United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

739-R-06-010
July 2006

EPA

Reregistration Eligibility Decision For Iodine And Iodophor Complexes

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 (EPA) has completed its review of the available data on the antimicrobial iodine and iodophor complexes. The enclosed Reregistration Eligibility Decision (RED) document was approved on July 27, 2006.

Based on the Agency's review, the iodine and iodophor complexes Reregistration Eligibility Decision (RED) and risk management decision with its associated human health and environmental risk assessment are now being published. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for iodine and iodophor complexes will be available to the public from the U.S. Federal Government website www.regulations.gov. The docket identification number is EPA-HQ-OPP-2006-0599.

The iodine and iodophor complexes RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, 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 attached RED document pertains only to iodine and presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to iodine and iodophor complexes alone. This document also contains 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. 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 iodine and iodophor complexes will be eligible for reregistration provided that all the conditions identified in this document are satisfied.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Heather Garvie, at (703) 308-0034. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Iodine
List C
CASE 3080

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
July 27, 2006

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LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)

TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
mg/kg/day	Micrograms Per Gram
mg/kg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its human health and environmental review for iodine and iodophor complexes and is issuing its risk management decision. The Agency has decided that iodine and iodophor complexes are eligible for reregistration provided any data gaps are fulfilled within the allotted timeframe described in Chapter V. There are a wide variety of uses for iodine and iodophor complexes. Iodine is used primarily for emergency drinking water disinfection. Potassium iodide is used to sanitize fresh fruits and vegetables. The surfactant iodophor complexes are used primarily for sanitizing food-contact surfaces in food processing plants and food handling establishments, and for disinfection of environmental surfaces in hospitals. The iodinated resins are used to purify human drinking water, impart antimicrobial and antifungal activity to materials and finished articles such as paints, stains, coatings and textiles, and microbial control in water systems.

Several tolerance exemptions exist for iodine and iodophor complexes when used as ingredients in antimicrobial pesticide formulations under 40 CFR 180.940 and 40 CFR 180.1022. Approximately 2 million pounds of iodine and iodophor complexes are sold annually in the United States for use in antimicrobial products registered by the US EPA.

This RED is inclusive of iodine and related compounds used as sanitizers and disinfectants. It includes: iodine, sodium/potassium iodides and iodine embedded in organic polymers (including polyvinlypyrrolodine/povidone and tetraglycine). The organic polymers are called iodophors. When embedded with iodine these moieties are called iodophor complexes. Technically, a complex would be defined as a chemical which is formed when a metal ion binds with ligands through a coordinate covalent bond. In this sense the iodophor complexes are not complexes. However, because the Agency has historically accepted the term *iodophor complexes* for these chemicals, we will retain the term for the purpose of this RED.

Overall Risk Summary

Hazard Profile/Human Health Risk

Based on a review of the available toxicology data, the Agency has concluded that iodine and iodophor complexes are of very low toxicity by the oral, dermal, and inhalation routes of exposure. The toxicology database is adequate to characterize the hazard of iodine, and no data gaps have been identified. There are no indications of special sensitivity of infants or children resulting from exposure to iodine. Therefore, the FQPA Safety Factor has been removed (i.e., reduced to 1X) for iodine. The Agency has not identified toxicological endpoints of concern for iodine. Therefore, a quantitative human health risk assessment was not conducted for this RED document. The Agency has no risk concerns for iodine and iodophor complexes with respect to human exposure through dietary, drinking water, residential and occupational routes.

Environmental and Ecological Risk

The uses of iodine and iodophor complexes considered in this RED make it unlikely that

any appreciable exposure to terrestrial or aquatic organisms would occur.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing iodine and iodophor complexes.

Summary of Mitigation Measures

The Agency has determined that iodine and iodophor complexes are eligible for reregistration. Since no risks of concern were identified, no specific mitigation measures are needed for iodine and iodophor complexes.

Data Requirements

No additional confirmatory data is required to complete the reregistration of iodine and iodophor complexes. However, product specific data is required for all products containing iodine and iodophor complexes as described in Section V of 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 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require a tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in the tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's human health and ecological review and the Reregistration Eligibility Decision for iodine.

Iodine and iodophor complexes are used for a variety of indoor antimicrobial uses. They all function as microbiocides by releasing iodine. A few examples of currently registered uses are: emergency drinking water purification, fresh food sanitization, food-contact surface sanitization, hospital surface disinfection, materials preservation, and commercial and industrial water cooling tower systems. Registered antimicrobial products account for approximately 2 million pounds of iodine and iodophor complexes annually.

The Agency has concluded that the FQPA Safety Factor for iodine and iodophor complexes should be removed (equivalent to 1X) because there is no pre- or post-natal evidence of increased susceptibility for infants and children following exposure to iodine and this risk assessment does not underestimate the potential risk for infants and children.

The evaluation summarized in this document concerns only potential exposures from the use of the active ingredients iodine and iodophor complexes. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for iodine and iodophor complexes and any other

II. CHEMICAL OVERVIEW

A. Regulatory History

Products containing iodine as the active ingredient were initially registered in the United States by the U.S. Department of Agriculture beginning in 1948. Approximately 2 million pounds of iodine are sold annually in the United States for use in antimicrobial products. Currently there are 69 products containing iodine or an iodophor complex as the active ingredient registered by the Agency.

Iodine is used primarily for emergency drinking water disinfection. Potassium iodide is mainly used to sanitize fresh fruits and vegetables. The surfactant iodophors are predominantly used to sanitize food-contact surfaces in food-processing plants and food-handling establishments and to disinfectant environmental surfaces in hospitals and institutions. The amino acid-iodine complexes are primarily used to purify (on an emergency basis) human drinking water. The iodinated resins are used to purify human drinking water, impart antimicrobial and antifungal activity to materials and finished articles such as paints, stains, coatings and textiles, and microbial control in water systems.

This Reregistration Eligibility Document (RED) covers iodine, potassium iodide and various iodine complexes. The iodine complexes are: 1) complexes of iodine with surfactants; 2) complexes of iodine with an amino acid; and 3) iodinated resins. The iodophor complexes all contain iodine as the active ingredient and function in the same manner by releasing molecular iodine, which is the actual biocide, upon use. Iodine, potassium iodide and iodine complexes have been divided into the following groups and sub-groups:

B. Chemical Identification

1. Iodine (includes Iodine and Potassium Iodide)

a. Iodine - PC Code: 046905/CAS # 7553-56-2

i. Chemical Overview

The chemical iodine is most commonly used in: sanitation, animal feed and pharmaceutical production.

ii. Chemical Identification

- Name: Iodine
- Chemical Family: Halogen
- Common/Trade Names: None
- CAS Number: 7553-56-2
- Molecular Formula: I_2

iii. Physical/Chemical Properties

The following characteristics have been reported for iodine:
Technical Grade Active Ingredient (TGAI):

- Molecular Weight: 253.809
- Color: Bluish-black
- Physical State: Solid; scales or plates
- Specific gravity: 4.93
- Dissociation Constant: No data available
- pH: No data available
- Stability: No data available
- Melting point: 113.6°C
- Boiling point: 185.24°C
- Water Solubility: 330mg/L at 25°C
- Log K_{ow} 0.40
- Vapor Pressure: 0.305 mm Hg at 25°C

Manufacturers: Johnson Diversey, Inc., West Agro, Inc., Polar Equipment Inc., Iogold Systems Inc., Baltimore AirCoil Company

b. Potassium Iodide PC Code: 075701/CAS # 7681-11-0

i. Chemical Overview

The chemical Potassium iodide is most commonly used in: sanitation, animal feed, catalysts, and for treatment of radioiodide poisoning resulting from nuclear accidents.

ii. Chemical Identification

- Name: Potassium iodide
- Chemical Family: Halogen
- Common/Trade Names: None
- CAS Number: 7681-11-0
- Molecular Formula: KI

iii. Physical/Chemical Properties

The following characteristics have been reported for potassium iodide:
Technical Grade Active Ingredient (TGAI):

- Molecular Weight: 166.02
- Color: Colorless or white
- Physical State: Solid; crystals, granules, or powder

- Specific gravity: 3.12
- Dissociation Constant: N/A: Completely ionized in aqueous medium
- pH: No data available
- Stability: Stable , but turn yellowish over prolonged period of time
- Melting point: 680°C
- Boiling point: 1323°C
- Water Solubility: 1429 g/L at 25°C
- pH; Aqueous Solution: neutral to basic: 7-9
- Log K_{ow}: 0.04
- Vapor Pressure: 9.9×10^{-18} mm Hg

Manufacturer: U.S. Army Research, Development & Engineering Command

2. Surfactant-Iodine Complexes

a. Propoxyethoxy (PO/EO) Copolymer Carriers or Polypropoxypolyethoxyethanol-Iodine Complexes

i. Butoxypolypropoxypolyethoxyethanol: PC Code: 046901/CAS # 68610-00-4

Butoxypolypropoxypolyethoxyethanol is a polymer made from a mixture of propylene oxide, ethylene oxide and butanol. It is synthesized by the ethoxylation reaction of propylene oxide (PO) and ethylene oxide (EO) with a butanol "starter." For iodophor production, so-called block copolymers are used. In the synthesis of these molecules, PO and EO are added in sequential steps (rather than simultaneously) to form "blocks" of polypropoxy and polyethoxy units within the molecule. The final polyalkylene glycol (PAG) is not a single compound but is a mixture of polymer chains which have an approximate normal distribution around the desired molecular weight. The molecular weights used in iodophor production range from 2000 to 4000 a.m.u.

Manufacturers: Richardson Chemical Products, Co., Ecolab, West Agro Inc., National Chemicals Inc., U.S. Chemical Corporation

ii. Polypropoxypolyethoxyethanol: PC Code 046904/CAS # 26617-87-8

Polypropoxypolyethoxyethanol is a polymer made from a mixture of propylene oxide, ethylene oxide and water. It is synthesized by the ethoxylation reaction of propylene oxide (PO) and ethylene oxide (EO) with a water "starter." Except for the initiator, these polymers are the same as the butoxypolypropoxypolyethoxyethanol carriers.

Manufacturers: West Chemical Products, Inc., West Agro, Inc., Lonza, Inc., H&S Chemicals Division

b. Phenoxypolyethoxyethanol Carriers (Phenoxypolyethoxyethanol-iodine complexes)

i. Nonylphenoxypolyethoxyethanol: PC Code 046903/CAS # 11096-42-7

Nonylphenoxypolyethoxyethanols (nonylphenol polyethoxylates; NPE) are commonly used surfactants in industrial cleaners, pesticide adjuvants, and, for the most commonly made 9-mole ethoxylate, spermicides. It is a polymer made from a mixture of nonyphenol, ethylene oxide and ethanol. A wide range of ethoxylation (approximately 4 to 100 moles of EO) are used to provide different properties. The NPEs are produced by introducing the preferred molar ratio of EO and nonylphenol (NP) into a reactor. The C9 chain of the NP is comprised of approximately 25-30 isomers with different branching. As with the EO/PO polymers discussed above, the final products are not a single compound but are mixtures of chains which have an approximate normal distribution around the desired molecular weight. For example, the most commonly produced 9-mole ethoxylate (known as Nonoxynol in spermicide use) contains congeners ranging from approximately 5 to 16 moles of EO. Therefore, each NPE is a complex mixture of isomers of the nonene chain and congeners of the EO chain. Nonylphenoxypolyethoxyethanol is in the form a blue liquid, with a specific gravity of 1.01. Nonylphenoxypolyethoxyethanol has a listed pH factor of 9.5 ± 2.

Manufacturers: Westfalia-Surge, Inc., An-Fo Manufacturing Comp., ABC Compounding Co., Inc., West Agro, Inc., Theochem/Time Products, Inc., Lonza, Inc., Webco Chemical Corp., Thatcher Co., H. Wilson Manufacturing Co., Inc., Controlled Release Technologies, Inc., Multi-Wash Medical, Ltd., Preserve International, PM Resources, Inc., Dupont

c. Polyvinylpyrrolidone Carriers (Polyvinylpyrrolidone-iodine complexes)

i. Polyvinylpyrrolidone (Povidone): PC Code 046914/CAS # 25655-41-8

Povidone (PVP; CAS No. 9003-39-8) is a synthetic polymer principally consisting of linear 1-vinyl-2-pyrrolidone groups, produced as a series of products having mean molecular weights ranging from about 10,000 to about 1 million a.m.u. or greater. The monomer molecular weight is 11.1 a.m.u. In addition to its use in disinfectants, it is used as a dispersing agent, and has been used as a tablet binder, coating agent, and viscosity-increasing agent in pharmaceutical preparations.

PVP is an odorless faintly yellow powder and is soluble in water, ethanol, and chloroform and insoluble in ether. PVP has a specific gravity of 1.1-1.3 and a pH ranging from 3.0 to 7.0 in a 1:20 solution. The melting point is 100°C. The amide region of the pyrrolidone substituent absorbs in the UV region at wavelengths below 235 nm.

Manufacturer: H&S Chemicals Division

3. Amino Acid-Iodine Complex

a. Tetraglycine hydroperiodide: PC Code 046923/CAS # 7097-60-1

For the iodophor used for emergency water disinfection (tetraglycine hydroperiodide), the iodine and iodophor complex is formed by a catalyst driven reaction with the essential amino acid glycine, to produce the complex: 2[(CH2NH2COOH)8 • (HI)2 2.5I2]

Manufacturers: U.S. Army Research, Development, & Engineering Command, The Brita Products Co., Wisconsin Pharmacal Comp, LLC.

4. Iodinated Resin Complex

a. Quat Amine divinylbenzene/ styrene copolymer: PC Code 046905/CAS # 7553-56-2

Triosyn® resin is a polymer made from a mixture of divinylbenzene quaternary amine and styrene. It is produced by thermally fusing pure iodine crystals under high pressure with a specialized quaternary amine divinylbenzene/styrene polymer. During this process, a stable electrochemical bond is formed between the iodine and the polymer, allowing no free release of iodine in the media employed. This electrochemical bond serves as a demand-release mechanism that allows iodine molecules to be released from Triosyn® resin in the presence of demand-causing microorganisms and in amounts required to eliminate the source of the demand. Triosyn® is activated by the strong ionic charge of surface proteins that cover microorganisms and then interacts with organisms through ionic transfer. Upon contact with a microorganism, ionic molecular iodine is transferred from Triosyn® resin, to the more strongly charged surface proteins of the microbe. The iodine immediately devitalizes the microorganism by removing electrons from the organism's surface proteins which are necessary for life and reproduction. This process provides disinfectant properties to items such as tent fabric and outdoor paint. There is little human contact with the poymeric Triosyn® resin.

Manufacturers: The Purolite Comp., Triosyn Corp., MCV Manufacturing Inc., Water Solution Technologies, Inc., Umpqua Research Company

C. Use Profile

The following is information on the currently registered uses of iodine and iodophor complex products and an overview of use sites and application methods. A detailed table of the use sites, method and rate of applications, and use limitations can be found in Appendix A.

III. SUMMARY OF IODINE AND IODOPHOR COMPLEXES RISK ASSESSMENTS

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for iodine and iodophor complexes. While the risk assessments and related addenda are not included in this document, they are available from the U.S. Federal Government website at www.regulations.gov. The docket number is: EPA-HQ-OPP-2006-0599. Hard copies of these documents may be found in the OPP public docket under the same docket number. The OPP public docket is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m.to 4:00 p.m

A. Human Health Assessment

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

1. Toxicity of Iodine and Iodophor Complexes

A brief overview of the toxicity of iodine and iodophor complexes is presented below. Further details on the toxicity of iodine and iodophor complexes can be found in the supporting documentation for this RED. The Antimicrobials Division Toxicology Endpoint Selection Committee (ADTC) memorandum, the toxicology chapter for the RED and other supporting documentation are available from the Federal Government Public Docket at www.regulations.gov.

The toxicological database for iodine and iodophor complexes is currently comprised of published and unpublished studies either submitted to the Agency or obtained directly from the open literature. Although the available studies may not meet the requirements of the Agency's OPPTS harmonized test guidelines published in 1998, it was determined that these studies contain useful information that is adequate for hazard characterization of iodine. These acceptable non-guideline studies include acute, subchronic, chronic, developmental, and reproductive toxicity, carcinogenicity, mutagenicity, metabolism/pharmacokinetic and dermal absorption studies. Therefore, the Agency has determined that the toxicological database is complete and sufficient for reregistration.

Major features of the toxicology profile are presented in Table 1. The acute toxicity of iodine (99.5% a.i.) is low for dermal toxicity, but shows higher toxicity for acute oral toxicity, inhalation toxicity, and primary dermal irritation. Iodine is not a dermal sensitizer.

Table 1. Acute Toxicity of Iodine Technical Grade Active Ingredient (TGAI)				
Guideline No.	**Study Type**	**MRID#**	**Results**	**Toxicity Category**
870.1100	Acute Oral- Rats	42326704	LD50 = 315 mg/kg	II
870.1200	Acute Dermal – Rats	42326705	LD50 = 3,333 mg/kg	III
870.1300	Acute Inhalation – Rats	42961002	LC50 = 0.363 mg/L	II
870. 2500	Primary Dermal Irritation – Rabbits	42326706	Corrosive; severe edema, erythema, and eschar	I
870.2600	Dermal Sensitization- Guinea Pigs	42326707	No sensitization using Buehler method	N/A

N/A = Not applicable

General Toxicity Observations

Upon reviewing the published data on dermal absorption and toxicity of iodine, and the estimated worst-case exposures from dermal and inhalation uses of iodine and iodophor complexes in antimicrobial pesticide formulations, the Agency concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to iodine. The Agency agreed that the data for dermal absorption of iodine and iodophor complexes show a low percentage of absorption (1%; ATSDR, 2004).

Carcinogenicity Classification

A review of the available data has shown iodine and iodophor complexes to be negative for carcinogenicity in studies conducted up to the testing limit doses established by the Agency.

Mutagenicity Potential

The Agency has granted waiver requests for a mutagenicity battery conducted with iodine for oral exposures to this chemical.

Metabolism and Excretion

Iodine is an essential dietary component and is required for synthesis of thyroid hormones. The iodide salts, sodium and potassium iodide, are soluble in water and oral doses are generally considered to have 100% gastrointestinal absorption. An acute exposure to iodine that may be above the Recommended Daily Allowance (RDA) is usually a temporary effect to which the body readily adapts through down-regulation of the iodine transporter mechanism in the thyroid gland.

Developmental and Reproductive Toxicity

There is no concern for increased susceptibility of infants and children to the exposures from antimicrobial uses of iodine and iodine complexes.

Neurotoxicity

There is no evidence in the available toxicity studies or scientific literature to indicate neurotoxic effects of iodine in humans or laboratory animals.

Endocrine Disruption Potential

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

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for iodine and iodophor complexes because there is no pre- or post-natal evidence for increased susceptibility following exposure. Further, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to iodine and iodophor complexes based on the low toxicity observed in studies conducted at or below the established testing limit doses. Therefore, a quantitative risk assessment was not conducted for iodine.

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. Since toxicological endpoints for risk assessment were not identified based on the available data, RfDs and PADs have not been calculated for iodine.

4. Dietary and Residential Exposure

A residential exposure risk assessment is required for an active ingredient if: 1) certain toxicological criteria are triggered; and 2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For iodine, the toxicological criteria are not met, and therefore, an assessment is not warranted.

Dietary exposure (food and drinking water) could potentially occur from the use of iodine and iodophor complexes as a food contact sanitizer and water disinfectant. Although the Agency has not identified any toxicological endpoints of concern for iodine or iodophor complexes, iodine's role in the synthesis of thyroid hormones is long and well established. Too much or too little dietary iodine can be deleterious. Therefore, the Agency conducted an exposure assessment to ensure dietary exposures from the pesticidal uses of iodine fall within an acceptable range. Based on calculations using current assumptions on food contact sanitizer uses, the tolerance exemption noted in 180.940 for iodine and iodophor complexes of 25 ppm translates into a dose of approximately 0.007 mg/kg/day for a 70 kg adult, and 0.033 mg/kg/day for a 15 kg child and represent worst-case exposures. These calculated oral exposures represent worst-case exposures. For adults and children, these estimated exposures fall between the RDA of 0.002 mg/kg/day and the Tolerable Upper Intake Level of 0.016 mg/kg/day for adults and 0.01 – 0.04 mg/kg/day for children 1-13. It is important to note that the tolerable upper intake level is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects in almost all individuals (Institute of Medicine, 2003), and that responses to intake of iodine and iodophor complexes between the RDA and the upper intake level do not represent adverse responses, but biological responses. Taking this into consideration, the Agency concluded that the calculated oral exposures from food contact sanitizer use of iodine and iodine complexes represented no risk of concern.

Again, an acute exposure to iodine and iodophor complexes that may temporarily be above the RDA is usually a temporary effect to which the body readily adapts through down-regulation of the iodine and iodophor transporter mechanism in the thyroid gland (ATSDR, 2004).

5. Aggregate Exposure

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure.

Since toxicological endpoints for risk assessment were not identified based on the available data, an aggregate risk assessment was not conducted for iodine.

6. Occupational Exposure

An occupational exposure assessment addresses potential exposures and risks to humans who may be exposed in "occupational settings". An occupational risk assessment is required for an active ingredient if: 1) certain toxicological criteria are triggered; and 2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. Although there are potential exposures from the use of these products, there are no toxicological endpoints of concern. Therefore, the exposures and risks have not been quantified.

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network (NPTN).

A total of 8 individual human incident cases submitted to the EPA Office of Pesticide Programs are associated with exposure to iodine and iodophor complexes containing compounds. Inhalation and dermal are the two important routes of exposure. The most common symptoms reported for cases of inhalation exposure were coughing, wheezing, tightness of chest and shortness of breath. Dermal exposure caused skin burning, blisters and rashes. None of these effects were considered severe effects. Incidences of death have been reported but these incidence cases were linked to ingestion of excessively high quantities to iodine. Irritation effects were reported with exposure to iodine compounds through oral, dermal or inhalation routes of exposure.

B. Environmental Risk Assessment

A summary of the Agency's environmental review is presented below. For detailed discussions of all aspects of the environmental review, see the Ecological Hazard and Environmental Risk Assessment and Environmental Fate chapters available from the U.S. Federal Government website at: www.regulations.gov. The docket number is EPA-HQ-OPP-2006-0599.

1. Environmental Fate and Transport

The transfer of iodine from air, water, and land is due to the chemical's volatility. The wet deposition of iodine is predominantly into soil. Iodine is not likely to volatilize from iodophors due to lower vapor pressure. The vapor pressure of iodine when embedded in the carrier polymer is less than when it is free (not bonded or embedded in ay polymer or resin). Mobility of iodine in soil depends on the soil porosity, saturation and the amount of organic matter and iron/aluminum oxides in the soil.

The Agency has evaluated iodine as an active and as an inert ingredient. In this assessment, no potential environmental concerns for these pesticides (chemicals assessed were:

(Colinus virginianus)	hydroperiodide, 100%	ppm ai NOEC= 2500 ppm ai	non-toxic	- analytical data for diet not provided - NOEC based on reduction in body weight	
Bobwhite quail *(Colinus virginianus)*	Nonylphenoxyp olyethodyethan ol-iodine complex, 100%	LC50 > 5620 ppm NOEC = 5620 ppm	Practically non-toxic	Yes - core study	ACC238200
Mallard (*Anas platyrhynchos*)	Nonylphenoxyp olyethodyethan ol-iodine complex, 100%	LC50 > 5620 ppm NOEC = 3160 ppm	Practically non-toxic	Yes - core study - NOEC based on signs of toxicity	ACC238200
Acute Toxicity of Iodine and Iodophors to Freshwater Fish					
Bluegill sunfish *(Lepomis macrochirus)*	Igepal CO-630 Atechnical@	96hr LC50 = 7.9 mg/L	Moderately toxic	No - supplemental study - test substance did not include iodine complex	ACC238200
	Iobio 99.8% iodine	96hr LC50 = 0.61 NOEC = .016	Highly toxic	Yes	43044501
Acute Toxicity of Iodine and Iodophors to Freshwater Invertebrates					
Waterflea *(Daphnia magna)*	Iodine, 99.8%	48-hr. EC_{50} = 0.33 (95% conf. limits 0.20 - 0.37) mg ai/L NOEC = 0.09 mg ai/L	Very highly toxic	Yes - Core study - NOEC based on signs of toxicity	42961001

Based on the indoor use patterns of iodine and iodophor complexes, minimal environmental exposure is expected, and, therefore, no ecological risk is anticipated.

3. Risk to Listed Species

Due to the low likelihood of exposure and low toxicity of iodine and iodophor complexes, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

IV. Risk Management, Reregistration and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

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

The Agency has completed its assessment of the dietary, drinking water, residential, ecological and occupational risks associated with the use of pesticide products containing the active ingredient iodine and iodophor complexes. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of iodine and iodophor complexes to make a decision as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that iodine and iodophor complexes containing products are eligible for reregistration. Appendix A summarizes the uses of iodine and iodophor complexes that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of iodine, and lists the submitted studies that the Agency found acceptable.

B. Public Comments and Responses

Supporting documents for iodine and iodophor complexes were not issued for public comment per the Agency's public participation process because no toxicological endpoints were identified and, as such, a quantitative risk assessment was not conducted. To ensure that opportunity is presented to the public to comment on the risk management decisions and supporting documents for iodine, the Agency will implement a 60-day public comment period on this RED document. A notice announcing the availability of this RED and the start of the public comment period will be published in the Federal Register.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to iodine. This conclusion is based on the results of toxicity testing of iodine and iodophor complexes in which dose levels near or above testing limits (as established in the OPPTS 870 series harmonized test guidelines) were employed in experimental animal studies and no significant toxicity observed. The Agency

has concluded that the exemption from the requirement for a tolerance is appropriate and is considered reassessed as required by FQPA. An aggregate assessment was not conducted for exposures through food, drinking water and residential exposure since toxicological endpoints for risk assessment were not identified based on the available data. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to iodine and iodophor complexes based on the low toxicity observed in studies conducted at or below the established testing limit doses. The Agency has determined that the established exemption from the requirement for a tolerance for iodine and iodophor complexes meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of iodine. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of iodine.

Because no toxicological endpoints were identified for iodine, the Agency has determined that exposure to it does not result in human health effects of concern. Therefore a quantitative risk assessment was not necessary for this pesticide.

c. Determination of Safety to Infants and Children

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

In determining whether or not infants and children are particularly susceptible to toxic effects from iodine and iodophor complexes residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for iodine and iodophor complexes because there is no pre- or post-natal evidence for increased susceptibility following exposure.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring

estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 EDSP have been developed, iodine and iodophor complexes may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

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

2. Tolerance Summary

The tolerance exemption for residues of iodine and iodophor complexes *per se* is established under 40 CFR 180.940 (69 FR 23124, Apr.28, 2004).

Tolerance Exemptions/Reassessment

Ten tolerance exemptions exist for iodine and iodophor complexes when used as ingredients in antimicrobial pesticide formulations under 40 CFR 180.940:

Table 3. Tolerance Exemptions in 180.940, 40 CFR			
Tolerance Exemption Expression	**CAS No.**	**40 CFR**	**Limits**
Iodine	7553-56-2	180.940(a)(b)(c)	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Potassium Iodide	7681-11-0	180.940(a)(b)(c)	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Sodium Iodide	7681-82-5	180.940(c)	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Hydriodic Acid	10034-85-2	180.940(b)(c)	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine

Residues of chemical substances listed in Sec.180.940 are exempt from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the chemical substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. Under 180.940 (a) (b) (c), chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to (a) food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils; (b) dairy processing equipment, and food-processing equipment and utensils, and (c) food-processing equipment and utensils.

In addition, the following exemption is listed in 180.1022:

180.1022 Iodine-detergent complex; exemption from the requirement of a tolerance.

"The aqueous solution of hydriodic acid and elemental iodine, including one or both of the surfactants (a) polyoxypropylene-polyoxyethylene glycol nonionic block polymers (minimum average molecular weight 1,900) and (b) % -(p- nonylphenyl)-omega- hydroxypoly (oxyethylene) having a maximum average molecular weight of 748 and in which the nonyl group is a propylene trimer isomer, is exempted from the requirement of a tolerance for residues in eggs and poultry when used as a sanitizer in poultry drinking water."

The Agency considers the ten tolerances for iodine, potassium iodide, sodium iodide and hydriodic acid reassessed.

or critical habitat and therefore makes a "no effect" determination for this chemical. Based on the indoor use patterns of iodine and iodophor complexes, minimal environmental exposure is expected, and, therefore, no ecological risk is anticipated.

b. General Risk Mitigation

Iodine and iodophor complex end-use products (EUPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing iodine and iodophor complexes specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need To Do

The Agency has determined that iodine and iodophor complexes are eligible for reregistration. No additional generic data are required at this time to support this decision.

For end-use products containing the active ingredient iodine or iodophor complexes, the registrants need to submit the following items for each product:

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

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

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

Within eight months from the receipt of the PDCI:

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

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

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

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

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

Please contact Marshall Swindell at (703) 308-6341 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
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing-Use Products

There are no currently registered iodine and iodophor complexes manufacturing-use products.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of iodine and iodophor complexes for the above eligible uses has been reviewed and determined to be substantially complete. Therefore at this time, there are no generic data requirements.

B. End-Use Products

1. Additional Product-Specific and Efficacy 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. Registrants 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 data requirements, will be sent to registrants at a later date. Possible efficacy studies that the Agency may call-in are listed in Table 4. The PDCI will be based upon current efficacy-related requirements for antimicrobial pesticide products, claims, or patterns of use. A summary of these requirements can be found on the Agency's Antimicrobials Science Policy website at http://www.epa.gov/oppad001/sciencepolicy.htm.

Table 4. Efficacy Data Requirements for Product Reregistration

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Sanitizer	(non-food contact surfaces – non-residual)	Sanitizer Test for Hard Inanimate Non—food contact surfaces	810.2100(l)	91-2(j)
Sanitizer	previously cleaned food-contact surfaces (non residual)	AOAC Germicidal and Detergent Sanitizers Method	810.2100 (m)(2)	91-2 (l)(2)
Disinfectant	Hard Inanimate Surfaces	AOAC Use Dilution Test (hard water and organic soil) Or AOAC Germicidal Spray Test Or AOAC Hard Surface Carrier Test (distilled water only)	810.2100 (c), (d), (e),	91-2 (b), (c) (d)
Disinfectant	Toilet bowl, urinal surfaces	AOAC Use Dilution Test (hard water and organic soil) Or AOAC Germicidal Spray Test Or AOAC Hard Surface Carrier Test (distilled water only)	91-7 (a) (1)	810.2600 (b) (1)
Disinfectant	Human drinking water; emergency water supplies	EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers or Controlled or Simulated In-Use Study	810.2700 (b) (1)	91-8 (a) (2)
Water Purification Claim	Water treatment units including Emergency water supplies	EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers	810.2700 (b)(2), (b)(3)	91-1 (a)(2), (a)(3), 91-8 (a) (2)
Virucidal Claim in Conjunction with Disinfectant Claim	Any site/application	Virucidal Activity Method used in conjunction with modifications of: AOAC Hard Surface Carrier Test (distilled water only) Or AOAC Germicidal Spray Test	810.2100(g)	91-2(f)

Fungicidal Claim	Any site/application	AOAC Fungicidal Test or AOAC Hard Surface Carrier Test (distilled water only) Or AOAC Germicidal Spray Products Test	810.2100(f)	91-2(e)
Tuberculocidal Claim	Any site/application	AOAC Tuberculocidal Activity Test Method (standard) Or AOAC Tuberculocidal Activity of Disinfectants Test Method (modified) Or Quantitative Tuberculocidal Activity Test Method Or AOAC Germicidal Spray Products Test (modified for spray products)	810.2100(h)	91-2 (g)

VI. APPENDICES

Appendix A: Use Patterns Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Farm Premises, Poultry Houses, Livestock Barns & Premises. Transportation Vehicles (Hard non-porous surfaces)	Soluble Concentrate (reg no. 875-97) (reg no. 4959-15) (reg no. 67517-9) (reg no. 66171-6) (reg no. 34052-10) (reg no. 71654-15) (reg no. 66171-10) (reg no. 6836-81) (reg no. 47371-93) (reg no. 47371-26)	Spray, mop cloth, sponge	½ oz per gallon of water 10 minute contact time 136 ppm 1:500 gallons (52 ppm) 68 ppm	Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water.
Farm Equipment	Soluble Concentrate (reg no. 66171-6) (reg no. 47371-26) (reg no. 47371-93)	Immersion	68 ppm 5:100 gallons 1:256 gallons (1.75%)	Not stated
Shoe Bath	Soluble Concentrate (reg no. 875-97) (reg no. 4959-15) (reg no. 67517-9)	Immersion	3 oz per gallon of water immerse for 30 seconds 272 ppm	None stated

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 52-254) (reg no. 71654-15)		50 ppm	
Mushroom Houses (Food Contact Surfaces)	Soluble Concentrate (reg. no 1677-89) (reg no. 67517-9) (reg no. 67517-30)	Spray	1 oz solution/13 gallons of water (25 ppm for food contact) spray for 2 minutes (75 – 100 ppm non-food contact surfaces)	Pre-clean to sanitize
Poultry Drinking Water	Crystalline, Impregnated materials (reg. no. 73158-1) (reg no. 1677-89) (reg no 875-97) (reg no. 66171-6) (reg no. 71654-15) (reg no. 6836-81) (reg no. 66171-8) (reg no. 47371-93) (reg no. 47371-26)	metered	12.5 mg/L of iodine in reconstituted drinking water to 300 mg/L of iodine Change recharge canister when iodine and iodophor complexes levels fall below 2mg/L 1 ounce solution/ 52 gallons water 6 ppm. 1 oz per 10 gallons of water	Not stated

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Egg Shell	Soluble Concentrate (reg. no. 875-183) (reg no 875-97) (reg no. 66171-10)	Not specified	1fl. ounce in 9 gallons of warm water (25ppm), thoroughly wet number of applications not stated.	Potable water rinse only if eggs are broken immediately
Dairy Farms – Udders/ Milking Equipment	Soluble Concentrate (reg no. 1677-89) (reg no. 1677-58) (reg no. 4959-48) (reg no. 4959-23) (reg no. 1317-87) (reg no 1317-68) (reg no. 6836-81) (reg no. 71654-15) (reg no. 8405-3) (reg no. 3862-18) (reg no. 1072-11) (reg no. 4959-21) (reg no. 4959-9) (reg no. 52-254) (reg no. 47371-26)	Spray or wash with paper towels	25 ppm titratable iodine solution	Do not re-use solution. Do not dip used towel back into sanitizing solution. Avoid contamination of sanitizing solution by dirt and soil.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Food handling/storage establishments premises and equipment				
Hand Sanitizer (food handling and meat cutting operations)	Soluble Concentrate (reg no. 875-97) (reg no. 4959-16) (reg no. 71654-15) (reg no. 66171-10)	Immersion	1 oz per 5 gallons of water 25 ppm.	None stated
Eating Establishments Premises (floors, walls, countertops)	Soluble Concentrate (reg no. 4959-27) (reg no. 67517-20) (reg no. 67517-9) (ren no. 4959-15) (ren no. 4959-16) (reg no. 34052-10) (reg no. 3862-18) (reg no. 47371-93)	Mop, cloth	23-25 ppm titratable iodine solution 68 ppm tiratable iodine	None stated
Egg Processing Plants/ hatcheries	Soluble Concentrate (reg no. 6836-195) (reg no 875-97) (reg no. 4959-15) (reg no. 4959-36) (reg no. 66171-8)	Mop, brush, sponge, cloth	50 ppm to clean 25 ppm to sanitize after preclean thoroughly wet	Industrial use only

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 875-183)			
Beverage Processing Equipment	Soluble Concentrate (reg no. 875-183) (reg no. 4959-36) (reg no. 66171-8) (reg no. 47371-26) (reg no. 47371-93)	Flood, coarse Spray, mop or immersion	12.5 ppm to 25 ppm thoroughly wet all surfaces. Allow surfaces to drain and air dry number of applications not stated.	Do not reuse circulated sanitizer for additional sanitizing.
Beverage Plant Premises & Equipment (non-food contact)	Soluble Concentrate (reg no. 4958-38) (reg no. 4959-36) (reg no. 4959-48) (reg no. 67517-20) (ren no. 875-188) (reg no. 4959-18)	Spray	1 oz. per 13 gallons of water 1 minute contact time may be used continuously 25 ppm	For Industrial use only.
Brewery Processing Equipment, (Storage tanks, bottles, cans)	Soluble Concentrate (reg no. 4959-38) (reg no. 4959-36) (reg no. 4959-48) (re no. 52-254)	Spray Automated cleaning systems	25 ppm 1 minute contact time 8 – 12 ppm	For industrial use only.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	reg no. 66171-8) (reg no. 47371-93) (reg no. 47371-26)			
Meat / Poultry Processing Equipment (Frozen and Fresh Pack)	Soluble Concentrate (reg no. 875-183) (reg no 1677-89) (reg no. 1677-58) (reg no. 6836-195) (reg no. 4959-36) (reg no. 66171-10) (reg no. 3862-18) (reg no. 1317-87)	Flood, coarse Spray, mop or immersion	12.5 ppm to 25 ppm thoroughly wet all surfaces. Allow surfaces to drain and air dry 50 ppm (Initial Clean) 25 ppm (after preclean) rinse with potable water	Do not reuse circulated sanitizer for additional sanitizing.
Food Processing Equipment	Soluble Concentrate Emulsifiable Concentrate (reg no. 875-183) (reg no. 875-97) (reg no. 4959-15) (reg no. 66171-6) (reg no. 71654-15) (reg no. 66171-10) (reg no. 1317-68) (reg no. 1317-87)	Flood, coarse Spray, mop or immersion	12.5 ppm to 25 ppm thoroughly wet all surfaces. Allow surfaces to drain and air dry 5.50 to 6 ppm (2 minute exposure time)	Do not reuse circulated sanitizer for additional sanitizing.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 3862-18) (reg no. 5991-7) (reg no. 61181-2) (reg no 66171-8) (reg no. 1317-87) (reg no. 47371-93)			
Milk, and Ice Cream Processing Plants Fruit Processing Plants	Soluble Concentrate (reg no. 6836-195) (reg no. 66171-8) (reg no. 4959-48) (reg no. 47371-93)	Spray	25 ppm	None stated
Dairy Processing Equipment	Soluble Concentrate (reg no. 1677-58) (reg no. 1317-68) (reg no. 8405-3) (reg no. 5991-7)	Immersion, spray	12.5 ppm to sanitize 75 ppm to disinfect.	Prepared solutions may not be reused for sanitizing but may be reused for other purposes such as cleaning
Mess gear	Soluble Concentrate (reg no 40510-1)	Not specified	One solution: 300 mg/l of iodine and iodophor complexes to treat 25	One solution per 100 mess kits

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			gallons of water Rinse twice in disinfectant solution	
Fruits and Vegetables	Soluble Concentrate (reg no. 40150-1)	immersion	380 mg/l of iodine in 20 gallons of water. Immersion for 10 minutes	After immersion, rinse with potable water
Food Contact surfaces – Kitchens & Lunchrooms (Hard non porous)	Soluble Concentrate (reg no. 1677-22) (reg no. 4959-15) (reg no. 4959-16) (reg no. 875-188) (reg no. 66171-10) (reg no. 1317-87) (reg no. 6198-12)	Cloth, mop or spray	½ oz. per ½ gallons of 75-100 degree water (25ppm)	Pre-clean. Not recommended for use on silver and silverplate
Eating, Drinking and Food Prep Utensils	Soluble Concentrate (reg no. 1677-22) (reg no. 881-10) (reg no. 6198-12) (reg no. 875-97)	Immersion	½ oz. to 2 ½ gallons of water. (12.5 - 25 ppm titratable iodine) immerse 1- 2 minutes or contact time specified by governing sanitizing code	Remove gross food particles by prescrape, preflush and when necessary. Presoak. Rinse with clear water. Air Dry.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 875-188) (reg no. 7546-13) (reg no. 4959-27) (reg no. 4959-16) (reg no. 881-10) (reg no. 67517-20) (reg no. 66171-10) (reg no. 5991-7) (reg no. 61181-2)		Renew application before amber color disappears.	
Retort Cooling Water	Soluble Concentrate (reg no. 875-97) (reg no. 4959-36) (reg no. 71654-15) (reg no. 34052-10)	Metered	1 oz per 5-10 gallons of retort water 12-25 ppm	None stated
Commercial, institutional and industrial premises and equipment				
Schools, Institutions – Hard Nonporous surfaces (walls, floors, countertops, tables chairs.)	Soluble Concentrate (reg no. 875-97) (ren no. 4959-16) (reg no. 4959-34) (reg no. 34052-10) (reg no. 66171-10) (reg no. 6836-81)	Cloth, mop, spray, sponge	½ oz per gallon of water 68 ppm	Preclean heavily soiled areas.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Veterinary Clinics – Hard Nonporous surfaces (walls, floors, countertops, tables chairs.)	Soluble Concentrate (reg no. 875-97) (reg no. 34052-10) (reg no. 71654-15)	Cloth, mop, spray, sponge	½ oz per gallon of water 68ppm	Preclean heavily soiled areas.
Zoos	Soluble Concentrate (reg no. 66171-6)	Spray	5:100 gallons of water (42 ppm)	Remove animals and feed from premises to assure surface coverage.
Kennels & Pet Shops	Soluble Concentrate (reg no. 4959-15) (reg no. 61181-1) (reg no 4959-34)	Mop, sponge, brush, immersion	3 ounces per 5 gallons of water 100 ppm	Remove all litter and manure from floors, walls and all surfaces to be treated. Empty all troughs, racks and other feeding and watering appliances
Bathroom Premises – toilet Bowls and Urinals	Soluble Concentrate (reg no. 34052-10) (reg no. 4959-16) (reg no. 71654-15) (reg no. 66171-10)	Brush	1 oz . to bowl. Allow to remain for 10 minutes	Pre-flush, rinse metal parts with water after disinfecting to prevent corrosion.
Laboratory Equipment	Soluble Concentrate (reg no. 52-254)	Spray, flush, sponge, immersion	25 ppm	Not stated
Garbage Pails, Refuse Containers	Soluble Concentrate	Swab, brush, mop or flood	1 oz per gallon of water	Not stated

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 71654-15)			
HVAC System	Soluble Concentrate (reg no. 59682-5)	Mechanical sprayer, mops, sponge, brush	8 oz to 2/1 gallons Allow 10 minutes contact time	Not Stated
Residential and public access premises				
Hard Surfaces	Ready-to-use Solution (reg no. 61181-2)	Spray	None stated	None stated
Medical premises and equipment				
Hospital/Medical Institutions Non-critical Premises	Impregnated Material (reg no. 74245-5)	Cartridge installation in pick-up tube in bottle water system by a dental technician	Prior to daily use wash the inside of the bottle and rinse thoroughly; wipe down the outside of the cartridge, and make sure intake end is not obstructed	Change cartridge after 40 liters of water usage or 60 calendar days after installation; adhere to CDC/ADA guidelines for aseptic procedures including a 2 minute morning flush, a 20-30 second flush between patients and hand piece sterilization
Hospital Hard non porous surfaces (critical and non critical premises)	Soluble Concentrate (reg no. 1677-22) (reg no. 34052-10)	Cloth, mop or spray	2/3 oz per gallon of water. (75 ppm titratable iodine) 68 ppm wet surface 10 minute contact time Mix fresh solution when amber color fades	Remove heavy soil or gross filth prior to disinfection

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(reg no. 67517-20) (reg no. 61181-1) (reg no. 61181-2) (reg no. 71654-15) (reg no. 66171-10) (reg no. 6836-81)		noticeably. ½ oz per gallon of water 23 ppm 150 ppm	
Human drinking water systems				
Human Drinking Water	Crystalline (reg. 50233-1)	Add solution to water	2000 quarts of drinking water per bottle 1 application per container of water.	Do not reuse bottle.
	Pelleted/ Tableted (reg no. 40510-3) (reg no. 79533-1)	Add tablets to water and shake	Two 8 mg tablets per one quart of water One application per canteen	Wait 30 min. before drinking. Only use when water is of questionable quality or known to be substandard. Not to be used on a continuous basis
	Impregnated Materials (reg no. 39444-12) (reg no. 54625-2)	filtration	1 tablet per quart of water/1 filter per 35 gallons or replace filter every 2 months	Not Stated
Materials preservatives				
Paints, stains, coating systems	Wettable Powder (reg. no. 72897-2)	Incorporated during manufacturing process	Add at levels between 20% and 30% (wt/wt). more may be required in hot, humid areas, where	Not for use in HVAC filters or products that come into contact with food. Finished products may not make public health claims relating to antimicrobial activity

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			mildew is particularly severe.	without first obtaining the necessary regulatory approvals.
Synthetic and non-woven textile materials (vacuum bags, air filters, door mats, awnings)	Wettable Powder (reg no. 72897-2)	Incorporated during manufacturing process	Add at levels between 12.5% and 45% (wt/wt) of the laminate.	Not for use in HVAC filters or products that come into contact with food. Finished products may not make public health claims relating to antimicrobial activity without first obtaining the necessary regulatory approvals.
Absorbent Clays	Soluble Concentrate (reg no. 47371-158)	Not stated	0.2 lbs of titratable iodine per 2,000 lbs. of clay 15-16 lbs. of 1.28 titratable iodine solution per 2,000 lbs of clay	None stated
Industrial processes and water systems				
Cooling Tower Water, Evaporative Condensers and fluid coolers	Soluble Concentrate (reg no. 82097-1)	Metered.	Replace canister once per year.	Do not use this product with air washers or direct air washers or direct evaporative coolers
Cooling Water systems	Impregnated Materials (reg no. 72897-3) (reg no. 82097-1)	Metered	1 gal every 4 minutes for 7 hours for 100 gallon tank 2- 4 times a month	Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans or other waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority.

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide To Appendix B

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

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

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

(1) Agricultural premises and equipment
(2) Food handling/ storage establishments premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(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 identify 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	2,3,4,5	43952701; 43955101; 42326701; 41333201; 43611801; 43918901; 43911001; 41808501; 43911701; 44059101; 43911601; 43919201; 43955101; 43966701; 44007701; 44011201; 43976701; 43979601; 43996601; 43916601; 44007801; 43919101; 43918001
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	2,3,4,5	43952701; 43955101; 43412002; 43919001; 43611801; 41559101; 41808501; 43911701; 44059101; 43911601; 43919201; 43976701; 43916601; 44007801; 43919101; 43952701; 43966701; 41968701; 43918901
830.1670	61-2B	Formation of Impurities	2,3,4,5	43952701; 43955101; 42326701; 43919001; 43611801; 41559101; 41808501; 43952701; 43911701; 44059101; 43911601; 43919201; 43911701; 43966701; 44007701; 44011201; 43976701; 43979601; 43996601; 43916601; 44007801; 43919101; 41968701; 43918001;

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
				42440101; 43918901
830.1700	62-1	Preliminary Analysis	2,3,4,5	43952701; 43955102; 42326702; 43919002; 43611801; 41559102; 41808501; 43911701; 43966301; 43911602; 43919202; 43911702; 43955102; 43966702; 44007702; 44011202; 43976702; 43979602; 43955102; 43996601; 43916602; 44007801; 43919102; 43966301; 43952701; 43966702; 42749901; 43918002; 42440101; 43918902
830.1750	62-2	Certification of Limits	2,3,4,5	43952701; 43955102; 43919002; 43611801; 43911002; 41808501; 43911702; 43966301; 43911602; 43919202; 43966702; 44007702; 43976702; 43996601; 43916602; 44007801; 43911602; 43919102; 43952701; 43911701; 43918002; 42440101; 43918902
830.1800	62-3	Analytical Method	2,3,4,5	43952701; 43955102; 42326702; 43919002; 43611801; 41808501; 43911702; 43966301; 43911602; 43919202; 43966702; 44007702; 44011202; 41647502; 43976702;

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
				43996601; 43916602; 44007801; 43919102; 43952701; 42749901; 43918002; 42440101; 43918902
830.6302	63-2	Color	2,3,4,5	43952701; 43955103; 42326703; 41333201; 43919003; 43611801; 41559103; 43911003; 41808501; 44059102; 44007703; 44011203; 43976703; 44059102; 41333201; 41968702; 43918004; 42440101; 43918903
830.6303	63-3	Physical State	2,3,4,5	42326703; 41333201; 43611801; 41559103; 43911003; 41808501; 43911703; 43952701; 44059102; 43911603; 43919203; 43955103; 43966703; 44007703; 44011203; 43996601; 43916603; 44007801; 43919103; 43952701; 41333201; 41968702; 43918004
830.6304	63-4	Odor	2,3,4,5	43952701; 43955103; 42326703; 41333201; 43919003; 41559103; 43911003; 41808501; 43911703; 44059102; 43911603; 43919203; 43955103; 43966703; 44007703; 44011203; 43976703; 43996601;

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
				43916603; 44007801; 43919103; 43952701; 43911703; 41333201; 42440101; 43918903
830.7200	63-5	Melting Point	2,3,4,5	43952701; 43955103; 42326703; 41333201; 43919003; 43611801; 41808501; 43911703; 44059102; 43911603; 43919203; 43966703; 44007703; 44011203; 43996601; 43916603; 44007801; 43919103; 43952701; 43955103; 43966703; 41968702; 43918004; 42440101; 43918903
830.7220	63-6	Boiling Point	2,3,4,5	Not Required
830.7300	63-7	Density	2,3,4,5	43952701; 43955103; 42326703; 41333201; 43919003; 43611801; 41559103; 43911003; 41808501; 43911703; 44059102; 43911603; 43919203; 43966703; 41647503; 43996601; 43916603; 44007801; 43919103; 44059102; 43952701; 41968702; 43918004; 42440101; 43918903
830.7840 830.7860	63-8	Solubility	2,3,4,5	43952701; 43955103; 43412001; 41333201; 43919003; 43611801;

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
				41808501; 43911703; 44059102; 43911603; 43919203; 43966703; 44007703; 44011203; 43976703; 43996601; 43916603; 44007801; 43919103; 43952701; 43918004; 43918903
830.7950	63-9	Vapor Pressure	2,3,4,5	43952701; 43955103; 43412001; 41333201; 43919003; 43611801; 43911003; 41808501; 43911703; 44059102; 43911603; 43919203; 43966703; 44007703; 44011203; 43976703; 43955103; 43996601; 43916603; 44007801; 43919103; 44059102; 42440101; 41968702; 43918004; 43918903
830.7370	63-10	Dissociation Constant in Water	2,3,4,5	Not Required
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	2,3,4,5	Not Required
830.7000	63-12	pH	2,3,4,5	Not Required
830.6313	63-13	Stability	2,3,4,5	43952701; 43955103; 43752101; 43919003; 43611801; 43911003; 41808501; 43911703; 43952701;;

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
				43919203; 43966703; 44007703; 44011203; 41647503; 43996601; 43916603; 44007801; 43911603; 43919103; 44059102; 43955103; 43918004; 43918903
830.6314	63-14	Oxidizing/Reducing Action	2,3,4,5	Not Required
830.6315	63-15	Flammability	2,3,4,5	Not Required
830.6316	63-16	Explodability	2,3,4,5	Not Required
830.6317	63-17	Storage Stability	2,3,4,5	Not Required
830.7100	63-18	Viscosity	2,3,4,5	Not Required
830.6319	63-19	Miscibility	2,3,4,5	Not Required
830.6320	63-20	Corrosion Characteristics	2,3,4,5	Not Required
830.6321	63-21	Dielectric breakdown voltage	2,3,4,5	Not Required
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity Test – Quail	2,3,4,5	43138401
	71-2A	Avian Acute Dietary - Quail	2,3,4,5	43191701
850.1075	72-1C	Fish Acute Toxicity – Bluegill sunfish or Rainbow trout	2,3,4,5	43044501
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity – Daphnia Magna	2,3,4,5	42961001

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
		TOXICOLOGY		
870.1100	81-1	Acute Oral – Rat	2,3,4,5	42326704; 40937801; 43736601
870.1200	81-2	Acute Dermal – Rabbit	2,3,4,5	42326705; 43736601; 43766401; 40937801; 43736001
870.1300	81-3	Acute Inhalation – Rat	2,3,4,5	42961002; 40937801
870.2400	81-4	Acute Eye Irritation – Rabbit	2,3,4,5	40937801; 42421501; 43736601;
870.2500	81-5	Acute Skin Irritation – Rabbit	2,3,4,5	42326706; 42421501; 40937801;
870.2600	81-6	Dermal Sensitization- guinea pig	2,3,4,5	42326707; 42421501; 43736601; 40937801
870.3100	82-1a	90-Day Feeding - nonrodent	2,3,4,5	43736601; 43736603; 43736604; 43766403; 43766402; 40937801
870.3150	82-1b	90-Day Oral Subchronic -rodent	2,3,4,5	Waived
870.3250	82-3*	90-Day Dermal Subchronic - rodent	2,3,4,5	40937801
870.3465	82-4*	90-Day Subchronic Inhalation	2,3,4,5	Waived
870.4100	83-1a	Chronic Toxicity - rat	2,3,4,5	Waived
870.4100	83-1b	Chronic Toxicity - non-rodent	2,3,4,5	Waived
	83-2a	Oncogenicity-rat	2,3,4,5	Waived

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
	83-2b	Oncogenicity-mouse	2,3,4,5	Waived
870.3700	83-3a	Prenatal Developmental Toxicity - Rat	2,3,4,5	43736610
870.3700	83-3b	Prenatal Developmental Toxicity - Rabbit	2,3,4,5	Waived
870.3800	83-4**	Reproduction and fertility effects - Rat	2,3,4,5	Waived
870.5100	84-2a	Bacterial Reverse Mutation Test	2,3,4,5	40937801; 42421501
870.5300	84-2b	In Vitro Mammalian Chromosome Aberration Test	2,3,4,5	42421501; 43736613
	84-4	Other genotoxic effects	2,3,4,5	43551801
870.7600	85-2	Dermal penetration	2,3,4,5	Waived
870.7485	85-1	Metabolism and Pharmocokinetics	2,3,4,5	Waived
*For guidelines 82-3 and 82-4, at least one is required to be fulfilled; not both (for both food and non-food uses). **Only required for food use.				
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of Parent and Degradates	2,3,4,5	Not Required

Please Note: Although the Open Literature studies do not satisfy any of the Agency's testing guideline requirements, this information is considered adequate for characterizing the potential hazard from exposure to IODINE. Therefore, no additional mammalian toxicity data will be required at this time.

Appendix D. Bibliography Citations

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http://www.inchem.org/documents/pims/pharm/iodine.htm)

http://www.chemfinder.com

MRIDs

MRID 134104. Fink, R.; Beavers, J.; Grimes, J.; et al. (1978) Eight-day Dietary LC50 ?in| Mallard Duck: Biopal NR-20: Project No. 164-102. Final rept. (Unpublished study received Mar 22, 1979; Feb 6, 1979 under 1529-18; prepared by Wildlife Internationl, Ltd. and Washington College, submitted by GAF Corp., Chemical Div., New York, NY; CDL:237871-C)

MRID 134576. Fink, R.; Beavers, J.; Brown, R. (1978) Eight-day Dietary LC50-- Bobwhite Quail: Biopal NR-20: Project No. 164-101. Final rept. (Unpublished study received Mar 22, 1979 under 1529-18; pre- pared by Wildlife International, Ltd. and Washington College, submitted by GAF Corp., Chemical Div., New York, NY; CDL: 237871-A)

MRID 134577. Fink, R.; Beavers, J.; Grimes, J.; et al. (1978) Acute Oral LD50-- Bobwhite Quail: Biopal NR-20: Project No. 164-103. Final rept. (Unpublished study received Mar 22, 1979 under 1529-18; pre- pared by Wildlife International, Ltd. and Washington College, submitted by GAF Corp., Chemical Div., New York, NY; CDL: 237871-B)

MRID 42328301. Pedersen, C.A. 1991. Tetraglycine Hydroperiodide: 21-day Acute Oral LD50 Studt in Bobwhite Quail. Unpublished data. Conducted by Bio-Life Associates for the U.S. Army Natick Research Development and Engineering Center.

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MRID 42961001. Zelinka, E.A., C.M. Holmes, K.H. Martin, and J.P. Swigert. 1993. A 48-hour Flow-through Acute Toxicity Test with the Cladoceran (*Daphnia magna*). Unpublished data. Conducted by Wildlife International for the Baltimore Aircoil Company.

MRID 43138401. Campbell, S.M. and J.B. Beavers. 1994. IOBIO: An Acute Oral Toxicity Study with the Northern Bobwhite. Unpublished data. Conducted by Wildlife International for the Baltimore Aircoil Company.

MRID 43191701. Campbell, S.M., and J. B. Beavers. 1994. IOBIO: A Dietary LC50 Study with the Northern Bobwhite. Unpublished data. Conducted by Wildlife International for the Baltimore Aircoil Company.

Appendix E. Generic Data Call-In

The Agency does not intend to issue a Generic Data Call-In at this time.

Appendix F. Product Specific Data Call-In

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

Appendix G. Batching of End-Use Products

EPA's Batching of *Iodine, KI* 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 active ingredients in the Reregistration Case *Iodine, KI*, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular), and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar," since they may not have similar use patterns.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see partial list of acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. The Agency must approve any new or canceled formulations (that were presented to the Agency after the completion of the RED) before data derived from them can be used to cover other products in a batch. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

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

whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

67 registered products were found which contain any of the active ingredients in the *Iodine, KI* Reregistration Case. Each of the 67 products contains iodine, potassium iodide, or an iodophor as an active ingredient. These products have been placed into nine primary batches, three sub-batches, and a "No Batch" category, in accordance with the active and inert ingredients and type of formulation. Any product in a batch may cite new or previously submitted acute toxicity data (if it meets current Agency standards) from any other product in the same batch, *except* as specified below:

- In Batch 2, each product must cite its own eye irritation data (or, if product is entirely a repackaging of another Batch 2 product, the source product's eye irritation data may be cited) .

- In Batch 3A, each product must cite its own eye irritation data (Batch 3A products otherwise are free to cite data from other Batch 3A or 3B products).

- In Batch 3B:
  -Each Batch 3B product must cite its own eye irritation data.
  -Batch 3B products may not cite skin irritation data from Batch 3A products.
  -Batch 3B products may not cite Reg. No. 66171-9 skin irritation data – and 66171-9 may not cite theirs – if the study result is in Toxicity Category IV.
  -Batch 3B products otherwise are free to cite data from other Batch 3B or 3A products.

- In Batch 4A, each product must cite its own eye irritation and skin irritation data. Batch 4A products may not cite data from Batch 4B products.

- In Batch 4B, each product must cite its own eye irritation and skin irritation data (Batch 4B products otherwise are free to cite data from other Batch 4B or 4A products).

- In Batch 5A, products may not cite data from Batch 5B products.
- In Batch 5B, however, products are free to cite data from Batch 5A products.
- In Batch 6, each product must cite its own eye irritation and skin irritation data, except as specified in the note underneath the Batch 6 table below.
- In Batch 9, EPA Reg. No. 61181-1 and 61181-2 must each cite its own eye irritation data.

In the No Batch category, each product must cite its own data. I.e., registrants of these products may only cite data obtained from the specific product itself to support the acute toxicity data requirements for that product.

Note: If the pH of undiluted product is less than 2, a request for waiver of eye and/or skin irritation data will be granted if the product label bears the applicable human-hazard wording for potential irritation/corrosion effects. This wording includes, but is not limited to, the signal word *DANGER* and, for eye effects, the word *Corrosive*.

In these tables, as in the body of the RED document, the term "complex" is used in reference to an iodophor rather than a true chemical complex.

Batch 1	EPA Reg. No.	Iodine Source
Each Batch 1 product may cite (its own data or) data from any other Batch 1 product.	50233-1	Iodine, elemental
	73158-1	Iodine, elemental
	82097-1	Iodine, elemental

Batch 2	EPA Reg. No.	Iodine Source
Each Batch 2 product must cite its own eye irritation data. (Or, if product is entirely a repackaging of another Batch 2 product, the source product's eye irritation data may be cited.) Batch 2 products otherwise are free to cite data from other Batch 2 products.	35917-2	Iodine bound to solid polymeric material
	39444-12	Iodine bound to solid polymeric material
	59454-2	Iodine bound to solid polymeric material
	72897-1	Iodine bound to solid polymeric material
	72897-2	Iodine bound to solid polymeric material
	72897-3	Iodine bound to solid polymeric material
	74245-5	Iodine bound to solid polymeric material
	74473-1	Iodine bound to solid polymeric material
	74473-2	Iodine bound to solid polymeric material

Batch 3A	EPA Reg. No.	Iodine Source
Each Batch 3A product must cite its own eye irritation data. Batch 3A products otherwise are free to cite data from other Batch 3A or 3B products.	1072-19	Surfactant-iodine complex
	9768-47	Surfactant-iodine complex
	46183-13	Surfactant-iodine complex

Batch 3B	EPA Reg. No.	Iodine Source
Each Batch 3B product must cite its own eye irritation data. Batch 3B products may not cite skin irritation data from Batch 3A products. Batch 3B products may not cite Reg. No. 66171-9 skin irritation data – and 66171-9 may not cite theirs – if the study result is in Toxicity Category IV. Batch 3B products otherwise are free to cite data from other Batch 3B or 3A products.	4959-13	Surfactant-iodine complex
	9152-23	Surfactant-iodine complex
	66171-9	Surfactant-iodine complex
	66171-11	Surfactant-iodine complex

Batch 4A	EPA Reg. No.	Iodine Source
Each Batch 4A product must cite its own eye irritation and skin irritation data. Batch 4A products otherwise are free to cite data from other Batch 4A products. However, Batch 4A products may not cite data from Batch 4B products.	1317-87	Surfactant-iodine complex
	1677-89	Surfactant-iodine complex
	4959-36	Surfactant-iodine complex
	4959-48	Surfactant-iodine complex
	6836-195	Surfactant-iodine complex
	66171-8	Surfactant-iodine complex

Batch 4B	EPA Reg. No.	Iodine Source
Each Batch 4B product must cite its own eye irritation and skin irritation data. Batch 4B products otherwise are free to cite data from other Batch 4B or 4A products.	875-97	Surfactant-iodine complex
	4959-15	Surfactant-iodine complex
	4959-16	Surfactant-iodine complex
	4959-23	Surfactant-iodine complex
	6836-81	Surfactant-iodine complex
	8405-3	Surfactant-iodine complex
	34052-10	Surfactant-iodine complex
	66171-10	Surfactant-iodine complex
	71654-15	Surfactant-iodine complex

Batch 5A	EPA Reg. No.	Iodine Source
Batch 5A products may cite data from other Batch 5A products but not from Batch 5B products.	3862-18	Surfactant-iodine complex
	4959-21	Surfactant-iodine complex
	7546-13	Surfactant-iodine complex
	67517-9	Surfactant-iodine complex
	67517-20	Surfactant-iodine complex
	67517-30	Surfactant-iodine complex

Batch 5B	EPA Reg. No.	Iodine Source
Batch 5B products may cite data from other Batch 5B or 5A products.	47371-26	Surfactant-iodine complex
	47371-93	Surfactant-iodine complex

Batch 6	EPA Reg. No.	Iodine Source
Each Batch 6 product must cite its own eye irritation and skin irritation data, except as specified below.* Batch 6 products otherwise are free to cite data from other Batch 6 products.	875-188	Surfactant-iodine complex
	881-10	Surfactant-iodine complex
	4959-18	Surfactant-iodine complex
	4959-27	Surfactant-iodine complex
	6198-12	Surfactant-iodine complex
	47371-158	Surfactant-iodine complex

*Reg. No[s]. 4959-18 and 4959-27 may cite each other's skin irritation data if the study result is *not* in Toxicity Category IV. Reg. No[s]. 881-10 and 6198-12 also may cite each other's skin irritation data if the study result is *not* in Toxicity Category IV.

Batch 7	EPA Reg. No.	Iodine Source
Each Batch 7 product may cite (its own data or) data from any other Batch 7 product.	4959-34	Surfactant-iodine complex
	59682-5	Surfactant-iodine complex

Batch 8	EPA Reg. No.	Iodine Source
Each Batch 8 product may cite (its own data or) data from any other Batch 8 product.	40510-3	Tetraglycine hydroperiodide
	54625-2*	Tetraglycine hydroperiodide
	79533-1	Tetraglycine hydroperiodide

*Reg. No. 54625-2 is a two-part product. Its placement into Batch 8 affects only the part – the sub-package – that contains the tetraglycine hydroperiodide. Acute toxicity data is required for each of the two parts.

Batch 9	EPA Reg. No.	Iodine Source
Reg. No. 61181-1 and 61181-2 must each cite its own eye irritation data. Batch 9 products otherwise are free to cite data from other Batch 9 products.	1072-11	Surfactant-iodine complex
	1677-22	Surfactant-iodine complex
	1677-58	Surfactant-iodine complex
	61181-1	Surfactant-iodine complex
	61181-2	Surfactant-iodine complex

No Batch	EPA Reg. No.	Iodine Source
Each *No Batch* product must cite its own data.	52-254	Surfactant-iodine complex
	875-183	Iodine and iodine monochloride
	4959-9	Surfactant-iodine complex
	4959-14	Surfactant-iodine complex
	4959-38	Surfactant-iodine complex
	6836-184	Surfactant-iodine complex
	40510-1	Potassium iodide
	47371-30	Surfactant-iodine complex
	66171-6	Surfactant-iodine complex

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

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf

8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation

Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: http://npic.orst.edu/

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.