13 Records
Same Parent, Connectivity	13 Records
Similar Compounds	1,667 Records

PubChem

4.3 Substances

4.3.1 Related Substances

Same	6 Records

PubChem

4.3.2 Substances by Category

PubChem

4.4 Entrez Crosslinks

PubMed	6 Records

PubChem

5 Drug and Medication Information

5.1 Drug Indication

For alleviating surface irritation in topical ocular administrations, such as artificial tear solutions. Hydroxyethyl cellulose is also found in topical formulations to aid in more efficient drug diffusion across the membranes. DrugBank

6 Pharmacology and Biochemistry

6.1 Pharmacology

Hydroxyethyl cellulose acts as a demulcent by relieving inflammation or irritation and dryness of eyes. It acts as one of the key ingredient and viscosity-enhancing agent to prolong corneal contact time and increase intraocular drug levels [A19151].

DrugBank

6.2 Mechanism of Action

Interacts with the solid surface through hydrogen bonding to thicken and prolong the formation time of a waterretaining film. Hydroxyethyl cellulose acts as a drug carrier or microsphere to entrap other drug molecules and form a viscous gel-like dispersion, enabling drug diffusion across biological membranes [A19150]. DrugBank

7 Toxicity

7.1 Toxicological Information

7.1.1 Toxicity Summary

May cause chemical pneumonitis in case of inhalation and skin irritation. Animal data suggests potential alteration in female fertility.

DrugBank

8 Literature

8.1 Depositor Provided PubMed Citations

PubChem

8.2 General Reference s

1. Mianehrow H, Moghadam MH, Sharif F, Mazinani S: Graphene-oxide stabilization in electrolyte solutions using hydroxyethyl cellulose for drug delivery application. Int J Pharm. 2015 Apr 30;484(1-2):276-82. doi: 10.1016/j.ijpharm.2015.02.069. Epub 2015 Feb 28. [PMID:25735667]
2. Wang J, Somasundaran P: Mechanisms of ethyl(hydroxyethyl) cellulose-solid interaction: influence of hydrophobic modification. J Colloid Interface Sci. 2006 Jan 15;293(2):322-32. Epub 2005 Aug 2. [PMID:16081080]
3. Giandalia G, De Caro V, Cordone L, Giannola LI: Trehalose-hydroxyethylcellulose microspheres containing vancomycin for topical drug delivery. Eur J Pharm Biopharm. 2001 Jul;52(1):83-9. [PMID:11438427]
4. Durand-Cavagna G, Delort P, Duprat P, Bailly Y, Plazonnet B, Gordon LR: Corneal toxicity studies in rabbits and dogs with hydroxyethyl cellulose and benzalkonium chloride. Fundam Appl Toxicol. 1989 Oct;13(3):500-8. [PMID:2612782]
5. Baranowski P, Karolewicz B, Gajda M, Pluta J: Ophthalmic drug dosage forms: characterisation and research methods. ScientificWorldJournal. 2014 Mar 18;2014:861904. doi: 10.1155/2014/861904. eCollection 2014. [PMID:24772038]
6. Mortazavi SA, Jaffariazar Z, Damercheli E: Formulation and In-Vitro Evaluation of Ocular CiprofloxacinContaining Minitablets Prepared with Different Combinations of Carbopol 974P and Various Cellulose

Derivatives. Iran J Pharm Res. 2010 Spring;9(2):107-14. [PMID:24363715]

7. Cellosize product information

DrugBank

9 Information Sources

FILTER BY SOURCE ALL SOURCES

1. DrugBank

Hydroxyethyl cellulose *http://www.drugbank.ca/drugs/DB11602*

2. PubChem

https://pubchem.ncbi.nlm.nih.gov

microSURE
ALL PURPOSE DISINFECTANT

microSURE Disinfectant is the new, quick and effective way to clean, disinfect and deodorize without bleach. microSURE Disinfectant not only wages war with dirt, grime and grease, but also eradicates and defends against viruses that can cause illness.

microSURE Disinfectant is a one-step germicidal disinfectant cleaner and odor neutralizer designed for general cleaning, and disinfecting of hard, non-porous surfaces. Quickly removes dirt, grime, food residue, and other organic matter commonly found in hospitals or health care facilities. It eliminates odors leaving surfaces smelling clean and fresh. Excellent for use where odors are a problem.

- Kills Cold & Flu Viruses
- Kills Hepatitis B (HPV) and C(HCV) In 60 seconds
- Kills HIV-1 (Aids Virus) and HPV In 30 Seconds
- Kills Staph MRSA and VPE In 2 Minutes
- Antibacterial Kills Norovirus, Canine Parvovirus and Rhinovirus In 2 Minutes
- Effective Disinfectant Against MDR, ESBL and NDM-1
- Leaves Hard, Non-Porous Surfaces Disinfected

ACTIVE INGREDIENTS

ALKYL (60% C14, 30% C16, 5% C12, 5% C dimethyl benzyl ammonium chlorides	0.15%
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	0.15%
INERT INGREDIENTS	99.70%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Net Contents: 1 Gallon

EPA REG# 1839-220-
EPA EST.#

MADE IN USA

General

BLEACH-FREE ALCOHOL-FREE
*VIRUCIDAL/BACTERICIDAL//PSEUDOMONICIDAL

Use on hard, non-porous surfaces: stainless steel, Formica, glass, glass tables, glazed porcelain, plastic, glazed stone, glazed granite, sealed stone, sealed granite.
Saves time. Cost Effective and Time Efficient when used with a refillable spray bottle or mechanical spray device. Ready to use (R-T-U) spray.

DIRECTIONS FOR USE

It is a violation fo Federal Law to use this product in a manner inconsistent with its labeling. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.
or
This product is not fur use on critical and semi-critical media device surfaces.

GENERAL CLEANING: Spray soiled are then wipe with a dry paper towel or lint-free cloth.

DISINFECTING, DEODORIZING: Remove gross filth or heavy soil prior to application of (the product). Apply product with a hand pump trigger sprayer, low pressure coarse sprayer. Hold sprayer six to eight inches from the surface to be treated. Spray area until it is covered with the product. Allow surface to remain visibly wet for 2 minutes. No scrubbing necessery. Allow treated surfaces to air dry or wipe off with a clean cloth, mop or sponge.
When using on food contact surfaces: counter tops, stovetops, highchairs, kitchen appliances, thoroughly rinse all treated surfaces with potable tap water. This product must not be used to clean eating utensils, glassware and dishes.
This product is an effective disinfectant against: Pseudomonas aeruginosa (ATCC 15442), Salmonella enterica (Salmonella) (ATCC 10708), Staphylococcus aureus (ATCC 6538), Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33591), Vancomycin Resistant Enterococcus faecium (ATCC 51559), Extended Spectrum Beta-Lactamase (ESBL) Escherichia coli and Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Risistant.

***VIRUCIDAL ACTIVITY:** This product is an effective virucide on hard non-porous surfaces against Human Immunodeficiency Virus Type-1 (HIV-1) and Avian Influenza Virus (H5N1) NIBRG-14, when the treated surface is allowed to remain wet for 30 seconds. (This product) is an effective virucide on hard, non-porous surfaces against Human Rotavirus (ATCC VR-2018), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Duck Hepatitis B Virus (DHBV) and Bovine Viral Diarrhea Virus (BVDV) when the treated surface is allowed to remain wet for 1 minute (60 seconds).
This product is an effective virucide on hard, non-porous surfaces against Feline Calicivirus, Norovirus (Norwalk Virus), Canine Parvovirus, Rhinovirus Type 14 (ATCC VR-284) and Rhinovirus Type 39 (ATCC VR-340), when the treated surface is allowed to remain wet for 2 minutes. This product is effective against Poliovirus Type 1 (ATCC VR-1562) when the treated surface is allowed to remain wet for 5 minutes. Allow treated surfaces to air dry or wipe off with a clean cloth, mop or sponge.
KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings Hospitals, Nursing Homes or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1, Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.
PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product).

CONTACT TIME: Allow surfaces to remain wet for 2 minutes. (HIV-1 is inactivated in 30 seconds. HBV and HCV are inactivated in 1 minute).

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in a dry place inaccessible to children.
container handling: Do not reuse empty spray bottle except with refill (container) (bottle), otherwise wrap spray bottle and discard in trash. Offer for recycling if available.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, r insate is a violation of Federal Law. If these wastes cannot be disposed of by us according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Barcode Insert

Distributed by: Strategia
1000 Jorie Blvd. Suite 370 Oakbrook, IL 60523
Microsure.com 254-717-1440 Made in the USA

microSURE™

first aid antiseptic

HAND SANITIZER

GENTLE FORMULA

- ALCOHOL FREE
- GUARDS AGAINST INFECTION
- EXTENDED PROTECTION
- SOOTHING FOAM FORMULA

Kills 99.99% of Germs

2 oz (59.14 mL)

microSURE™

DRUG FACTS

ACTIVE INGREDIENT	PURPOSE
Benzalkonium Chloride 0.13%.....	First Aid Antiseptic

USES: Sanitizes hands lo help reduce bacteria that potentially cause diseases

WARNINGS: For external use only. Do not use in the eyes or apply over large areas of the body.

Do not use i_n eyes. In case of contact, rinse eyes thoroughly with waler

Stop use and ask a doctor: If irritation or redness develops, or **if** condition persists for more than 72 hours.

Keep out of reach of children: If swallowed, get medical hel p or contact a Poison Control Center.

DIRECTIONS: Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until hands are entirely dry_

Inactive Ingredients: Water Hydrated Silica Complex

Distributed by Strategia 1000 Lorie Blvd. Suite 370

4

microSURE™

first aid antiseptic

WOUND CARE

GENTLE **FOAM** FORMULA

- PROMOTE HEALING
- GUARD AGAINST INFECTION
- EXTENDED PROTECTION
- SOOTHING FOAM FORMULA

Kills 99.99% of Germs

50 mL (1.7 oz)

microSURE™

DRUG FACTS

ACTIVE INGREDIENT	PURPOSE
Benzalkonium Chloride 0.13%.....	First Aid Antiseptic

USES: For first aid to help protect against infection in minor cuts, scrapes and burns. Recommended for repeated use.

WARNINGS: For external use only. Do not use in the eyes or apply over large areas of the body. Consult a doctor in case of: deep puncture wounds • animal bites • serious burns.

Stop use and ask a doctor: If irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center.

DIRECTIONS:
Clean the affected area. Pump a generous amount onto affected area 3 times daily, let dissipate into wound. Allow to air dry before covering with sterile bandage.

Inactive Ingredients: Water, Hydrated Silica Complex

Distributed by Strategia 1000 Jorie Blvd. Suite 370
Oak Brook, IL 60523
Visit Microsure.com
Strategia Toll Free:
866-37-STRAT
866-377-8726

NDC 72513-100-01

3 72513 00001 4

Technical Information *Confidential* Company

January 29, 2020

Subject: Emerging Viral Pathogen – 2019 novel coronavirus-Wuhan
EPA Reg. No. XXXX-XXX

Dear Company Subregistrant,

In regards to the 2019 novel coronavirus-Wuhan (also 2019-nCoV), which caused the recent outbreak of respiratory illness first detected in Wuhan City, Hubei Province, China and continues to expand globally, EPA has confirmed that the 2019 novel coronavirus-Wuhan (also 2019-nCoV) has met the conditions outlined in EPA's emerging viral pathogens guidance and has triggered the emerging viral pathogen policy.

The Company RTU DISINFECTANT CLEANER (EPA Registration No. XXXX-XXX) master label has the preapproved emerging viral pathogen policy language for an enveloped virus. Subregistrants may now communicate their XXXX-XXX subregistration product efficacy against 2019 novel coronavirus-Wuhan (also 2019-nCoV) (off-label claim) in accordance with the policy and terms of subregistration.

Per the master label for EPA Registration No. XXXX-XXX, the following statement can be made on an XXXX-XXX subregistration:

> *Product **X** (EPA Reg # **XXXX-XXX-xxx**) has demonstrated effectiveness against viruses similar to 2019 novel coronavirus-Wuhan (also 2019-nCoV) on hard non-porous surfaces. Therefore, this product can be used against 2019 novel coronavirus-Wuhan (also 2019nCoV) when used in accordance with the directions for use against Human Rotavirus, Feline Calicivirus, Canine Parvovirus, Rhinovirus Type 14, Rhinovirus Type 39 and Poliovirus Type 1 on hard, non-porous surfaces. Refer to the CDC website ((https://www.cdc.gov/coronavirus/2019-ncov/index.html) for additional information.*

Per the EPA's emerging viral pathogen policy, the statements shall be made only through the following communication outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). ***These statements shall not appear on marketed (final print) product labels.***

In addition, per the EPA's emerging viral pathogen policy, all such non-label communications intended for consumers shall be ceased and removed no later than 24 months after the original notification of

the outbreak on the CDC website, unless the agency provides guidance to the contrary due to continued public health concerns.

Per the terms and conditions of the subregistration agreement, the subregistrant is responsible for complying with all applicable laws and regulations relating to its sale and marketing of subregistration products, including, without limitation, the EPA's emerging viral pathogen policy.

Thank you,

Confidential Company

FDAHome[3]

FDA Label Search

NDC Search Results on Proprietary Name: microsure

Click on Proprietary Name to view the label.

Proprietary Name	NDC	CompanyName	Application Number or Regulatory Citation	Product Type	Marketin Category
Microsure Wound Care[4]	72513-100-01	Strategia Project Management, Inc.	part333A	HUMANOTC DRUG	OTC monograp not final
Microsure Wound Care[5]	72513-100-03	Strategia Project Management, Inc.	part333A	HUMANOTC DRUG	OTC monograp not final
Microsure[6] Wound Care	72513-100-02	Strategia ProjectInc.Management,	part333A	HUMANDRUG	OTC monograp not final

Return to the FDA Label Search Page[7]

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4. http://www.accessdata.fda.gov/spl/data/8861bb54-0900-9cd3-e0532995a90a1db7/8861bb54-0900-9cd3-e053-2995a90a1db7.xml
5. http://www.accessdata.fda.gov/spl/data/8861bb54-0900-9cd3-e0532995a90a1db7/8861bb54-0900-9cd3-e053-2995a90a1db7.xml
6. http://www.accessdata.fda.gov/spl/data/8861bb54-0900-9cd3-e053-2995a90a1db7/8861bb54-0900-9cd3-e053-2995a90a1db7.xml
7. http://labels.fda.gov/

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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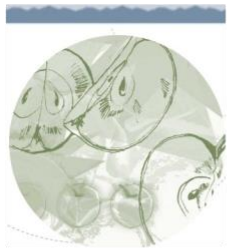
U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA



OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program regulations.

Product

Hedge Natural Defense Plant Protectant

Company

CHCM Industries
Product Inquiries Department
3315 Williams Boulevard Southwest
Suite 2, #242
Cedar Rapids IA 52404 United States

Status	Category	Issue date
Allowed with Restrictions	NOP: Oils	07-Mar-2018

Product number	Class	Expiration date
chc-10447	Crop Pest, Weed, and Disease Control	01-Jun-2020

Restrictions

May only be used if the requirements of 205.206(e) are met, which requires the use of preventive, mechanical, physical, and other pest, weed, and disease management practices.

Executive Director/CEO

OMRI LISTED For Organic Use

Organic Materials Review Institute
P.O. Box 11558, Eugene, OR 97440-3758, USA
541.343.7600 · info@omri.org · OMRI.org

To whom it mayconcern

Date 27 July2017

Subject: CM Multi Surface Cleaner andDisinfectant

CM Multi Surface Cleaner and Disinfectant is for use on all surfaces requiring cleaning and disinfection. The product has been tested in accordance with BS EN 1276: 2009 concerning chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

The test was performed using *Pseudomonas aeruginosa* , *Escherichia coli*, *Staphylococcus aureus* and *Enterococcus hirae* as test organisms in dirty and clean conditions using the obligatory test conditions of20 (± 1) °C for 5 min± 10 s.

Theproduct meets the requirements ofEN1276:2009 test with at least a 5Log10 reduction in all 4 obligatory test bacteria within 5minutes.

The product formulation is considered out-of-scope of the Biocidal Products Regulation (EU) No 528/2012, in accordance with Article 3 (la) asthe product formulation utilises physical or mechanical action to exert the biocidal effect.

Article 3

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'biocidal product'means

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action

The product complies with the general chemicals legislation required in the UK and Ireland and has been registered with the National Poison Information Centre. No authorisation certificates or registration numbers are issued by the authorities. The product CM Multi Surface Cleaner and Disinfectant is therefore fully compliant and ready to be placed on the market in the UK and Ireland

Yours sincerely

Q-S, ,'\a..s JSC International Limited

JSC International Limited

The Exchange | Station Parade | Harrogate | North York shire | HG11TS | UK T. +44 (0)1423 520245 | F. +44 (0)1423520297
www .jsci.co .uk

Current through February 08, 2020

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS%3A//ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULTS.CFM

W TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE|DIRECTORY&URL=HTTPS%3A//ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULTS.CFM

B EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE|DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULTS.CFM

You have searched Finished drug products

Search Results: *'microsure'*

Public Health Service Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Back to Search Page () | **Search Again ()**

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Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
Microsure Wound Care	72513-100-01	.13 g/100mL	LIQUID	TOPICAL	part333A	Strategia Project Management, Inc.	72513-100	Benzalkonium Chloride.	BENZALKONIUM CHLORIDE	HUMAN OTC DRUG	08/28/2018
Microsure Wound Care	72513-100-03	.13 g/100mL	LIQUID	TOPICAL	part333A	Strategia Project Management, Inc.	72513-100	Benzalkonium Chloride.	BENZALKONIUM CHLORIDE	HUMAN OTC DRUG	08/28/2018
Microsure Wound Care	72513-100-02	.13 g/100mL	LIQUID	TOPICAL	part333A	Strategia Project Management, Inc.	72513-100	Benzalkonium Chloride.	BENZALKONIUM CHLORIDE	HUMAN OTC DRUG	08/28/2018

Showing 1 to 3 of 3 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services

Certificate US19/81841540

The management system or

Solo Laboratories, Inc.

2200 Parkes Drive, Broadview, IL 60155, United States

Has been assessed and certified as meeting the requirements or

ISO 22716
Cosmetics- Guidelines on Good Manufacturing Practices (GMP)

(First edition 2007-11-15)

For the foloi.Mng activities

Formulation, manufacturing and packaging of hair care (shampoos, conditioners, gels, relaxers, sprays) skin care (mask & scrubs, moisturizers, cleansers, toners, body lotions/butter, shower gels, body mist, creams, massage oils), cosmetics (cream foundations, lip balms) and OTC Products.

This certificate is valid from 25 April 2019 until 25 April 2022
and remains valid subject to satisfactory surveillance audits
Issue 1. Certified since 25 April 2019 .

Au!horised by

PieterWetemgs
Cel1ification Manager
SGS Belgium NV
SGS House Noorde!laan 87 2030AnlWelp Belgium
t+32(0)3545-48-48 f+32(0)3545-48-49 www.sgs .com

Below, you will find all the answers to the questions requested. We are hopeful that this information will suffice, should there be any additional information necessary please do not hesitate to ask.

Questions: Lab & Data information

■ **Names and addresses for labs this product has been tested in**.

- University of Liverpool: Liverpool L69 3BX, United Kingdom
- University of Iowa: 451 Newton Road, 200 medicine administration building Iowa City, IA 52242 USA
- Ames Research Lab: 4840 Venture Drive Ann Arbour, MI 48108 USA
- Tox Monitor Laboratories, Inc. 33 West Chicago Avenue. USA

■ **Addresses and Names of related certification companies**

- Organic Materials Review Institute: P.O. Box 11558 Eugene, OR 97440, USA
- Solo Labratories: 2200 Parkes Drive, Broadview, IL. 60155 USA
- JSC International Limited: North York Shire HG11TS. UK,

■ **Names for each scientist that has led each study.**

- Dr. Paul Copper
- Mr. Michael Cunningham
- Lieutenant General Gary H. Mears Joint Chief
- Dr. Alina Oknianska
- Michael Kulkinski

- **Reports and data from each study.**

  **Please see annotated bibliography of studies attached as a separate file*

FDA Marketing

- **MicroSure in the OTC FDA Process, currently at the "Not Final" Level in their application?**

- Application is completed and FDA approved for current claims and use. To get a "final" the product we would have to go through full clinical trials which would take years and possibly hundreds of millions of dollars to be a prescription drug, which we do not want to do at this time for strategic reasons.

- **Please provide further information or guidance the FDA has given you to complete your application.**

- Application is Completed and accepted and we are able to market, sale and make the claims that we currently do.

**Please see attached email file with the provided FDA labels*

- **Can you provide an Example: How much longer until they are approved?**

- Application is approved and ready for use. We do not want to take the product any further in the process until we possibly take it to full prescription level.

**Please see attached email file with the provided FDA labels*

- **What guidance has the FDA given MicroSure as to how they should reference where there are in the FDA process?**

- No guidance necessary as we are approved. We speak to FDA representatives regularly

- **What is MicroSure allowed to claim?**

- *Please see product labels for claims, they have been attached as separate files*

- **We need actual communications with the FDA.**

- Please see FDA website and check NDC #

**We have provided FDA labels and NDC #'s in the separate file attachments.*

<u>Mechanisms/Forms for Application:</u>

- **Does MicroSure provide/sell a spraying device?**

- We can, but we do not regularly.

- **What is the name of the device(s) recommended to use for application?**

- Pressure sprayer, misters. foggers and electrostatic sprayers are the best choice.

- **Who can use the fogger? Self Use? Does it need a professional/ someone trained?**

- This answer varies depending on a case by case basis. Each consumer may have their own rules or regulations regarding who is able to apply the product and whether those persons need special training or certifications.

- **Is there a How -To- Manual?**

- We can provide detailed how-to manuals at a later time.

General Organic Questions:

- **You have stated you are certified organic**.

  - Organic would be Hedge Plant Protectant for Plants. The SIO2, and oil extracts are organic and listed under the GRAS rules. We have inert products naturally occurring

- **Please provide certification and from what institution.**

  - OMRI

    **Please see attached certification file provided*

- **Newly advanced green product? what defines this? where are they getting the certified organic from?**

  - OMRI CERTIFIED

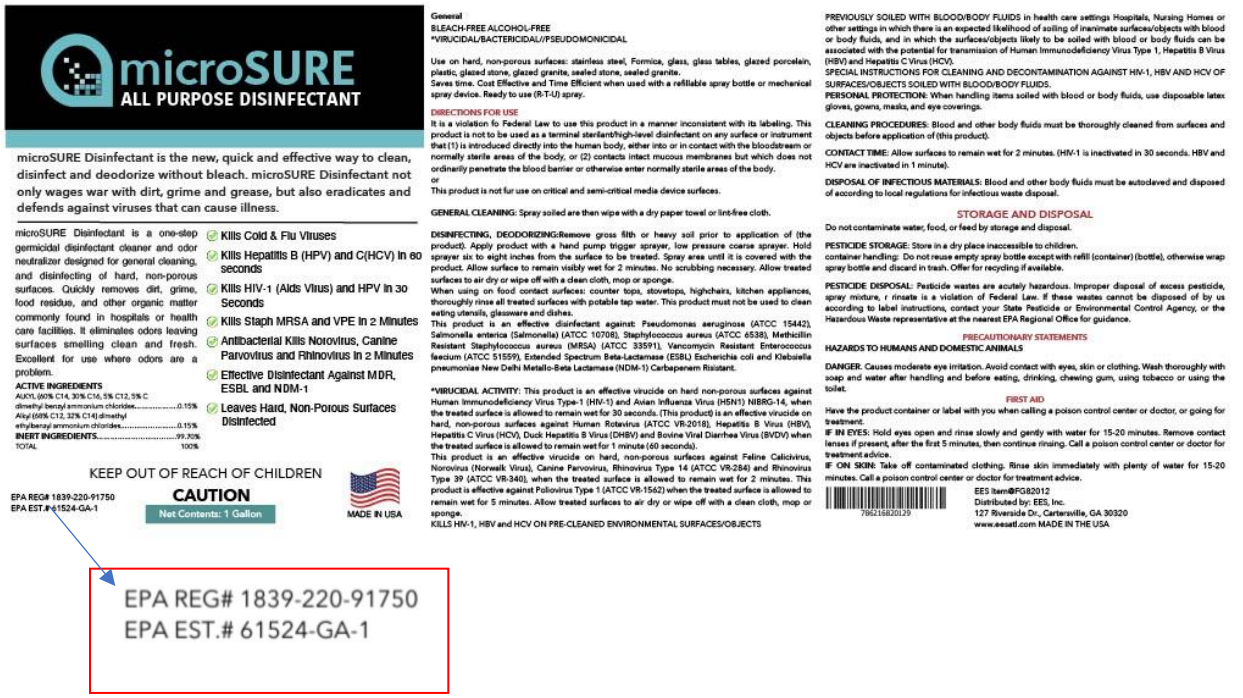
    *Please see attached certification file provided.

A: 1000 Jorie Blvd. Suite 370
Oak Brook IL 60523
E: info@microsure.com
T: +1 (866) 377-8728

Understanding EPA Product Registration and Approval as It Relates to microSURE All Purpose Disinfectant

The United States Environmental Protection Agency (EPA) works to ensure the protection of human health and the environment. *microSURE ALL PURPOSE DISINFECTEANT* was specially designed in a manner that places these factors at the top of its mission while also providing a product that effectively eradicates and halts the spread of harmful, unwanted pathogens.

The *microSURE ALL PURPOSE DISINFECTEANT* label provided below delivers all necessary information that consumers may have questions about. This includes but is not limited to the products description, applications for use, active ingredients, proper storage and disposal guidelines as well as the assigned EPA product registration number granted by the EPA. A brief explanation what these numbers mean and how they relate to *microSURE ALL PURPOSE DISINFECTEANT*


microSURE
ALL PURPOSE DISINFECTANT

microSURE Disinfectant is the new, quick and effective way to clean, disinfect and deodorize without bleach. microSURE Disinfectant not only wages war with dirt, grime and grease, but also eradicates and defends against viruses that can cause illness.

microSURE Disinfectant is a one-step germicidal disinfectant cleaner and odor neutralizer designed for general cleaning, and disinfecting of hard, non-porous surfaces. Quickly removes dirt, grime, food residue, and other organic matter commonly found in hospitals or health care facilities. It eliminates odors leaving surfaces smelling clean and fresh. Excellent for use where odors are a problem.

ACTIVE INGREDIENTS
Alkyl (60% C14, 30% C16, 5% C12, 5% C dimethyl benzyl ammonium chlorides..... 0.15%
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides..... 0.15%
INERT INGREDIENTS..... 99.70%
TOTAL 100%

- Kills Cold & Flu Viruses
- Kills Hepatitis B (HPV) and C(HCV) in 60 seconds
- Kills HIV-1 (Aids Virus) and HPV in 30 Seconds
- Kills Staph MRSA and VPE in 2 Minutes
- Antibacterial Kills Norovirus, Canine Parvovirus and Rhinovirus in 2 Minutes
- Effective Disinfectant Against MDR, ESBL and NDM-1
- Leaves Hard, Non-Porous Surfaces Disinfected

KEEP OUT OF REACH OF CHILDREN
CAUTION
Net Contents: 1 Gallon
MADE IN USA
EPA REG# 1839-220-91750
EPA EST.# 61524-GA-1

General
BLEACH-FREE ALCOHOL-FREE
*VIRUCIDAL/BACTERICIDAL/PSEUDOMONICIDAL

Use on hard, non-porous surfaces: stainless steel, Formica, glass, glass tables, glazed porcelain, plastic, glazed stone, glazed granite, sealed stone, sealed granite.
Saves time. Cost Effective and Time Efficient when used with a refillable spray bottle or mechanical spray device. Ready to use (R-T-U) spray.

DIRECTIONS FOR USE
It is a violation fo Federal Law to use this product in a manner inconsistent with its labeling. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.
or
This product is not fur use on critical and semi-critical media device surfaces.

GENERAL CLEANING: Spray soiled are then wipe with a dry paper towel or lint-free cloth.

DISINFECTING, DEODORIZING:Remove gross filth or heavy soil prior to application of (the product). Apply product with a hand pump trigger sprayer, low pressure coarse sprayer. Hold sprayer six to eight inches from the surface to be treated. Spray area until it is covered with the product. Allow surface to remain visibly wet for 2 minutes. No scrubbing necessary. Allow treated surfaces to air dry or wipe off with a clean cloth, mop or sponge.
When using on food contact surfaces: counter tops, stovetops, highchairs, kitchen appliances, thoroughly rinse all treated surfaces with potable tap water. This product must not be used to clean eating utensils, glassware and dishes.
This product is an effective disinfectant against: Pseudomonas aeruginose (ATCC 15442), Salmonella enterica (Salmonella) (ATCC 10708), Staphylococcus aureus (ATCC 6538), Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33591), Vancomycin Resistant Enterococcus faecium (ATCC 51559), Extended Spectrum Beta-Lactamase (ESBL) Escherichia coli and Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase (NDM-1) Carbepenem Risistant.

*VIRUCIDAL ACTIVITY: This product is an effective virucide on hard non-porous surfaces against Human Immunodeficiency Virus Type-1 (HIV-1) and Avian Influenza Virus (H5N1) NIBRG-14, when the treated surface is allowed to remain wet for 30 seconds. (This product) is an effective virucide on hard, non-porous surfaces against Human Rotavirus (ATCC VR-2018), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Duck Hepatitis B Virus (DHBV) and Bovine Viral Diarrhea Virus (BVDV) when the treated surface is allowed to remain wet for 1 minute (60 seconds).
This product is an effective virucide on hard, non-porous surfaces against Feline Calicivirus, Norovirus (Norwalk Virus), Canine Parvovirus, Rhinovirus Type 14 (ATCC VR-284) and Rhinovirus Type 39 (ATCC VR-340), when the treated surface is allowed to remain wet for 2 minutes. This product is effective against Poliovirus Type 1 (ATCC VR-1562) when the treated surface is allowed to remain wet for 5 minutes. Allow treated surfaces to air dry or wipe off with a clean cloth, mop or sponge.
KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings Hospitals, Nursing Homes or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1, Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.
PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product).

CONTACT TIME: Allow surfaces to remain wet for 2 minutes. (HIV-1 is inactivated in 30 seconds. HBV and HCV are inactivated in 1 minute).

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in a dry place inaccessible to children.
container handling: Do not reuse empty spray bottle except with refill (container) (bottle), otherwise wrap spray bottle and discard in trash. Offer for recycling if available.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, r rinsate is a violation of Federal Law. If these wastes cannot be disposed of by us according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

7862168201129
EES Item#FG82012
Distributed by: EES, Inc.
127 Riverside Dr., Cartersville, GA 30320
www.eesatl.com MADE IN THE USA

EPA REG# 1839-220-91750
EPA EST.# 61524-GA-1

What these numbers mean?

EPA Product Registration #: 1839-220-91750

-The first set of numbers: '1839' refers to the company number
-The second set of numbers: '220' refers to the formulation
-The third set of numbers: '91750' refers to the sub registrant

strategia

A: 1000 Jorie Blvd. Suite 370
Oak Brook IL 60523
E: info@microsure.com
T: +1 (866) 377-8728

EPA Establishment#: 61524-GA-1
-The '61524' is the company number
-The 'GA' is relating to the manufacturing site
-The'1' refers to the assigned pesticide production/manufacturing site.

*Each EPA approved product can be found on the EPA website database. All relative product information including the current EPA status can be retrieved. When entering the EPA registration number '1839-220-91750' found on the lower left corner of the *microSURE ALL PURPOSE DISINFECTANT* label the following information will be portrayed:

Details for the guardian all purpose disinfectant cleaner & deodorizer

Distributor Product Number: 1839-220-91750
Company Name: EES INDUSTRIAL, LLC
Address: 127 RIVERSIDE DRIVE
City, State Zip: CARTERSVILLE , GA 30120
First Registered Date: OCTOBER 10, 2019
Current Status (Date): Active (OCTOBER 10, 2019)
Section 3 (Related Registered Product): 1839-220, SC-RTU DISINFECTANT CLEANER
Restricted Use: See Section 3 (Related Registered Product)

*Note that this EPA number provided is linked to *Guardian All Purpose disinfectant cleaner & deodorizer.* This is the previous name used prior to the name change of *microSURE ALL PURPOSE DISINFECTEANT* and transfer to Strategia being placed into effect. To ensure the satisfaction of this statement please see the related portion of the letter sent to the appropriate EPA personnel provided below.

> *'Dear Ms. Liu,*
>
> *EES, Indus LLC. Would like to change its product, Guardian (1839-91750), to MicroSure.*
>
> *Please note, this registered product will change name only. All wordings in the label remains the same.*
>
> *Ming SU*
>
> *Consultant for EES'*

The EPA website database is continuously making updates to its platform and these changes are expected to be reflected on the database in due time. We are confident that the information provided aids in the clear explanation of how EPA numbers are generated, what each set of numbers means and most importantly proves that *microSURE ALL PURPOSE DISNFECTANT* holds an 'active' EPA status.

As the EPA guidelines alter overtime microSURE *ALL PURPOSE DISNFECTANT* formerly known as *Guardian All Purpose disinfectant cleaner & deodorizer* will continue to abide by the necessary rules and regulations to ensure that this 'active' status remains intact.