United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-07-011
December 2007

Reregistration Eligibility Decision (RED) for Busan 77 (Case 3034)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the draft risk assessments for the antimicrobials, Busan 77. The enclosed Reregistration Eligibility Decision (RED) document was approved on December 21 2007. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for Busan 77 and the associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for Busan 77 are available to the public in EPA's Pesticide EPA-HQ-OPP-2007-0834 at: http://www.regulations.gov.

The Busan 77 RED was developed through EPA's public participation process, published in the Federal Register on September 28, 2007 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 Busan 77 risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, residential, occupational and ecological risks posed by exposure to Busan 77 alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that Busan 77 will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by Busan 77. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, ShaRon Carlisle, (703) 308-6427. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY

DECISION

for

Busan 77

Case Number 3034

Approved by:

Frank T. Sanders, Director
Antimicrobials Division

12/20/07

Date

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Glossary of Terms and Abbreviations

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

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

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Busan 77 and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of Busan 77 that pose risks of concern. As a result of this review, EPA has determined that Busan 77 containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 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 U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be 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 tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for Busan 77.

This document presents the EPA decision regarding the reregistration eligibility of the registered uses of the Poly [oxyethylene(dimethylminino) ethylene(dimethyliminio)ethylene dichloride], which is commonly referred to as Busan 77. There is one active PC Code (069183) in the Busan 77 case.

Busan 77 is currently registered as an active ingredient in end use products (EUPs) as an algaecide, bacteriostat, fungicide, microbiocide/microbiostat and molluscicide. The registered Busan 77 products are formulated as liquid concentrates and granules. Examples of these use sites with products containing Busan 77 are: swimming pools, spas, whirlpools, hot tubs, metal working fluids, fire water protection systems, cooling water towers, petroleum secondary recovery systems, paper mill process water, air washer water systems, ornamental ponds, aquariums and various fabrics. Concentrations of Busan 77 in these products range from 1.7% to 60%. There are no current registrations for Busan 77 as an inert ingredient.

The Agency has concluded that no special hazard-based safety factor under the Food Quality Protection Act (FQPA) of 1996 is needed for Busan 77 based on an acceptable developmental and reproductive toxicity studies that adequately characterize the dose-response of this compound along with the lack of evidence for any sensitivity of offspring to the adverse effects of Busan 77.

Risks summarized in this document are those that result only from the use of the active ingredients Busan 77. 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 the pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not yet initiated a review to determine if there were any other chemicals that have a mechanism of toxicity common with that of Busan 77. For the purposes of this action, therefore, EPA has not assumed that Busan 77 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of Busan 77. In an effort to simplify the RED, the information presented herein is summarized from more detailed information, which can be found in the technical supporting documents for Busan 77 referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (EPA-HQ-OPP-2007-0834).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of Busan 77 and its regulatory history. Section III, Summary of Busan 77 Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

EPA registered the first product containing Busan 77 on January 12, 1971. The Busan 77 case consists of a single pc code, 069183. It is registered as a microbicide concentrate used for the control of algae in swimming pools, hot tubs, whirlpools and fountains without fish. It is also registered to control and combat the growth of algae, bacteria, and fungi in recirculating cooling towers, industrial air washing systems, and metal cutting fluids. Currently there are 151 active products containing Busan 77. There are no current inert applications and no tolerances listed for this chemical.

B. Chemical Identification

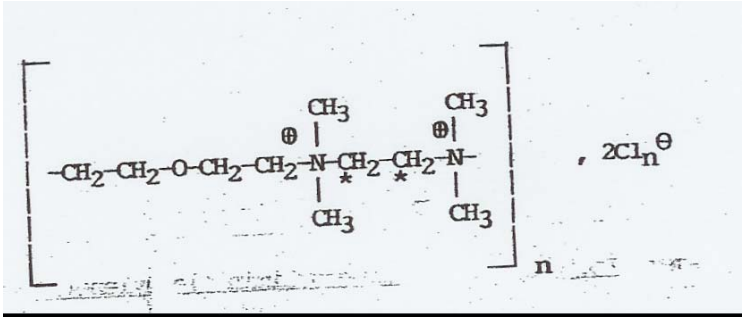

Figure 1. Molecular Structure of Busan 77

Common Name:	Busan 77
Chemical Name:	Poly (oxyethylene (dimethylminino) ethylene (dimethy liminio) ethylenedichloride)
Other Name(s):	Poly (oxy-1, 2-ethanediyl (dimethylminio)-1, 2-ethanediyl (dimethylimio)-1, 2-ethanediyl dichloride
CAS Registry Number:	31512-74-0
OPP Chemical Code:	069183
Case Number:	3034

Empirical Formula: Variable as the polymeric units differ

Molecular Weight: 3,886 g/mol

Manufacturer: Buckman Laboratories

Highest Percent of Active Ingredient: 60%

Chemical Properties: Busan 77 is a light amber/pale yellow colored clear liquid of mildly unpleasant fishy odor. It has a density of 1.103- 1.1417 g/cc. The melting point for Busan 77 is not applicable**.** The boiling point for Busan 77 is 111 ˚C. The vapor pressure for Busan 77 is 10.8 mm Hg (20 ^{o}), 14.4 mm Hg (25 ^{o} C). Busan 77 is completely soluble in water. The pH for Busan 77 is 6.9-7.3 ± 0. It has a viscosity of 1.52 (20 ^{o} C).

C. Use Profile

The following is information on the currently registered uses of Busan 77, including an overview of use sites and application methods. The various EUP can be listed in five categories, which are residential, and public access, materials preservation, industrial process and water systems swimming pools and aquatic areas. A detailed table of the Busan 77 uses eligible for reregistration is available in Appendix A.

Summary of Uses:

Residential and Public Access:
Used in residential and non-commercial environments including swimming pools, spas, whirlpools and hot tubs, waterbed mattress water, aquariums and ornamental ponds and fountains.

Materials Preservatives:
Used in the production of industrial items such as metal working fluids.

Industrial Process and Water Systems:
Used on fresh water supplies for commercial and industrial systems such as water cooling towers (recirculating and once-through), air washer water systems, fire protection systems, textile water systems and pulp and paper water systems

Target Pests: Algae, bacteria, and fungi.

Formulation Types: Formulation intermediate, ready to use, soluble concentrate, granular/pelleted.

Methods and Rates of Application:

To inhibit the growth of bacteria in waterbed mattresses. Eight (8) fluid ounces of product is applied to fiber waterbed mattress of 90-180 gallons capacity. Add 4 to 12 gallons capacity to a twin or hybrid type waterbed up to 90 gallons capacity. Repeat 10-12 months in fiber or foam beds. In free flow waterbeds repeat 18-24 months.

To control the growth of algae, bacteria and fungi in recirulating cooling towers. An initial slug addition of .9 to 94 fluid ounces per 1000 gallons of water. Subsequent slug additions .2 to 59 fluid ounces per 1000 gallons of water should be employed every 1 to 5 days or as needed. Slug additions should be made in the sump of water cooling towers.

To control the growth of algae, bacteria and fungi in air washer water systems. An initial slug dose of 3.3 to 83.25 fluid ounces per 1000 gallons of water. Subsequent slug additions 2.25 to 83.25 fluid ounces per 1000 gallons of water should be employed 1 to 5 days or as needed.

To control microbial growth that causes degradation of cooked starch used in paper manufacture. Add 75 to 750 ppm based on total weight of the starch and water. Do not use in paper and paperboard that will contact food.

To control slime-forming and sulfide-producing bacteria in petroleum secondary recovery systems. Using a continuous feed method add 11.6 to 92.8 fluid ounces.

To inhibit the growth of bacteria in metalworking fluids employed as lubricants or coolants in machinery and processing metals. Add to diluted metalworking fluid at a concentration of .01 to .10 percent based on total weight of the metalworking fluid.

To help control microorganisms that may foul or cause corrosion in fire water protection systems. For the initial dose add 11.6 to 6.4 fluid ounces per 1000 gallons.

To control the growth of algae in swimming pools add an initial dose of 13 to 24 fluid ounces per 1000 gallons of water. Add subsequent additions of 2 to 27 fluid ounces per 10,000 gallons of water every 5 to 7 days after initial treatment for maintenance.

To control the growth of algae in spas, whirlpools or hot tubs. Add an initial dose of 0.5 to 12 fluid ounces per 1000 gallons of water. Subsequent additions of .2 to 9 fluid ounces per 1000 gallons of water should be made every 5 to 7 days after initial dose for maintenance.

To control the growth of algae in aquarium water systems. Add 1 ml to 480 ml according to volume of water. Do not use in aquariums with invertebrates or crustaceans e.g. crabs, shrimps, or crayfish.

To control the growth of algae in ornamental ponds. Add an initial dose of 0.5 to 24 fluid ounces per 1000 gallons of water. Subsequent additions of .2 to 9 fluid ounces per 1000 gallons of water should be made every 5 to 7 days after initial dose for maintenance.

III. Summary of the Busan 77 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 the Busan 77. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0834, and may also be accessed from www.regulations.gov. Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The Agency's use of human studies in the Busan 77 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.

A. Human Health Risk Assessment

1. Toxicity of the Busan 77

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 1. Further details on the toxicity of Busan 77 can be found in the "Revised *Busan 77:* Toxicology Chapter for Issuance of the Reregistration Eligibility Decision (RED) Document," dated September 30, 2007. This document is available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0834).

The Agency has reviewed all toxicity studies submitted for Busan 77 and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented in Table 1 below.

Table 1. Acute Toxicity Profile for Busan 77

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral- Rat purity 61.6% -Busan 77	41373401/ 93062009	LD_{50} = 1951 (1727-2203) mg/kg (M); LD_{50} = 2587 (2059-3250) mg/kg (F)	III
870.1200 (§81-2)	Acute Dermal- Rabbit purity 61.6% – Busan 77	41327101/ 93062010	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute Inhalation- Rabbit Purity 60% - Busan 77	41877501	LC_{50} = 4.0 (2.3-7.1) mg/L (M); 2.4 (1.7-3.3) mg/L (F); 2.9 (2.3-3.7) mg/L (combined)	III
870.2400 (§81-4)	Primary Eye Irritation- Rabbit purity 61.6% -Busan 77	41361701/ 93062011	Redness cleared on day 3	III

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/Citation	Results	Toxicity Category
870.2500 (§81-5)	Primary Dermal Irritation-Rabbit 61.6% - Busan 77	41298601/ 93062012	Slight Irritant	IV
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 60.1 % - Busan 77	40750301/ 93062013	Not a sensitizer.	NA

General Toxicity Observations

Acute Toxicity

Busan 77 exhibits moderate toxicity (Category III) for oral, dermal, inhalation, and primary eye irritation. Acute dermal studies indicate that Busan 77 is classified as a slight irritant.

Dietary

A dietary assessment was generated for Busan 77 based on the potential for dietary exposure Busan 77 is used in the paper manufacturing processes as a slimicide for pulp and paper mill technologies or for starch preservation. No toxic effects were identified that were attributable to a single exposure. Therefore, an acute dietary assessment is not required.

Incidental Oral

The NOAEL for the short-term (1 – 30 days) incidental oral endpoint is 500 mg/kg/day, based on a developmental toxicity study in the rat in which increased mortality was observed. For intermediate-term (30 days – 6 months) incidental oral exposure, a NOAEL of 221 mg/kg/day was selected based on a subchronic toxicity study in rats and was based on renal tubular mineralization. The target margin of exposure (MOE) for both is 100 for the short- and intermediate-term (10X for inter-species extrapolation and 10X for intra-species variation).

Dermal

The short-term dermal NOAEL is 10 mg/kg/day, based on dermal irritation, selected from a 90-day dermal toxicity study in rats. The target MOE is 10 for the Short-term dermal duration. There were no endpoints identified for intermediate and long-term durations.

Inhalation

The short-term inhalation exposure assessment (<30 days), is based on a developmental toxicity study in the rat, in which increased mortality was observed; an oral NOAEL of 500 mg/kg/day was selected. For intermediate-term (30 days – 6 months) inhalation exposure, an oral NOAEL of 221 mg/kg/day was selected based on a subchronic toxicity study in rats and was based on renal tubular mineralization. The long-term inhalation exposoure (>60 months), was

derived from the chronic toxicity /carcinogenicity study in rats using the NOAEL of 100 mg/kg/day based on effects observed at 300 mg/kg/day (decreased body weight gain, decreased albumin and total protein, increased urine pH). The target margin of exposure (MOE) is 100 for short-, intermediate-, and long-term durations.

Carcinogenicity

Busan 77 is currently classified as a 'Group D' (inadequate evidence) carcinogen. Negative results were observed in a mouse carcinogenicity study, but in a rat chronic toxicity/carcinogenicity study, increases in the incidence of thyroid C-cell adenomas were observed in female rats at doses of 300 and 900 mg/kg/day. The increase in thyroid C-cell adenoma was statistically significant at 300 mg/kg/day.

Mutagenicity

In mutagenicity studies (reverse mutation assay, mouse micronucleus assay, unscheduled DNA synthesis assay, sex-linked recessive lethal assay), Busan 77 was found to be non-mutagenic.

Endocrine Disruption

The EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (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 Agency's EDSP have been developed, Busan 77 may be subject 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 Antimicrobials Division's

Toxicology Endpoint Selection Committee (ADTC) has recommended that the special hazard-based FQPA safety factor for Busan 77 be removed. This conclusion is based upon the (1) availability of acceptable developmental and reproductive toxicity studies with Busan 77 that adequately characterize the dose-response of this compound (2)the lack of evidence for any sensitivity of offspring to the adverse effects of Busan 77 and (3) the risk assessment does not underestimate the potential exposure for infants and children.

3. Dietary Risk Assessment

A chronic dietary assessment for Busan 77 is warranted based on the use in the paper manufacturing processes as a slimicide for pulp and paper mill technologies or for starch preservation. No toxic effects were identified that were attributable to a single exposure. Therefore, an acute dietary assessment is not required. The registrant has indicated that they no longer support the starch uses, and that they will be removed from product labels. Further, based on the very low application rates for the slimicide use in pulp and paper mills (10ppm) the Agency believes that exposures will be negligible and, therefore does not have dietary risk concerns. This conclusion is supported by the fact that previous assessments for other chemicals with similar toxicological endpoints but much higher application rates (1000-1200 ppm) resulted in very low exposure and risk estimates. Additional information can be found in the document titled, "Dietary Risk Assessment (Indirect Food Contact) Uses in Paper Manufacturing Process of Poly[(oxyethylene)(dimethylimino)ethylene(dimethylimino) ethylene dichloride] [Busan 77]," dated September 30, 2007.

a. Dietary Risk from Drinking Water

The chemical adsorbs strongly to soil, such that a drinking water exposure is not likely. The modeled results for incidental oral exposures, based on the swimming pool use, are higher than those resulting from the conservative modeling of the once through cooling water use. Considering that the risk estimates for the highest exposure swimming scenario yielded MOEs greater than 50,000, the Agency does not expect drinking water exposures resulting from the once through cooling water system use to be of concern because the low potential for exposure.

4. Residential Risk Assessment

The residential uses of Busan 77 are primarily aquatic and include pools, spas, whirlpools, hot tubs, ornamental ponds/fountains, and aquariums. In addition, it can be used to control odor-causing and slime-forming bacteria in waterbed mattress water. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose.

For this screening level assessment, the Agency selected scenarios based on the application/handling methods and use amounts specified on product labels. The specific scenarios assessed were selected because they are believed to be representative of the majority of the residential uses and provide the high-end estimates for exposure and risk. For additional

information, please refer to "Occupational and Residential Exposure Chapter for the Busan 77 Reregistration Eligibility Decision (RED) Document (Case 3034)," dated July 27, 2007.

a. Residential Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the residential and occupational risks for Busan 77 are listed in Table 2.

Table 2: Summary Table of Toxicological Doses and Endpoints for Busan 77

Exposure Scenario	Dose (mg/kg/day) UF / MOE	Hazard Based Special FQPA Safety Factor	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (gen pop)	This risk assessment is not required.		
Acute Dietary (females 13+)	This risk assessment is not required.		
Chronic Dietary	NOAEL = 100 mg/kg/day UF = 100 **Chronic RfD** = 1.0 mg/kg/day	1x	Chronic toxicity in rats LOAEL = 300 mg/kg/day based on clinical alterations and reduced body weight gain
Incidental Oral Short-Term (1 - 30 Days)	NOAEL = 500 mg/kg/day **MOE** = 100	1x	Developmental Toxicity - Rat LOAEL = 700 mg/kg/day (increased mortality)
Incidental Oral Intermediate-Term (1 - 6 Months)	NOAEL = 221 mg/kg/day **MOE** = 100	1x	Subchronic toxicity in Rats LOAEL = 752 mg/kg/day Based on renal tubular mineralization
Non-Dietary Risk Assessments			
Dermal Short-Term	NOAEL = 10 mg/kg/day (125 µg/cm^2) MOE =10	1x	90-day dermal toxicity study in rats MRID 40170601 LOAEL = 100 mg/kg/day, based on dermal irritation.
Dermal Intermediate and Long-Term		1x	No endpoint identified in the database.
Inhalation Short-Term (1 - 30 Days)	NOAEL = 500 mg/kg/day MOE = 100	1x	Developmental Toxicity - Rat LOAEL = 700 mg/kg/day (increased mortality)

Exposure Scenario	Dose (mg/kg/day) UF / MOE	Hazard Based Special FQPA Safety Factor	Study and Toxicological Effects
Dietary Risk Assessments			
Inhalation Intermediate-Term (1 - 6 Months)	NOAEL = 221 mg/kg/day MOE = 100	1x	Subchronic toxicity in Rats LOAEL = 752 mg/kg/day Based on renal tubular mineralization
Inhalation Long-Term (> 6 Months)	NOAEL = 100 mg/kg/day UF = 100 MOE = 100	1x	Chronic toxicity in rats LOAEL = 300 mg/kg/day based on clinical alterations and reduced body weight gain
Cancer	Group "D" based on increased thyroid C-cell adenomas by ad hoc committee. Referred to the full HED CARC for evaluation of carcinogenic potential.		

Notes: UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, and MOE = margin of exposure.

For Busan 77, the target MOE is 100 for all routes and duration of exposure. It should be noted that since the inhalation NOAEL is based on an oral study that an additional 10X (i.e., MOE = 1,000) may be warranted to request that an inhalation-specific study be conducted.

b. Residential Handlers

i. Exposure Assessment

Residential exposure to Busan 77 can occur in a variety of residential settings. For the residential exposure risk assessment, the EPA selected high-end exposure scenarios that are considered to be representative of all residential handler exposure scenarios. These scenarios were evaluated using maximum application rates as stated on product labels. To assess the handler and post-application exposures and risks, the Agency used standard assumptions, surrogate unit exposure data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study.

Busan 77 is currently registered for several residential aquatic uses. It is used to control algal growth in swimming pools, spas, hot tubs, ornamental ponds, decorative fountains, and aquariums. Furthermore, Busan 77 can also be used to control odor-causing and slime-forming bacteria in waterbed mattress water. Table 3 identifies the representative residential exposure scenarios assessed in this document.

Table 3. Representative Uses Associated with Residential Exposure

Representative Use	Exposure Scenario	Application Method	Reg. #	Application Rate

Representative Use	Exposure Scenario	Application Method	Reg. #	Application Rate
Swimming Pool	ST handler: dermal (irritation) and inhalation (aerosol)	• Open pour (solid)[1]	3432-28	0.0012 fl oz ai/gal (30 oz/5,000 gal x 20%ai)
		• Open pour (liquid)	57787-11	0.0012 oz ai/gal (117 fl oz/10,000 gal x 10%ai) (product density = 8.5lb/gal)
	ST and IT post-app: incidental oral and dermal[2]	NA	57787-11	9.3 mg ai/L (117 fl oz/10,000 gal x 10%ai x gal/128oz x 8.5 lb/gal x 4.54E5 mg/lb x 0.264 gal/L)
Spa/whirlpool/hot tub/ornamental ponds	ST handler: dermal (irritation) and inhalation (aerosol)	• Open pour (liquid)	1448-346	0.0012 fl oz ai/gal (3 fl oz/1000 gal x 40%ai) (product density =9.12lb/gal)
Aquarium	ST handler: dermal (irritation) and inhalation (aerosol)	• Open pour (liquid)	14802-8	0.00023 fl oz ai/gal (5ml/40 gal x 5.4%ai x fl oz/29.57ml) (product density = 8.4lb/gal)
Waterbed mattress water	ST handler: dermal (irritation) and inhalation (aerosol)	• Open pour (liquid)	42373-6	0.0044 fl oz ai/gal (8 fl oz/180 gal x 10%ai) (product density = 8.5lb/gal)

[1] Note: since the application rates are the same, the dermal irritation exposure from the open solid pour scenario was represented by the open pour liquid scenario. Furthermore, the open liquid pour scenario is considered worst-case as compared to the solid pour for dermal irritation due to physical nature of the product and its potential to contact skin during the application.
[2] Note: post-application exposure to swimming pool residues is representative for post-application exposure to spa/whirlpool residues since the application rates are the same for both uses

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. A MOE greater than or equal to 10 is considered adequately protective for the residential exposure assessment for the short-term dermal route of exposure. An MOE of 100 is considered adequately protective for the residential inhalation route of exposure for all durations.

For the Busan 77, the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000 (10x inter-species extrapolation, 10x intra-species variation, 10x route extrapolation). In cases where inhalation endpoints are set using oral toxicity studies the Agency will consider requiring an inhalation toxicity study to confirm that the use of route-to-route extrapolation does not underestimate risk. The Agency determines the need for confirmatory inhalation data by evaluating the inhalation

MOEs. For the Busan 77, if MOEs are greater then 100 there are no risks of concern. However, if MOEs are less than 1,000 confirmatory inhalation toxicity data are necessary to account for the use of route-to-route extrapolation.

In order to conduct the comprehensive risk assessment, the Agency used standard assumptions, surrogate unit exposure data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study, EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments*, and EPA's SWIMODEL. The specific input parameters and assumptions are discussed in the supplementary exposure assessment. It is important to note that most of the CMA data are of poor quality therefore, the Agency needs additional confirmatory monitoring data be generated to support the values used in these assessments. In addition, the values utilized for the quantities handled/treated were estimated based on information from various sources and these can be further refined with input from registrants.

All of the calculated MOEs were above the target of 10 for dermal and of 100 for inhalation for all scenarios. Furthermore, all inhalation MOEs exceeded 1,000 therefore, a confirmatory inhalation toxicity study is not warranted based on the results of these exposure scenarios. The resulting short- and intermediate-term exposures and MOEs for the representative residential handler scenarios are presented in Table 4.

Table 4 Residential Handler Exposures and MOEs for Busan 77

Exposure Scenario	Application Method	Unit Exposure		Amount treated (gal/day)	Use Rate	Amount ai handled (lb ai/day)[b]	ST/IT Exposure		ST MOEs[f]		IT MOEs[f] Target MOE = 100
		Dermal (mg/lb ai/cm^2)	Inhal (mg/lb ai)				Dermal (mg/cm^2)[c]	Inhalation (mg/kg/day)[d]	Dermal Target MOE=10	Inhalation Target MOE=100	Inhalation
Swimming pools	Open pour - liquid	0.00023	0.00346	20,000	0.0012 fl oz ai/gal	1.6	3.6E-04	7.7E-05	350	6,500,000	2,900,000
	Open pour - solid	NA	0.0119	20,000	0.0012 oz ai/gal	1.5	NA	2.6E-04	NA	2,000,000	870,000
Spas/whirlpools/ ponds	Open pour - liquid	0.00023	0.00346	1,000	0.0012 fl oz ai/gal	0.086	2.0E-05	4.2E-06	6,400	120,000,000	52,000,000
Aquariums	Open pour - liquid	0.00023	0.00346	100	0.00023 fl oz ai/gal	0.0015	3.4E-07	7.4E-08	360,000	6,800,000,000	3,000,000,000
Waterbed mattress	Open pour - liquid	0.00023	0.00346	180	0.0044 fl oz ai/gal	0.053	1.2E-05	2.6E-06	10,000	190,000,000	84,000,000

b: Liquid Amt ai handled (lb ai/day) = use rate (fl oz ai/gal) x gal/128oz x product density (lb/gal) x amt treated (gal treated/day)
Solid Amt ai handled (lb ai/day) = use rate (oz ai/gal) x lb/16oz x amt treated (gal treated/day)
c: Dermal exposure (mg/cm^2) = Dermal unit exposure (mg/lb ai/cm^2) x Amt ai handled (lb ai/day)
e: Inhalation exposure (mg/kg/day) = Inhalation unit exposure (mg/lb ai) x Amt ai handled (lb ai/day)/70 kg
f: MOE = NOAEL / Exposure; where ST dermal NOAEL = 125 µg/cm^2 (or 0.125 mg/cm^2); ST inhalation NOAEL = 500 mg/kg/day; IT inhalation NOAEL = 221 mg/kg/day

c. Residential Post-application

i. Exposure Assessment

Residential post-application dermal exposures result when adults and children come in contact with Busan 77 in areas where pesticide end-use products have recently been applied (e.g., swimming pool and spas/whirlpool), or when children incidentally ingest the pesticide residues through swallowing treated swimming pool water. It is anticipated that absorbents such as textiles will absorb Busan 77 and post-application residential dermal and incidental oral exposures to treated textiles may occur. Note that inhalation exposures (vapor) are not expected due to the extremely low vapor pressure of Busan 77; therefore, these exposures were not assessed.

a. Dermal Exposure

Textile Freshwater System Use

Busan 77 can be used "*to control the growth of bacteria and fungi in holding and processing tanks of industrial fresh water systems supplying water to pulp and paper mills, textile mills, and other manufacturing plants"* (EPA Reg. No. 1448-42). As stated on the label "*absorbents rapidly absorb the product."* Therefore, it is anticipated that absorbents such as textiles will absorb Busan 77 and post-application residential dermal and incidental oral exposures to treated textiles may occur. However, the level of residues remaining on the textile is unknown and can not be accurately modeled at this time. Busan 77 is intended to control microorganism growth in the water used in the facility not to preserve the textile. Since the application rate is in terms of volume of water not textile, the rate cannot be extrapolated to estimate the amount of residue remaining on the textile that comes in contact with the treated water. Therefore, a textile residue study is needed in order to conduct the post-application residential exposures.

Swimming Pool and Spa Uses

There are post-application dermal exposures to Busan 77 associated with the swimming pool and spa use. The SWIMODEL 3.0 was developed by EPA as a screening tool to conduct exposure assessments of pesticides found in swimming pools and spas (2003). The SWIMODEL uses well accepted screening exposure assessment equations to calculate the total worst-case exposure for swimmers expressed as a mass-based intake value (mg/event). The model estimates absorbed dermal exposure based on the chemical's permeability constant (Kp). For Busan 77, the dermal toxicological effect is based on skin irritation not an absorbed systemic effect. Therefore, the SWIMODEL is not appropriate to use to estimate dermal exposure for Busan 77.

The film thickness methodology was used to estimate dermal exposure to pool and spa treated water. The following equation was used to develop the short-term dermal doses:

$$Dose = Cw \times FT$$

where:

Dose	=	Daily dose for pools (µg/cm^2);
Cw	=	Chemical concentration in pool water (mg ai/L = µg ai/cm^3); and
FT	=	Film thickness of water on the skin (cm).

It should be noted that adults and children, competitive and noncompetitive swimmers, and pool users and spa users will all have the same exposures and MOEs using the film thickness approach.

b. Incidental Ingestion

Swimming Pool and Spa Uses

The SWIMODEL 3.0 was used to estimate post-application incidental ingestion of treated swimming pool water. Although, the actual model was not used in this assessment, the same equations and default parameters as provided in the SWIMODEL User's Manual (version 3.0) were used in a spreadsheet format to estimate post-application incidental oral exposures. Incidental ingestion of treated water is typically associated with use of swimming pools not spas or whirlpools therefore; the oral exposures were only estimated for swimming pool use. Both short- and intermediate-term exposures durations were assessed since there is a potential for exposure every day for competitive swimmers.

ii. Post-Application Risk Assessment

Based on the registered use patterns, toxicological criteria and potential for exposure, the Agency has conducted dermal and incidental oral exposure assessments. The scenarios included in the risk assessment are considered to represent high-end exposures. A MOE greater than or equal to 10 for dermal and 100 for inhalation exposures is considered adequately protective for the residential post-application exposure assessment for all routes of exposure.

Swimming Pool and Spa Uses (Dermal)

The short-term dermal doses and MOEs for adults and children are presented in Table 5. It should be noted that adults and children, competitive and noncompetitive swimmers, and pool users and spa users will all have the same exposures and MOEs using the film thickness approach. The resulting MOE is above the target MOE of 10 and therefore not of concern.

Table 5: Short-term Adult and Child Dermal Exposures and MOEs for Busan 77 used in Swimming Pools and Spas

Scenario	Dose (µg/cm2)	MOE[a]
ST Adult and Child Dermal Exposures and MOEs From the Use of Pools and Spas[a]	0.046	2,700
Child (7-10 years) Incidental Ingestion exposures for both competitive and non-competitive swimmers in pools[b]	0.016	32,0000 (ST) and 14,000 (IT)
ST Child (11-14 years) Incidental Ingestion exposures for both competitive and non-competitive swimmers in pools[b]	0.0097	52,000 (ST) and 23,000 (IT)
ST Adult competitive swimmers in pools; Incidental Ingestion Exposure[b]	0.0050	100,000 (ST) and 44,000 (IT)
ST Adult non-competitive swimmers in pools; Incidental Ingestion Exposure[b]	0.0030	150,000 (ST) and 66,000 (IT)

a: MOE = NOAEL mg/kg/day/ Dose (mg/kg/day). ST Oral NOAEL = 500 mg/kg/day, IT Oral NOAEL = 221 mg/kg/day; ST and IT Target MOE = 10

Swimming Pool Uses (Incidental Oral)

The water concentration in pool water is based on information provided in the labels. The ingestion rate used in the SWIMODEL 3.0 is based on the value used in EPAs Residential SOPs (U.S. EPA, 1997a) and an EPA pilot study as discussed in ACC's swimmer survey (ACC, 2002). The exposure time is based on ACC's swimmer survey for competitive swimmers (ACC, 2002) and the NHAPs data for non-competitive/recreational swimmers (US EPA, 1996). Table 6 presents the incidental ingestion exposures and MOEs for swimmers in Busan 77 treated pools. All of the MOEs are above the target MOE of 100 and are therefore not of concern.

Table 6. Short-and Intermediate-term Adult and Child Incidental Ingestion Exposures and MOEs for Busan 77 used in Swimming Pools

	Adult		Child 7-10 yrs		Child 11-14 yrs	
	Comp.	Non-Comp.	Comp.	Non-Comp.	Comp.	Non-Comp.
Cw (mg/L)	9.31	9.31	9.31	9.31	9.31	9.31
IR (L/hr)	0.0125	0.0125	0.05	0.05	0.025	0.05
ET(hr/day)	3	1	1	1	2	1
BW(kg)	70	70	30	30	48	48
Dose (mg/kg/day)	0.0050	0.0033	0.016	0.016	0.0097	0.0097

	Adult		Child 7-10 yrs		Child 11-14 yrs	
	Comp.	**Non-Comp.**	**Comp.**	**Non-Comp.**	**Comp.**	**Non-Comp.**
ST MOE	100,000	150,000	32,000	32,000	52,000	52,000
IT MOE	44,000	66,000	14,000	14,000	23,000	23,000

[a]MOE = NOAEL mg/kg/day/ Dose (mg/kg/day). ST Oral NOAEL = 500 mg/kg/day, IT Oral NOAEL = 221 mg/kg/day; ST and IT Target MOE

5. Aggregate Risk Assessment

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 typically includes exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

The aggregate risk assessment is designed to provide estimates of risks likely to result from exposures to the pesticide or pesticide residues in food, water, and from residential (or other non-occupational) pesticide uses. An acute aggregate assessment was not conducted because there was no tox endpoint selected.

The chemical adsorbs strongly to soil, such that a drinking water exposure is not likely. The modeled results for incidental oral exposures, based on the swimming pool use, are higher than those resulting from the conservative modeling of the once through cooling water use. Considering that the risk estimates for the highest exposure swimming scenario yielded MOEs greater than 50,000, the Agency does not expect drinking water exposures resulting from the once through cooling water system use to be of concern because the low potential for exposure.

Short-Term Aggregate Exposures and Risks

Short- and intermediate-term aggregate exposures and risks were considered for adults and children that could be exposed to Busan 77 from the use of products in non-occupational environments. The use patterns of Busan 77 products and probability of co-occurrence were addressed when selecting scenarios for incorporation in the aggregate assessment. The exposure scenarios that were considered for the aggregate assessment are summarized in Table 7, and it is important to note that because the use on paper is no longer being supported, there are no identified routes of dietary exposures to Busan 77.

It should be noted that there is a potential for an adult to apply a Busan 77 product to a swimming pool and subsequently swim in the treated pool in one day. However, because the dermal toxicological effect is skin irritation and not a systemic effect, any product remaining on the residential handler following an application would be diluted or "washed off"once the handler enters the swimming pool. Therefore, an aggregate assessment incorporating these scenarios would actually overestimate dermal exposure and is thus was not included in the

assessment.

The Agency determined that an aggregate assessment could not be conducted at this time due to the lack of textile residue data. The aggregate assessment would need to include post-application exposures to swimming pool water residues along with post-application exposure to textile residues.

6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Based on examination of product labels describing uses for Busan 77, it has been determined that exposure to handlers can occur in a variety of occupational environments such as material preservation as well as industrial processes and water systems via liquid pour and liquid pump applications. In addition, there is the potential for occupational handlers to come into contact with treated products (e.g., metalworking fluids, etc).

a. Occupational Toxicity

The toxicological endpoints used in the occupational handler assessment of Busan 77 can be found in Table 2, "Residential and Occupational Toxicological Doses and Endpoints for Busan 77", of this document.

b. Occupational Handler Exposure

Occupational risk for all potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. Occupational risk is assessed for exposure at the time of application (termed "handler" exposure). Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site and by the application rate required to achieve an efficacious dose.

The exposure scenarios assessed in this document for the representative uses selected by the Agency are shown in Table 8. For handlers, the representative uses assessed include: material preservative (metalworking fluid), industrial water systems biocide and, swimming pool and spa algaecide.

Potential occupational handler exposures can occur during the application of Busan 77 through either liquid/solid pour or liquid pump methods. Liquid/solid pour refers to transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow. There is also the potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-product.

Short-term dermal exposures were not assessed for most occupational handler scenarios because the endpoint is based on dermal irritation. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products that result in classification of category I, II, or III for skin irritation potential will be a long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential. Most of the labels currently do not require PPE; based on this assessment all of these labels will need to be updated to reflect the PPE requirement.

Since gloves are also not a viable mitigation option for a machinist using biocide treated metalworking fluids, the short-term dermal exposure was assessed for this scenario.

Table 8. Representative Exposure Scenarios Associated with Occupational Exposures to Busan 77

Representative Use	Method of Application	Exposure Scenario	Registration #	Application Rate
Residential Premises				
Swimming Pools	• Liquid pour • Solid pour	Handler: ST and IT inhalation	3432-28	0.0012 fl oz ai/gal (30 oz/5,000 gal x 20%ai)
			57787-11	0.0012 oz ai/gal (117 fl oz/10,000 gal x 10%ai) Product density = 8.5lb/gal
Material Preservatives				
Metalworking fluid	• Liquid pour • Liquid pump	Handler (worker pouring preservative into fluid being treated): ST and IT inhalation	1448-42	0.006% to 0.06% ai (or 60 to 600 ppm ai) (0.01 to 0.1% product based on total weight of fluid x 60% ai)
	• Use of treated metalworking fluid	Machinist: ST dermal and IT ST and IT/LTinhalation		Product density = 9.6 lb/gal
Industrial Processes and Water Systems				
Pulp/paper and textile water systems	• Liquid pump	Handler: ST and IT inhalation	1448-42	0.0007 fl oz ai/gal (11 fl oz/10,000 gal x 60% ai) Product density = 9.6 lb/gal

Representative Use	Method of Application	Exposure Scenario	Registration #	Application Rate
Cooling tower waters (recirculating)	• Liquid pour • Liquid pump	Handler: ST and IT inhalation	1448-398	Initial dose: 0.0042 fl oz ai/gal (69.6 fl oz/1,000 gal x 6%ai) Maintenance dose: 0.0021 fl oz ai/gal (34.8 fl oz/1,000 gal x 6%ai) Product density = 8.7 lb/gal
Cooling tower waters (once-through)	• Liquid pour • Liquid pump	Handler: ST and IT inhalation	55137-1	0.0012% ai (60 ppm x 20%ai) Product density = 8.69 lb/gal
Air washer water systems	• Liquid pour • Liquid pump	Handler: ST and IT inhalation	402-123	0.0042 fl oz ai/gal (83.25 fl oz/1,000 gal x5%ai) Product density = 8.4 lb/gal
Fire protection systems	• Liquid pour • Liquid pump	Handler: ST and IT inhalation	1448-398	0.0056 fl oz ai/gal (92.8 fl oz/1,000 gal x 6%ai) Product density = 8.7 lb/gal
Petroleum secondary recovery systems	• Liquid pour • Liquid pump	Handler: ST and IT inhalation	1448-398	0.0056 fl oz ai/gal (92.8 fl oz/1,000 gal x 6%ai) Product density = 8.7 lb/gal

Note: inhalation exposure refers to exposure to the aerosols not the vapor

Swimming Pool Systems

Busan 77 can be used to control the growth of algae in swimming pools (EPA Reg. No. 57787-11 and 3432-28). Table 8 above, presents the scenarios and associated application rates assessed for this algaecide use. Based on standard assumptions, the Agency assumed that a professional pool maintenance worker can treat ten 20,000 gallon pools per day (e.g., 200,000 gallons of pool water are treated per day). It should be noted that the spa/whirlpool algaecide use is represented by the pool use since the application rates are the same.

The potential for occupational exposure was based on the loading of the product by liquid open pouring and granular open pouring. Chemical-specific exposure data were not submitted to support the algaecide use. Therefore, the Agency developed a screening-level assessment using surrogate data to determine the potential risks associated with swimming pool treatments. The most representative data available are the monitoring data from the CMA study data. The following lists the unit exposures used in this assessment:

- liquid open pour: CMA inhalation UE of 0.00346 mg/lb ai from the liquid open pour preservative study, which was based on only 2 replicates, was used. Although this exposure scenario is based on minimal replicates, the exposure values are similar to those found in Pesticide Handler's Exposure Data (PHED) for similar scenarios.
- solid open pour: CMA inhalation UE of 0.0119 mg/lb ai from the solid open pour preservative study, which was based on 10 replicates, was used.

Metal Working Fluid

Busan 77 can be used "*for the inhibition of bacterial degradation of aqueous solutions or emulsions of the cutting fluids or oils employed as lubricants in the machining and processing of metals"* (EPA Reg. No. 1448-42). Table 8 presents the scenarios and associated application rates assessed for this materials preservative (e.g., metalworking fluid) use. Based on standard assumptions, the Agency assumed that 300 gallons of fluid is preserved per day.

The potential for occupational exposure was based on the loading of the product by liquid open pouring and connecting/disconnecting a chemical metering pump from a tote. Chemical-specific exposure data were not submitted to support the materials preservative use. Therefore, the Agency developed a screening-level assessment using surrogate data to determine the potential risks associated with metalworking fluid preservation. The most representative data available are the monitoring data from the CMA study data. The following lists the unit exposures used in this assessment:

- liquid open pour: CMA inhalation UE of 0.00854 mg/lb ai from the metalworking fluid study, which was based on 8 replicates, was used.
- liquid pump: CMA inhalation UE of 0.00348 mg/lb a.i. from the metalworking fluid study, which was based on 2 replicates, was used.

Industrial Freshwater Systems: Pulp/Paper and Textile Mills

Busan 77 can be used "*to control the growth of bacteria and fungi in holding and processing tanks of industrial fresh water systems supplying water to pulp and paper mills, textile mills, and other manufacturing plants. In pulp and paper mills, treatments of the fresh water with Busan 77 can make an important contribution to slime control. The use of Busan 77 as described will reduce the development of slime in fresh water pipes, fresh water spraying nozzles, and on the pulp and paper mill machining parts contacted by fresh water. However, Busan 77 is not recommended for use as the primary microbiocide for pulp and paper mill slime control since absorbents such as wood pulp rapidly absorb the product and greatly reduce its concentration in the circulating water"* (EPA Reg. No. 1448-42). Table 8 presents the scenarios and associated application rates assessed for this freshwater microbiocide use. Based on standard assumptions, AD assumed that 20,000 gallons of water is treated per day.

It should be noted that Busan 77 can also be used to preserve starch used in paper manufacturing (EPA Reg. No. 1448-42 and 55137-1). However, the technical registrant recently stated that this use will be cancelled. Therefore, all labels listing the starch preservation use must be updated to reflect this cancellation.

The potential for occupational exposure was based on the loading of the product by and connecting/disconnecting a chemical metering pump from a tote. Chemical-specific exposure data were not submitted to support the pulp and paper and textile manufacturing uses. Therefore,

AD developed a screening-level assessment using surrogate data to determine the potential risks associated with pulp and paper and textile manufacturing. The most representative data available are the monitoring data from the CMA study data. The following lists the unit exposures used in this assessment:

- liquid pump: CMA inhalation UE of 0.000265 mg/lb ai from the pulp and paper preservative loading study, which was based on 7 replicates, was used.

Cooling Water Systems and Air Washer Systems

Busan 77 can be used *"to control the growth of microorganisms including bacteria, algae, and fungi in recirculating cooling water system"* (EPA Reg. No. 1448-398). Furthermore, Busan 77 can be used "*to control mollusks such as Corbicula species in once-through cooling water systems"* as well as "*control algae and mollusks such as Corbicula and Dreissena species in potable water treatment systems"* (EPA Reg. No. 55137-1). Table 8 presents the scenarios and associated application rates assessed for the various cooling water system uses. It should be noted that the once-through cooling water system scenario also represents the potable water system scenario.

At this time, a screening-level assessment has been developed for the recirculating use as well as the once through use. The daily amount of biocide handled that was used in this assessment was based on the following information provided by the registrant: Workers in small systems could manually pour 5 to 10 gallons of biocide into the system but larger systems would utilize chemical pumps in order to save time and labor expense. Recirculating cooling water systems can vary tremendously in volume and are believed to be generally less than 50 million gallons. The range of volume assessed for the large scale once through power generators (label does not restrict the product to power generators but they represent the high end) includes 2 to 500 million gallons. The 2 million gallons were selected as the low range based on it representing the "*de minimus*" flow for EPA's Cooling Water Intake Structure Rule (40CFR125.90). Although a few power generators may have water flows of approximately 1 to 3 billion gallons, these few utilities are atypical. EPA assumed that if the large utilities apply Busan 77 it would be applied as a continuous feed over 6 days (i.e., 500 million gallons treated/6 days = 83.3 million gallons of water treated per day).

Based on the above information, EPA assumed that workers handle 10 gallons of biocide per day when making open pour applications. Furthermore, EPA assessed exposure to workers of recirculating cooling water systems ranging from 20,000 to 50 million gallons treating via chemical metering pumps as well as, exposure to workers of once-through cooling water systems ranging from 2 to 83 million gallons treating via chemical metering pumps.

The potential for occupational exposure is based on the loading of the product by liquid open pouring and connecting/disconnecting the chemical metering pump. Chemical-specific exposure data were not submitted to support the cooling tower use. Therefore, the Agency has developed a screening-level assessment using surrogate data to determine the potential risks

associated with the cooling tower uses. The most representative data available for industrial scenarios are the monitoring data from the CMA study. The following lists the unit exposures used in this assessment:

- liquid open pour: CMA inhalation UE of 0.45 mg/lb ai from the cooling water systems liquid open pour study, which was based on only 5 replicates, was used. Although this exposure scenario was based on minimal replicates, the exposure value is similar to those found in PHED for similar scenarios.
- liquid pump in small systems: CMA inhalation UE of 0.00432 mg/lb ai from the cooling water system liquid pump loading study, which was based on 4 replicates, was used.
- liquid pump in large systems: CMA inhalation UE of 0.000265 mg/lb ai from the pulp and paper preservative loading study, which was based on 7 replicates, was used. It should be noted that the UE from the pulp and paper study was selected for this scenario rather than data from the cooling water study because the pulp and paper scenario is more representative of large scale systems such as those in large cooling water systems.

Air Washer Systems and Fire Water Protection systems

Busan 77 can be used to control algae, bacteria and fungi in industrial air washing systems (EPA Reg. No. 402-123). Based on the use information provided by the registrant via personal communication, it was assumed that 10,000 gallons of air washer water is treated per day. Busan 77 can also be used to control "*microorganisms which may foul or cause corrosion in firewater protection systems"* (EPA Reg. No. 1448-398). Based on the use information provided by the registrant, it was assumed that 50,000 gallons of fire protection water is treated per day. Table 8 presents the scenarios and associated application rates assessed for air washer system uses.

Oil-Well Uses

Busan 77 can be used to maintain bacterial control in oil field water systems (EPA Reg. No. 1448-398). Table 8 presents the scenarios and associated application rates assessed for the various oilfield uses.

The following use information provided by the registrant was used to estimate the amount of product handled per day during oil-well activities. Biocide is typically added directly to drilling rig mud tanks via open pouring. Over a 3 to 6 week period, while a 13,000 ft well is being drilled, 1 to 2 drums (1 drum = 42 gallons) of biocide may be used if microbiological problems are encountered. Therefore, the short-term exposure assessment used 5.6 gallons for the amount of biocide handled per day by the drilling rig worker [i.e., (2 drums x 42 gal/drum) / (5 days/week x 3 weeks) = 5.6 gal/day]. The intermediate-term exposure assessment used 2.8 gallons for the amount of biocide handled per day by the drilling rig worker [i.e., (2 drums x 42 gal/drum) / (5 days/week x 6 weeks) = 2.8 gal/day]. For the secondary recovery application, the biocide is meter pumped into the produced water before it is reinjected into the formation or

well. In large operations produced water volume can exceed 10,000 barrels/day (1 barrel = 42 gallons); therefore 420,000 gallons of water can be treated in secondary recovery operations. Furthermore, although crew changes may occur in drilling rig operations, typically a designated customer representative is responsible for the biocide feeding. Therefore, one person would be involved with the biocide application activities on a daily basis.

c. Occupational Handler Risk Summary

The occupational handler risk assessment for the antimicrobial uses of the Busan 77 includes both dermal and inhalation exposure scenarios. The target MOEs are 10 for dermal and 100 for inhalation. Table 9 presents the potential ST and IT inhalation exposures and risks for the previously mentioned scenarios. All of the MOEs are above the target MOE and therefore not a concern. Furthermore, the inhalation MOEs are also above 1,000 therefore a confirmatory inhalation toxicity study is not warranted based on these uses.

Table 9. Occupational Handler Exposures and MOEs for Busan 77									
Exposure Scenario	Application Method	Unit Exposure Inhalation (mg/lb ai)	Amount handled/ treated (gal/day)	Use Rate		Amount ai handled (lb ai/day)	ST/IT Exposure Inhalation (mg/kg/day)	ST MOEs Target MOE = 100 Inhalation	IT MOEs Target MOE = 100 Inhalation
Residential Premises									
Swimming pools	Open pour - liquid	0.00346	200,000	0.0012	fl oz ai/gal	15.5	7.7E-04	650,000	290,000
	Open pour - solid	0.0119	200,000	0.0012	oz ai/gal	15.0	2.6E-03	200,000	87,000
Materials Preservative									
Metal working fluid	Open pour - liquid	0.00854	300	0.06%	%ai	1.73	2.1E-04	2,400,000	1,000,000
	Metering pump	0.00348	300	0.06%	%ai	1.73	5.2E-08	9,700,000,000	4,300,000,000
Industrial Processes and Water Systems									
Paper/Textile Mills	Metering pump	0.000265	20,000	0.0007	fl oz ai/gal	0.99	2.5E-09	200,000,000,000	90,000,000,000
Oil Field: Water-based drilling fluids	Open pour - liquid	0.00346	5.6 (ST) 2.8 (IT)	0.0056	fl oz ai/gal	0.0021 (ST) 0.0011 (IT)	1.0E-07 (ST) 5.2E-08 (IT)	4,800,000,000	4,200,000,000
Oil Field: Secondary recovery	Metering pump	0.000265	420,000	0.0056	fl oz ai/gal	158.9	6.02E-04	830,000	370,000
Recirculating Cooling Water	Open pour - liquid	0.45	10	0.0042	fl oz ai/gal	0.0028	1.8E-05	27,000,000	12,000,000
	Metering pump	0.00432	20,000	0.0042 (ST) 0.0021 (IT)	fl oz ai/gal	5.68 (ST) 2.84 (IT)	3.5E-04 (ST) 1.8E-04 (IT)	1,400,000	1,300,000
	Metering pump	0.000265	50,000,000	0.0042 (ST) 0.0021 (IT)	fl oz ai/gal	14192 (ST) 7096 (IT)	5.4E-02 (ST) 2.7E-02 (IT)	9,300	8,200
Once-through Cooling Water	Open pour - liquid	0.45	10	0.0012%	%ai	0.0010	6.7E-06	75,000,000	33,000,000
	Metering pump	0.000265	2,000,000	0.0012%	%ai	208.56	7.9E-04	630,000	280,000
	Metering pump	0.000265	83,000,000	0.0012%	%ai	8655.24	3.3E-02	15,000	6,700
Air washer systems	Open pour - liquid	0.00346	10,000	0.0042	fl oz ai/gal	2.73	1.4E-04	3,700,000	1,600,000
	Metering pump	0.000403	10,000	0.0042	fl oz ai/gal	2.73	1.6E-05	32,000,000	14,000,000
Fire water protection systems	Open pour - liquid	0.00346	50,000	0.0056	fl oz ai/gal	18.92	9.4E-04	530,000	240,000
	Metering pump	0.000403	50,000	0.0056	fl oz ai/gal	18.92	1.1E-04	4,600,000	2,000,000

Metalworking Fluids: Machinist

There is the potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-product.

Dermal Exposure

Exposure Calculations

Short-term exposures for machinists were assumed to pose potential risks due to dermal irritation. Short-term exposure estimates based on surface area were derived using the following equation:

PE = % ai x FT

where:

PE	=	Potential exposure (mg/cm^2)
% ai	=	Fraction active ingredient in treated metalworking fluid (unitless)
FT	=	Film thickness of paint on hands (mg/cm^2)

- The percent active ingredient in the treated fluid was assumed to be the highest use rate for metalworking use scenarios (60 -600 ppm ai, or 0.006 - 0.06%, a.i. in treated metalworking fluid; Reg. No. 1448-217).
- It was assumed that exposure to a machinist's hands would occur in the absence of gloves.
- For short-term duration exposures, the film thickness on the hands was assumed to be 10.3 mg/cm^2 (US EPA, 1992). This film thickness is based on a machinist completing a double dip in which both hands are immersed and remain wet. The film thickness was chosen because the dermal endpoint for short-term durations is based on dermal irritation effects and represents an estimate in the absence of more specific data

Results

Table 10 shows the calculation of the dermal doses and dermal MOEs for a machinist working with metalworking fluids. The MOE value at the low application rate is above the target MOE of 10 and therefore not a concern.

Table 10. Short- term Dermal Exposures and MOEs for Machinist Exposure to Metalworking Fluids

Exposure Scenario	% ai	Film thickness (mg/cm^2)	Exposure (mg ai/cm^2)	Dermal MOE (Target MOE = 10)
Machinist - two hand immersion	0.006	10.3	6.2E-04	200
	0.06	10.3	6.2E-03	20

Inhalation Exposures

The screening-level intermediate and long term inhalation exposure estimate for treated metalworking fluids have been developed using the OSHA PEL for oil mist. The equation used for calculating the inhalation dose is:

$$PDR = \frac{PEL \times IR \times \%\ ai \times ED}{BW}$$

where:

PDR	=	Potential dose rate (mg/kg/day);
PEL	=	OSHA PEL (mg/m^3);
IR	=	Inhalation rate (m^3/hr)
% ai	=	Fraction active ingredient in treated metalworking fluid (unitless)
ED	=	Exposure duration (hrs/day);
BW	=	Body weight (kg)

Assumptions

- The high-end oil mist concentration is based on OSHA's Permissible Exposure Limit (PEL) of 5 mg/m^3 (NIOSH, 1998).
- The percent active ingredient was selected from the label that provides an application rate for the non-concentrate fluid (EPA Registration No. 1448-217).
- The inhalation rate for a machinist is 1.25 m^3/hr.
- A machinist is exposed to the metalworking fluid 8 hours a day, for 5 days a week.
- The body weight of an adult is 70 kg (US EPA 1997b).

Results

Table 11 shows the calculation of the inhalation doses and MOEs for a machinist working with metalworking fluids. The inhalation ST and IT/LT MOE values for Busan 77 are above the target MOE of 100. Furthermore, these MOEs are also above 1,000 therefore a confirmatory inhalation toxicity study is not warranted based on the results of this scenario.

Table 11. Short-, Intermediate- and Long-Term Inhalation Exposures and MOEs Associated with Metalworking Fluids Treated with Busan 77 (Machinist)

Exposure Scenario	% a.i.	OSHA PEL (mg/m^3)	Inhalation rate (m^3/hr)	Exposure Duration (hrs/day)	Exposure (mg/kg/day)	Inhalation MOEs (Target MOE is 100)		
					ST/IT/LT	ST	IT	LT
Machinist	0.06%	5	1.25	8	4.3E-04	1,200,000	520,000	230,000

d. Occupational Post-application Exposure and Risk Summary

No occupational post-application exposures are assumed to occur for the scenarios summarized in Table 8; any post-application exposures from these uses are expected to occur in a residential setting. These exposure scenarios are assessed in the residential exposure section of this document.

7. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to Busan77. EPA consulted the following sources of information for human poisoning incidents related to Busan 77 use: (1) OPP Incident Data System (IDS) - The Office of Pesticide Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) California Department of Pesticide Regulation (1982-2004) – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Information Center (NPIC) - NPIC is a toll-free information service supported by OPP That provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991; (4) National Poison Control Centers (PCC) (1993-1996); and (5) Published Scientific Literature on Incidents.

There were 34 incidents reported from use of Busan 77; although limited, incidents reported in OPP IDS support that exposure to Busan 77 may cause some irritation through dermal, inhalation, and/or ocular exposures. Most of the symptoms are considered minor. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash, itching and skin discoloration/redness. The most common symptoms reported for cases of inhalation exposure were minor respiratory irritation/burning. In some cases, a headache is reported after inhalation exposure. The symptoms associated with ocular exposure include blurred vision, edema and irritation around eyes.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The majority of the uses for Busan77 are considered indoor and to have minimal to no environmental exposure potential, with the exception of the once-through cooling water use. For a detailed discussion of all aspects of the environmental risk assessment, refer to the Environmental Risk Assessment in the "Revised Preliminary Ecological Hazard and Environmental Risk Assessment Science Chapter for the Busan 77 Reregistration Eligibility Decision (RED) Document," dated September 30, 2007; the "Revised Environmental Fate Science Chapter for the Busan 77 Reregistration Eligibility Decision (RED) Document", dated September 30, 2007 and the "Revised Environmental Exposure Assessment for Releases of BUSAN 77 from Once-through Cooling Water System", dated September 30, 2007.

1. Environmental Fate and Transport

The available data indicate that Busan 77, is a water-soluble, cationic ionene polymer (WSCP) with an average molecular weight of 3,386 g/mol. Based on its miscibility in water and high molecular weight, volatility from water is highly unlikely. It is also stable to both abiotic degradation (hydrolysis and photolysis) and to metabolism in soil and sediment water systems. In the presence of soil or sediment, tight sorption of nearly all residues was observed almost immediately. Busan 77 was almost exclusively (96 %) found in the top two inches of 12 inch columns leached with water. Less than 1 % was found in the leachate collected at the bottom of the columns. These conclusions on mobility are consistent with the fact that Busan 77 is positively charged and soil/sediment is negatively charged. As a result, Busan 77 is not expected to contaminate surface and ground waters.

In addition, the results from the study on the bioconcentration in fish, indicate that bioconcentration is not likely to occur. This conclusion is consistent with the fact that Busan 77 is a cation that will not concentrate in fat. However, it is important to recognize that in some conditions the presence of Busan 77 in the water may cause some acute risk to fish.

The environmental fate database is considered to be complete. The various studies that were considered for the environmental fate assessment are identified and summarized below in Table 12.

Table 12: Environmental Fate Properties of Busan 77

Guideline No./ Study Type	Results	Reference Information
835.2110 Hydrolysis	Mean: 103-137mg/L over 30 day period The hydrolytic stability of aqueous solutions of Busan 77 was tested at pH 5, 7 and 9. No degradation was observed at any tested pH over a 30 day period at 25 °C in the dark.	**41407401/93062026** Smith, A. (1990) Determination of Aqueous Hydrolysis Rate Constant and half-life of Busan 77: Final Report: Lab Project Number: 995-1089-6116-715: Lab Report Number 90-2-3216. Unpublished study prepared by Springborn Laboratories, Inc. 32 p. **Acceptable**
835.2210 Direct photolysis rate in water by sunlight	Avg. mean recovery: 79.5 ± 3.5% Under the aseptic test conditions employed with a solution temperature of 25.6 ± 1.6 °C for the pH 5 and 7 phase of this study and 25.7 ± 1.7 °C for the pH 9 phase of this study, Busan 77 is photolytically stable. Definitive testing was performed over a 30 day period with no appreciable degradation observed, within experimental error, in any	**41420901/93062027** Smith, A. (1990) Determination of Aqueous Photolysis Rate Constant and half-life of Busan 77: Lab Project Number: 995-1089-6117-720; 90-3-3251. Unpublished study prepared by Springborn Laboratories, Inc. 37 p. **Acceptable**

Guideline No./ Study Type	Results	Reference Information
	solution at any of the pHs tested. Busan 77 is considered photolytically stable (EPA Standard Evaluation Procedure, 1985).	
835.3100 Aerobic aquatic biodegradation	**First Experiment**. Under aerobic aquatic conditions, ^{14}C-Busan 77 (5.07 ppm) rapidly became sediment-bound. In this experiment, sediment bound residues increased from approximately 11% at Day 0 to 53% at Day 2 and retained in the range of 52% to 70% for the 30-day study. Approximately 4.0% of the total dose was trapped as CO2 and 0.1% of the applied radioactivity was trapped as organic volatiles by Day 30. Total recoveries averaged approximately 63% for the experiment, which resulted from strong adsorption of the test material to laboratory glassware during sale extraction. **Second Experiment**. In the second experiment, ^{14}C Busan 77 (4.77 ppm) rapidly because sediment bound in aerobic aquatic samples. This sediment bound radioactivity increased from approximately 31% at Day 0 to 94% at Day 1, and then remained fairly constant for the 31 day study. Approximately 5% of the total applied radioactivity was trapped as CO2. No radioactivity was detected as organic volatiles. Total recoveries averaged 100.0% for the experiment.	**MRID 40334101** Obrist, J. (1987) Aerobic Aquatic Metabolism of Busan 77: Laboratory Project ID: HLA 6015-251: Final Report. Unpublished study prepared by Hazleton Laboratories America, Inc. 69 p. **Acceptable**
835.3300 Anaerobic biodegradability of organic chemicals	Under laboratory conditions at 25°C ±2°. Busan 77 rapidly became sediment-bound in an anaerobic aquatic system (Lake Mendota water and sediment) following treatment at 4.75 ppm. Sediment bound residues accounted for more than 90% of the total applied dose at all sampling points (except Day 0) through 365 days. The majority of the sediment bound radioactivity was associated with the humic fraction after treatment with a sodium hydroxide solution. Approximately 0.7% of the total applied dose was detected in the carbon dioxide trap, and less than 0.1% of the applied radioactivity was found in the organic volatiles trap.	**40165201** Obrist, J. 1987. Anaerobic Aquatic Metabolism of Busan 77. Hazelton # 6015-250. Unpublished study prepared by Hazelton Laboratories Inc. 50 p. **Acceptable**
835.3300 Aerobic Soil Metabolism	Under laboratory conditions at 23-25^{o}C ± 1 ^{o}C, Busan 77 was stable to aerobic soil metabolism. Good material balance was observed	**40165202** Das, Y. (1987) Aerobic Soil Metabolism of WSCP: Biospheric No. 84E-301A. Unpublished study

Guideline No./ Study Type	Results	Reference Information
		prepared by Biospheric Inc. 50 p. **No record review, based on material balance it appears to be valid.**
835.1220 Soil Column Leaching	Busan 77 was found almost exclusively (96 %) in the top 2 inches of 12-inch columns (average). <1 % was found in the leachate of the columns.	**00157906** Cargile, N. (1986). Soil column leaching of ^{14}C-WSCP. Final Report Project No. 84E-303L. Study conducted by Biospherics, Inc. **00157907** Cargile, N. Leaching characteristics of Aged 14C-WSCP. Final Report Project No. 34E-303AL. Study conducted by Biospherics, Inc. **Acceptable**
850.1730 Bioconcentration in Fish	Busan 77 did not bioconcentrate (BCF=2) in channel catfish.	**00159308** Barrows, B.A. 1985. Bioconcentration of ^{14}C-Radiolabeled WSCP in the Channel Catfish, Ictalurus punctatus, in a Static Test System. Study conducted by Biospherics, Inc., and submitted by Buckman Laboratories. **Unacceptable**

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics and pesticide use data. A summary of the submitted data is provided below.

a. Environmental Toxicity

Toxicity Birds

Available data indicate that Busan 77 is moderately to slightly toxic to birds on an acute oral basis and slightly to relatively non-toxic to birds on a sub-acute dietary basis. Therefore, an avian environmental hazard statement for birds is not required on Busan 77 labels.

Toxicity to Terrestrial Animals

Based on the results of mammalian studies conducted to meet human toxicity data requirements, Busan 77 exhibits moderate oral, dermal, inhalation toxicity and eye irritation (toxicity category III). Busan 77 is not a dermal sensitizer.

Toxicity to Aquatic Animals

On an acute basis, Busan 77 is very highly toxic to highly toxic to fish. The submitted studies fulfill the guideline requirements, however because acute toxicity values to fish is <1.0 mg/L, the environmental hazard section of Busan 77 labels must state: "This pesticide is toxic to fish."

Busan 77 is also highly toxic to moderately toxic to estuarine/marine invertebrates on an acute basis and relatively nontoxic to estuarine/marine fish on an acute basis, however because the estuarine/marine acute toxicity values are < 1.0 mg/L, the environmental hazard section of Busan 77 labels must state: "This pesticide is toxic to clams."

Toxicity to Plants

Testing has been conducted with Busan 77 on several aquatic and terrestrial plant species. The guideline requirement for an algal toxicity test (850.5400, 123-2) is partially fulfilled. Two additional algal toxicity tests under 850.5400 are outstanding because they do not meet guideline requirements; which require a test with the freshwater green alga, *Selenastrum capricornutum*, and a test with the marine diatom, *Skeletonema costatum*. The other non-target aquatic plant toxicity requirement, floating freshwater aquatic macrophyte duckweed (*Lemna gibba*) – guideline 850.4400 - is not satisfied. A study on the rooted freshwater macrophyte rice (*Oryza sativa*) – 850.4225 (seedling emergence test) - has not been submitted.

A summary of the submitted ecological toxicity data for Busan 77 are provided in Tables 13, 14, 15 and 16.

Table 13. Toxicity to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg a.i.)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Acute Avian Toxicity					
Mallard duck (*Anas platyrhynchos*)	Busan 77 61.7%	LD_{50} = 497 NOAEL = 51	Moderately toxic	Yes (core) - 14-day test duration - 36 weeks of age	416548-01
Bobwhite quail (*Colinus virginianus*)	Busan 77 % purity unknown	LD_{50} = 690 NOAEL = <172 (based on the assumption of 60% a.i.)	Slightly toxic	No (supplemental) - 21-day test duration - young adult - study conducted before adoption of GLP principles	ID 0522-010-20
Subacute Avian Toxicity					
Mallard duck (Anas platyrhynchos)	Busan 77 60.3%	LC50 (diet) = >12,000 NOAEC = 3,000	Relatively nontoxic	No (supplemental) - 8-day test duration - 10 days of age - study conducted before adoption of GLP principles	414115-01
Bobwhite quail (Colinus virginianus)	Busan 77 61.6%	LC50 (diet) = >3,462 NOAEC = 3,462	Slightly toxic	Yes (core) - 8-day test duration - 11 days of age	001593-07

Table 14. Toxicity to Aquatic Animals

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg a.i./L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Acute Toxicity to Freshwater Fish					
Rainbow Trout (*Oncorhynchus mykiss)*	Busan 77 61.9%	LC_{50} = 0.047 NOAEC = 0.037	Very highly toxic	Yes (core) - 96-hr test duration - static test system	413520-01
Bluegill sunfish (*Lepomis macrochirus)*	Busan 77 61.9%	LC50 = 0.21 NOAEC = 0.13	Highly toxic	Yes (core) - 96-hr test duration - static test system	413520-02
Rainbow Trout (*Oncorhynchus mykiss)*	Busan 77 60%	LC_{50} = 0.26 NOAEC = 0.11	Highly toxic	No (supplemental) - 96-hr test duration - static test system - study lacks important information - study conducted before adoption of GLP principles	001072-07
Acute Toxicity to Freshwater Invertebrates					
Waterflea (*Daphnia magna)*	Busan 77 61.9%	EC_{50} = 0.280 NOAEC = 0.130	Highly toxic	Yes (core) - 48-hr test duration - static test system	413520-03
Acute Toxicity of Busan 77 to Estuarine and Marine Organism					
Sheepshead minnow (*Cyprinodon varigates*)	Busan 77 60.0%	LC_{50} > 360 NOAEC = 360	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	401392-02
Mysid shrimp (*Mysidopsis bahia*)	Busan 77 60.0%	LC_{50} = 7.8 NOAEC <7.8	Moderately toxic	Yes (core) - 96-hr test duration - static test system	401392-03
Quahog clam (*Mercenaria mercenaria*)	Busan 77 60.0%	EC_{50} = 0.21 NOAEC = 0.14	Highly toxic	Yes (core) - 48-hr test duration - static test system - embryo/larval stage	403342-01

Table 15. Chronic Toxicity to Freshwater Organisms

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg a.i./L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Waterflea (*Daphnia magna*)	Busan 77 60.3%	LOEC = 0.020 NOAEC = 0.012	No (supplemental) - 21-day test duration - static renewal test system - organisms not distributed or fed properly - excess mortality	424796-01

Table 16. Toxicity to Plants

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg a.i./L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Seedling Emergence (Tier I) Toxicity of Busan 77 to Terrestrial Plants				
Monocot Oat (*Avena sativa*)	Busan 77 60.3%	EC_{25} = >73 NOAEC = 73	Yes (core) - 14-day test duration -most sensitive parameter: shoot length (14% reduction)	420381-01
Dicot Lettuce (*Lactuca sativa*)	Busan 77 60.3%	EC_{25} = >73 NOAEC = 73	Yes (core) - 14-day test duration - most sensitive parameter: shoot length (17% reduction)	420381-01
Vegetative Vigor (Tier I) Toxicity of Busan 77 to Terrestrial Plants				
Monocot Corn (*Zea mays*)	Busan 77 60.3%	EC_{25} = >74 NOAEC = 74	Yes (core) - 14-day test duration - most sensitive parameter: shoot length (17% reduction)	420381-01
Dicot Cucumber (*Cucumis sativus*)	Busan 77 60.3%	EC_{25} = >74 NOAEC = 74	Yes (core) - 14-day test duration - most sensitive parameter: root length (31% reduction	420381-01
Vegetative Vigor (Tier II) Toxicity of Busan 77 to Terrestrial Plants				

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg a.i./L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Monocot Ryegrass (*Lolium perenne*)	Busan 77 60.3%	EC_{25} = >74 NOAEC = 74	No (supplemental) - 14-day test duration - most sensitive parameter: root length (0% reduction)	420381-01
Dicot Tomato (*Lycopersicon esculentum*)	Busan 77 60.3%	EC_{25} = >74 NOAEC = 74	No (supplemental) - 14-day test duration - most sensitive parameter: shoot length (15% reduction)	420381-01
Toxicity of Busan 77 to Aquatic Plants				
Marine diatom (*Skeletonema costatum*)	Busan 77 60.3%	EC_{50} = 0.090 NOEC < 0.024	No (supplemental) - 120-hour test duration - static test system	420133-02
Freshwater diatom (*Navicula pelliculosa*)	Busan 77 60.3%	EC_{50} = 0.083 NOEC = 0.044	Yes (core) - 96-hour test duration - static test system	420133-03
Bluegreen cyanobacteria (*Anabaena flos-aquae*)	Busan 77 60.3%	EC_{50} = 0.11 NOEC = 0.05	Yes (core) - 120-hour test duration - static test system	420133-04
Green alga (*Selenastrum capricornutum*)	Busan 77 60.3%	EC_{50} = 0.0088 NOEC < 0.001	No (supplemental) - 120-hour test duration - static test system	420133-05
Duckweed (*Lemna gibba*)	Busan 77 60.3%	EC_{50} > 0.65 NOEC = 0.043	No (supplemental) - 14-day test duration - static renewal test system - maximum concentration tested produced only 30% growth inhibition	420133-01

b. Ecological Exposure and Risk

An ecological risk assessment is not typically conducted for the types of uses registered for Busan 77 except for the once-through cooling water use. The Agency has evaluated the once-through cooling water use being considered for reregistration. A risk assessment for once-through cooling water uses using maximum application rates and the toxicity values for various organisms has been conducted. All other uses are considered indoor and have minimal to no environmental exposure potential and an ecological risk assessment was not needed.

The Agency performed environmental exposure and risk assessments for releases of Busan 77 when it used for the control of mollusks in once-through cooling water systems. The Probabilistic Distribution Model (PDM) (version 4) was used to estimate the number and percentage of days per year that Busan 77 concentrations exceed ecotoxicity concentrations of concern (COCs) [1]. The treatment scenarios that were utilized for the analyses of Busan 77 were derived from product label information. The approach used to generate the ecological risk assessment is based on the methodology used on other similar antimicrobial pesticides. The comprehensive discussion of the parameters, calculations, model output conclusions and data limitations and uncertainties are all available in the supporting "Revised Environmental Exposure Assessment for Releases of BUSAN 77 from Once-through Cooling Water System", dated September 30, 2007; and the "Revised Preliminary Ecological Hazard and Environmental Risk Assessment Science Chapter for the Busan 77 Reregistration Eligibility Decision (RED) Document", dated September 30, 2007.

The PDM is a screening-level exposure assessment tool developed by EPA to model chemical releases from point sources to flowing surface waters. For this analysis, the PDM component within EPA's Exposure and Fate Assessment Screening Tool Version 2.0 (E-FAST2) was used.[2] PDM uses detailed U.S. Geological Survey (USGS) stream flow data and facility-specific data from National Pollutant Discharge Elimination System (NPDES) permits to model chemical releases from actual facilities. For a modeling period of a given number of days, PDM calculates the probability distribution of the chemical concentration in the receiving stream, and then estimates the number of days during which the in-stream chemical concentration is expected to exceed a COC. PDM counts a day as having an exceedence of a COC if the COC is exceeded for any part of a 24-hour day. As a screening-level model, PDM outputs do not include the duration, location, or aerial extent of exceedences. The COCs identified and selected from the ecological effects information for Busan 77 are provided in Table 18.

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[1] "Environmental Exposure Assessment for Releases of Bromonitrostyrene from Once-through Cooling Water Systems," memorandum to David Bays, EPA OPP/AD, from Joshua Cleland and Keith Drewes, ICF International, April 26, 2007. Also, see "Environmental Exposure Assessment for Releases of Busan 77 From Once-through Cooling Water Systems," memorandum to Norm Cook, EPA OPP/AD, from Siroos Mostaghimi, EPA OPP/AD, July 27, 2007.

[2] The E-FAST2 model is available from EPA at http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm and documentation is available at http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf.

Table 17: Concentrations of Concern Selected for the Environmental Exposure Assessment of Busan 77

COC	Test Species	Endpoint Type	Study Type	Reference (MRID)
12 µg/L[a]	Waterflea (*Daphnia magna*)	NOEC	Life-cycle toxicity to freshwater invertebrates	42479601
130 µg/L	Waterflea (*Daphnia magna*)	NOEC	Acute toxicity to freshwater invertebrates	41352003
140 µg/L	Quahog clam (*Mercenaria mercenaria*)	NOEC	Acute toxicity to estuarine and marine organisms	40334201
260 µg/L[a]	Rainbow trout (*Oncorhynchus mykiss*)	LC_{50}	Acute toxicity to freshwater fish	00107207
7,800 µg/L	Mysid shrimp (*Mysidopsis bahia*)	NOEC	Acute toxicity to estuarine and marine organisms	40139203
360,000 µg/L	Sheepshead minnow (*Cyprinodon varigates*)	NOEC	Acute toxicity to estuarine and marine organisms	40139202

The model estimated the number of days exceeding each COC, as a result, the averages and standard deviations were calculated. In addition, the percent of days per year above the COCs was calculated along with the percent of days during the release period above COCs (maximum 100 percent). The results are provided in Table 19 and the percentage of facilities that had exceedences at least once (i.e., on at least one day) for each COC are provided in Table 20. If the number of days a COC is exceeded is greater than the number of days used to determine the endpoint in toxicity testing, risk is assumed. This assumes that the number of days exceeded are consecutive, a conservative but not impossible assumption. Based on this assumption, Table 19 shows there will be risk at the average number of days exceeded to freshwater fish, freshwater invertebrates (both acute and chronic), and estuarine/marine invertebrates.

Table 18: Number and Percent of Days with Downstream Busan 77 Concentrations Exceeding COCs

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12 µg/L[a]	207	72	57%	20%	83%	29%
130 µg/L	152	94	42%	26%	61%	37%
140 µg/L	149	94	41%	26%	60%	37%
260 µg/L[a]	129	92	35%	25%	51%	37%

Table 18: Number and Percent of Days with Downstream Busan 77 Concentrations Exceeding COCs						
COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
7,800 µg/L	12	18	3%	5%	5%	7%
360,000 µg/L	1	5	<1%	2%	<1%	2%

[a] COC is based on a study that does not fulfill the guideline requirements.

Table 19: Percent of Facilities with Downstream Busan 77 Concentrations Exceeding COCs on at Least One Day (n = 30)	
COC (µg/L)	Percent of Facilities with at Least One Day with an Exceedence
12 µg/L[a]	97%
130 µg/L	87%
140 µg/L	87%
260 µg/L[a]	87%
7,800 µg/L	57%
360,000 µg/L	10%

[a] COC is based on a study that does not fulfill the guideline requirements

c. Risk to Listed Species

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

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment.

This preliminary analysis for the once-through cooling water uses of Busan 77 indicates that there is a potential for Busan 77 use to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects. The more refined assessment should involve clear delineation of the action area associated with proposed once-through use of Busan 77 and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this action and an endangered species effect determination is unable to be made at this time.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing Busan 77 as an active ingredient. 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 Busan 77.

The Agency has completed its assessment of the occupational, residential, and ecological risks associated with the use of pesticide products containing the active ingredients Busan 77. Based on a review of these data and on public comments on the Agency's assessments for the active ingredients Busan 77, the Agency has sufficient information on the human health and ecological effects of Busan 77 to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that Busan 77 products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of Busan 77 that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of Busan 77and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of Busan 77, the Agency has determined that Busan 77products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measure identified in this document, the Agency may take regulatory action to address the risk concerns from the use of Busan 77. If all changes outlined in this document are incorporated into the product labels, then all current risks for Busan 77 will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, the EPA worked with stakeholders and the public to reach the regulatory decision for Busan 77. The EPA released its preliminary risk assessment for Busan 77 for public comment on September 28, 2007. The Agency received no comments during the 60-day public comment period on the Busan 77 risk assessment and supporting science documents, which closed on November 27, 2007.

C. Regulatory Position

The EPA assessed the risks associated with Busan 77 use. The Agency has determined that if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to Busan 77 are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to Busan 77 from all possible sources.

a. Determination of Safety to U.S. Population

The Agency has determined that the Busan 77, with amendments and changes specified in this document, 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 Busan 77. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of the Busan 77.

A chronic dietary assessment for Busan 77 is warranted based on the use in the paper manufacturing processes as a slimicide for pulp and paper mill technologies or for starch preservation. No toxic effects were identified that were attributable to a single exposure. Therefore, an acute dietary assessment is not required. The registrant has indicated that they no longer support the starch uses, and that they will be removed from product labels. Further, based on the very low application rates for the slimicide use in pulp and paper mills (10ppm) the Agency believes that exposures will be negligible and, therefore does not have dietary risk concerns. This conclusion is supported by the fact that previous assessments for other chemicals with similar toxicological endpoints but much higher application rates (1000-1200 ppm) resulted in very low exposure and risk estimates. Additional information can be found in the document titled, "Dietary Risk Assessment (Indirect Food Contact) Uses in Paper Manufacturing Process of Poly[(oxyethylene)(dimethylimino)ethylene(dimethylimino) ethylene dichloride] [Busan 77]," dated September 30, 2007.

b. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of Busan 77, with changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the toxicity, use practices, and environmental behavior noted above , but also takes into account the possibility of increased susceptibility to the toxic effects of Busan 77 residues in this population subgroup.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. This conclusion is based upon the availability of acceptable developmental and reproductive toxicity studies with Busan 77 that adequately characterize the dose-response of this compound along with the lack of evidence for any sensitivity of offspring to the adverse effects of Busan 77. The Agency does not anticipate dietary or drinking water or residential exposures based on the registered use patterns and there

are no tolerances or tolerance exemptions for the use of the Busan 77 as active ingredients. Therefore, an FQPA hazard analysis is not necessary at this time.

c. 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, the Busan 77 may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of Busan 77. 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 Busan 77. 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/.

D. Regulatory Rationale

The Agency has determined that the Busan 77 is eligible for reregistration provided that additional required data confirm this decision, the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the uses of Busan 77. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. -

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

A dietary assessment was generated for Busan 77 based on the use patterns potential for dietary exposure. Busan 77 is used in the paper manufacturing processes as a slimicide for pulp and paper mill technologies or for starch preservation. The Agency has previously conducted dietary risk assessments for various REDs with application rates in the range of 1,000 to 1,200 ppm levels for pulp and paper mill uses and concluded for these rates that there were not any dietary risks to any set of population groups. Based on this, it is assumed that the low application rate of 10 ppm for the label Busan 77 is not of a concern. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

Busan 77 adsorbs strongly to soil, such that a drinking water exposure is not likely. The modeled results for incidental oral exposures, based on the swimming pool use, are higher than those resulting from the conservative modeling of the once through cooling water use. Considering that the risk estimates for the highest exposure swimming scenario yielded MOEs greater than 50,000, the Agency does not expect drinking water exposures resulting from the once through cooling water system use to be of concern because the low potential for exposure. Therefore, no mitigation measures are necessary at this time.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler dermal and inhalation risks were assessed for the use of Busan 77 in swimming pools, spas/whirlpools/ponds, aquariums and waterbed mattresses. All of the calculated MOEs were above the target for all scenarios. Furthermore, all inhalation MOEs exceeded 1,000 therefore, a confirmatory inhalation toxicity study is not warranted based on the results of these exposure scenarios. No mitigation measures are necessary at this time.

ii. Post-Application Risk Mitigation

Residential post-application dermal exposures result when adults and children come in contact with Busan 77 in areas where pesticide end-use products have recently been applied (e.g., swimming pool and spas/whirlpool), or when children incidentally ingest the pesticide residues through swallowing treated swimming pool water. It is anticipated that absorbents such as textiles will absorb Busan 77 and post-application residential dermal and incidental oral exposures to treated textiles may occur. The inhalation exposures (vapor) were not assessed due

to the extremely low vapor pressure of Busan 77. All MOEs were above the target and not of concern. Therefore, no risk mitigation measures are necessary at this time.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

Potential occupational handler exposures can occur during the application of Busan 77 through either liquid/solid pour or liquid pump methods. Liquid/solid pour refers to transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow. There is also the potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-product.

Short-term dermal exposures were not assessed for most occupational handler scenarios because the endpoint is based on dermal irritation. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products that result in classification of category I, II, or III for skin irritation potential will be a long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential. Most of the labels currently do not require PPE; based on this assessment all of these labels will need to be updated to reflect the PPE requirement.

Since gloves are also not a viable mitigation option for a machinist using biocide treated metalworking fluids, the short-term dermal exposure was assessed for this scenario. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-use product. The MOE value is above the target of 10 and therefore not a concern.

ii. Post-Application Risk Mitigation

No occupational post-application exposures are expected to occur from these uses. Therefore, no risk mitigation is necessary.

2. Environmental Risk Management

The majority of the uses for Busan77 are considered indoor and to have minimal to no environmental exposure potential, with the exception of the once-through cooling water use. Busan 77 is used for the control of mollusks in once-through cooling water systems. The Probabilistic Distribution Model (version 4) was used to estimate the number and percentage of

days per year that Busan 77 concentrations exceed ecotoxicity concentrations of concern (COCs) [3]. The treatment scenarios that were utilized for the analyses of Busan 77 were derived from product label information. Upon execution of the model, the number of days exceeding each COC were provided and the averages and standard deviations were calculated. In addition, the percent of days per year above the COCs was calculated along with the percent of days during the release period above COCs (maximum 100 percent). If the number of days a COC is exceeded is greater than the number of days used to determine the endpoint in toxicity testing, risk is assumed. This assumes that the number of days exceeded are consecutive, a conservative but not impossible assumption. Based on this assumption, there will be risk at the average number of days exceeded to freshwater fish, freshwater invertebrates (both acute and chronic), and estuarine/marine invertebrates.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing Busan 77. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

The following statement must be added to all product labels because the acute toxicity to fish, aquatic invertebrates, and estuarine/marine species are less than 1.0 mg/L:

"This product is toxic to fish, aquatic invertebrates, and clams"

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any

[3] "Environmental Exposure Assessment for Releases of Bromonitrostyrene from Once-through Cooling Water Systems," memorandum to David Bays, EPA OPP/AD, from Joshua Cleland and Keith Drewes, ICF International, April 26, 2007. Also, see "Environmental Exposure Assessment for Releases of Busan 77 From Once-through Cooling Water Systems," memorandum to Norm Cook, EPA OPP/AD, from Siroos Mostaghimi, EPA OPP/AD, July 27, 2007.

action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination.

This preliminary analysis for the once-through cooling water uses of Busan 77 indicates that there is a potential for Busan 77 use to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects. The more refined assessment should involve clear delineation of the action area associated with proposed once-through use of Busan 77 and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this action and an endangered species effect determination is unable to be made at this time.

b. General Risk Mitigation

Busan 77 end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing Busan 77 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 the Busan 77 are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. To implement the risk mitigation measure, the registrants must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For the Busan 77 technical grade active ingredient products, the registrant needs to submit the following items:

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

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

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

Within the time limit specified in the generic DCI:

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

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

By US mail:

Document Processing Desk
ShaRon Carlisle
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
ShaRon Carlisle
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the Busan 77 as an active ingredient, the registrant needs to submit the following items for each product.

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

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

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

Within eight months from the receipt of the PDCI:

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

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

3. Five copies of the draft label incorporating all label amendments outlined in Table 23 of this document;

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

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

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

Please contact Adam Heyward at (703) 308-6422 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
Adam Heyward
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
Adam Heyward
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

1. Additional Generic Data Requirements

The generic database supporting the reregistration of the Busan 77 have been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements and are included in the generic data call in (DCI) for this RED.

Ecological Effects:

- 850.1300: Aquatic invertebrate life-cycle study (using TGAI and most sensitive species - freshwater or estuarine/marine)
- 850.1400: Fish early-life stage study (using TGAI and most sensitive species - freshwater or estuarine/marine)
- 850.4225: Seedling emergence study - dose response using rice (*Oryza sativa*)
- 850.4400: Freshwater floating macrophyte duckweed study
- 850.5400: Aquatic plant growth (algal toxicity) – 2 studies outstanding (marine diatom - *Skeletonema costatum* and green algae - *Selenastrum capricornutum*); Tier II (using TGAI or TEP)
- 850.1735: Whole sediment, acute invertebrates (freshwater) (using TGAI)
- 850.1740: Whole sediment, acute invertebrates (estuarine/marine) (using TGAI)
- Depending on the results of the whole sediment, acute invertebrate studies, the following data may be required: Whole sediment - chronic invertebrates (freshwater and/or estuarine/marine) (using TGAI or TEP)
- Special Aquatic Field Monitoring Once-Through Cooling Water Systems)

Residential/Occupational Data Gaps:

- A textile residue study for the fresh water microbiocide use in textile manufacturing facilities is needed to conduct the post-application residential dermal and incidental oral exposure assessment.
- Confirmatory monitoring data be generated to support the values used in the risk assessment due to poor quality of the CMA data that was used.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 20, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 20, Label Changes Summary Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measure outlined in Section IV of the Busan 77 RED. The following table describes how language on the labels should be amended.

Table 20: Labeling Changes Summary Table

BUSAN 77		
Description	**Amended Labeling Language**	**Placement on Label**
All End Use Products		
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish, aquatic invertebrates, and claims. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Starch Preservation Use	All labels listing the starch preservation use must be updated to reflect the cancellation of this use	
Directions For Use		
End Use Products Intended for Occupational use	In order to reduce potential occupational handler exposures the following mitigation is required: • Personal Protective Equipment (PPE) is required for end-use products that result in classification of category I, II, or III for skin irritation. (long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron) • Personal Protective Equipment (PPE) is required for end-use products that result in classification of category I or III for eye irritation. (Chemical-resistant eyewear)	Directions for Use

VI. APPENDICES

Busan 77 Appendix A

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Residential and public access premises				
Fabric	42373-6	Add product to mattress.	Add 8 fluid ounces to fiber waterbed mattress of 90-180 gallons capacity. Add 4 to 12 gallons capacity to a twin or hybrid type waterbed up to 90 gallons capacity. Repeat 10-12 months in fiber or foam beds. In free flow waterbeds repeat 18-24 months.	None Listed
Industrial Processes and Water Systems				
Cooling Water Tower	402-123 527-106 527-122 527-127 1020-14 1448-42 1448-60 1448-61 1448-62 1448-63 1448-108 1448-109 1448-110 1448-113 1448-114 1448-205 1448-206	Slug or sump method (Soluble Concentrate)	Initial dose: An initial slug addition of .9 to 94 fluid ounces per 1000 gallons of water. Repeat initial dose until control is evident. Subsequent Dose: Subsequent slug additions .2 to 59 fluid ounces per 1000 gallons of water should be employed every 1 to 5 days or as needed. Slug additions should be made in the sump of water cooling towers.	Prior to initial dose systems must be cleaned to remove algal growth, microbiological slime, and other deposits.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-207 1448-208 1448-211 1448-212 1448-232 1448-233 1448-234 1448-235 1448-236 1448-237 1448-302 1448-305 1448-379 1448-380 1448-396 1448-397 1448-398 1448-400 1706-159 1757-100 3525-65 3635-273 3635-274 3635-275 3635-277 3862-153 5185-339 6836-159 8540-8 10088-40 12005-4			

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	15300-1 15300-2 15300-11 15300-22 15300-23 35571-1 38635-2 39959-1 39959-2 39959-3 43553-1 44392-2 45309-38 51219-2 52867-1 55137-1 56244-2 66806-1			
Petroleum Secondary Recovery Systems	1448-396 1448-398		Add 11.6 to 92.8 fluid ounces	None Listed
Paper Mill Process Water	55137-1	Added directly to mill system	Add 75 to 750 ppm based on total weight of the starch and water.	Do not use in paper and paperboard that will contact food.
Air Washer Water Systems	402-123 527-106 527-122 1448-42 1448-60 1448-61	Intermittent or Slug method	<u>Initial dose:</u> An initial slug dose of 3.3 to 83.25 fluid ounces per 1000 gallons of water. Repeat initial dosage until control is evident.	Prior to initial dose systems should be cleaned to remove bacterial slime and other deposits

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-62 1448-63 1448-108 1448-109 1448-110 1448-113 1448-114 1448-205 1448-206 1448-207 1448-208 1448-211 1448-212 1448-232 1488-233 1448-234 1448-235 1448-236 1448-237 1448-302 1448-305 1448-396 1448-397 1448-398 1448-400 1706-159 1757-100 3635-273 3635-274 3635-275 3635-277		<u>Subsequent Dose</u>: Subsequent slug additions 2.25 to 83.25 fluid ounces per 1000 gallons of water should be employed 1 to 5 days or as needed. Slug additions may be made to the sump or to the water collection trays of the air-wash systems.	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	5185-339 12005-4 15300-1 15300-2 15300-11 15300-22 15300-23 38635-2 39959-1 39959-2 39959-3 43553-1 44392-2 45309-38 52867-1 55137-1 56244-2 66806-1			
Material Preservatives				
Metal Working Fluid	1448-216 1448-217 1448-218 1448-315 1448-396 1448-397 1448-398 (Soluble Concentrate)	(Sump Dose Soluble)	Add to diluted metalworking fluid at a concentration of .01 to .10 percent based on total weight of the metalworking fluid. Treatment of the diluted metalworking fluid should be repeated every four weeks as long as the fluid is used. Add to undiluted metalworking fluid at a concentration which will provide .01 to .10 percent concentration when diluted with water for use.	None Listed
Fire Water Protection Systems	1448-396 1448-397 1448-398	Pour	Initial Dose: Add 11.6 to 6.4 fluid ounces per 1000 gallons Subsequent doses should be evaluated	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			based on microbiological activity and product level testing	
Swimming Pools				
Swimming Pool Water Systems - Pools	527-122 1258-1078 1258-1269 1258-1272 1258-1274 1448-42 1448-60 1448-61 1448-62 1448-63 1448-108 1448-109 1448-110 1448-113 1448-114 1448-205 1448-207 1448-208 1448-211 1448-212 1448-232 1448-233 1448-234 1448-235 1448-236 1448-237 1448-346 1448-347 1448-378		Initial Dose: Range of dose is 13 to 24 fluid ounces per 1000 gallons of water. Subsequent Dose: Subsequent additions of 2 to 27 fluid ounces per 10,000 gallons of water every 5 to 7 days after initial treatment for maintenance.	Do not mix with concentrated dry or liquid chlorine products.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-379 1448-380 1448-400 2230-51 3432-26 3432-28 3432-31 3432-42 3432-74 3432-80 3525-66 3525-71 3525-109 3525-117 3525-133 3635-277 5185-339 7124-77 7124-91 7124-92 7364-22 7364-81 7364-82 7364-87 7364-93 7616-57 7616-58 7616-73 8959-26			

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	8959-37 8959-37 10088-78 10897-13 11411-11 19369-2 41547-1 42177-9 42177-32 42177-33 44392-1 44392-2 45309-1 45309-2 45309-11 45309-30 45309-31 45309-37 45309-79 45309-80 45458-21 45458-22 46043-4 46043-24 46978-4 47158-2			

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	48520-15 48520-16 48520-17 53842-5 54998-4 55137-1 57787-2 57787-11 57787-23 57787-25 62498-6 67262-10 67262-20 69461-2 69681-1 69681-2			
Swimming Pool Water Systems - Pools	3635-277 45309-10 48520-14		Initial dose: Add 50 to 241 fluid ounces per 10,000 gallons of water. Subsequent dose: Subsequent additions of 13.6 to 54 fluid ounces per 10,000 gallons of water.	Do not mix with concentrated dry or liquid chlorine products.
Swimming Pool Water Systems - Pools	7364-82		Solid Covered pools ½ gallon per 20,000 gallons of	Do not mix with concentrated dry or liquid chlorine products.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			water. Mesh or uncovered pools 1 gallon per 20,000 gallons of water.	
Spas, Whirlpools, or Hot Tubs	527-122 1258-1078 1258-1080 1448-42 1448-62 1448-108 1448-109 1448-110 1448-113 1448-114 1448-205 1448-207 1448-208 1448-211 1448-212 1448-232 1448-233 1448-234 1448-235 1448-236 1448-237 1448-346 1448-347 1448-379 1448-380 1448-400 2230-51		Initial dose: An initial dose of 0.5 to 12 fluid ounces per 1000 gallons of water. Subsequent dose: Subsequent additions of .2 to 9 fluid ounces per 1000 gallons of water should be made every 5 to 7 days after initial dose for maintenance.	Do not mix with concentrated dry or liquid chlorine products.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	3432-80 3525-71 3525-114 3635-277 7124-91 7124-92 7364-93 7616-57 7616-73 8959-27 10088-78 10897-13 11411-11 19369-2 35571-1 42177-9 42177-32 42177-33 42373-6 44392-1 44392-2 45309-10 45309-79 45309-80 45458-21 45458-22 46043-24 46978-4 47158-2 48520-14 48520-15			

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	48520-16 48520-17 53842-5 54998-4 57787-2 57787-23 67262-8 67262-20 69461-2 69681-1 69681-2			
Spas Whirlpools, or Hot Tubs	45309-1 45309-2		Initial dose: Add ½ to 2 ½ teaspoons per 100 gallons. Subsequent dose: Subsequent additions ¼ to ½ teaspoons per 100 gallons.	Do not mix with concentrated dry or liquid chlorine products.
Spas Whirlpools, or Hot Tubs	45309-11 7124-85		Initial dose: Add 4 to 13 fluid ounces per 500 gallons. Subsequent dose: Subsequent additions of 1 to 5 fluid ounces per 500 gallons of water.	Do not mix with concentrated dry or liquid chlorine products.
Aquariums Water Systems - Pools	8709-8 14802-8 81584-1		Add 1ml to 480 ml according to volume of water.	Do not use in aquariums with invertebrates or crustaceans e.g. crabs, shrimps, or crayfish.
Ornamental Ponds	1258-1078 1448-62		Initial dose: An initial dose of 0.5 to	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-108 1448-109 1448-110 1448-113 1448-114 1448-205 1448-207 1448-208 1448-211 1448-212 1448-232 1448-233 1448-234 1448-235 1448-236 1448-237 1448-346 1448-347 1448-379 1448-380 1448-400 1448-434 1706-159 1757-100 2230-51 3635-277 5185-339 7124-91 7124-92 7364-93 7616-57		24fluid ounces per 1000 gallons of water. <u>Subsequent Dose</u>: Subsequent additions of .2 to 9 fluid ounces per 1000 gallons of water should be made every 5 to 7 days after initial dose for maintenance.	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	7616-73 8709-8 8959-26 10088-78 10897-13 11411-11 14802-8 44392-2 45309-11 45309-79 45309-80 45458-21 45458-22 46043-24 46978-4 47158-2 48520-14 48520-15 48520-16 48520-17 53842-5 54998-4 55137-1 69681-2 81584-1			

APPENDIX B: Busan 77* (Case 3034)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Busan 77. These requirements apply to Busan 77 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. **Guideline Description** (Column 3). Identifies the guideline type.

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

(1) Agricultural premises and equipment
(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
Aquatic areas

3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column **(12)** will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	4,7,8,11	41898401,
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	4,7,8,11	41898401
830.1670	61-2b	Formation of Impurities	4,7,8,11	41898401
830.1700	62-1	Preliminary Analysis	4,7,8,11	41898401, 41898402
830.1750	62-2	Certification of Limits	4,7,8,11	41898401, 41898402
830.1800	62-3	Analytical Method	4,7,8,11	41898401,41898402
830.6302	63-2	Color	4,7,8,11	41898401, 41898402, 41898403 42372401, 46832601
830.6303	63-3	Physical State	4,7,8,11	41898401, 41898403, 42372401, 46832601
830.6304	63-4	Odor	4,7,8,11	41898401, 41898403, 42372401, 46832601
830.7200	63-5	Melting Point	4,7,8,11	41898401, 41898403, 42372401
830.7300	63-7	Density	4,7,8,11	41898401, 41898403, 42372401, 46832601
830.7840 830.7860	63-8	Solubility	4,7,8,11	41898401, 41898403, 42372401
830.7950	63-9	Vapor Pressure	4,7,8,11	41898401, 41898403, 42372401
	63-10	Dissociation Constant	4,7,8,11	41898401, 41898403, 42372401

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	4,7,8,11	41898401
830.7000	63-12	pH	4,7,8,11	41898401, 41898403, 42372401
830.6313	63-13	Stability	4,7,8,11	41898401, 41898403, 42372401
830.6317	63-17	Storage Stability	4,7,8,11	42615901
	63-18	Viscosity	4,7,8,11	Required
	63-20	Corrosion characteristics	4,7,8,11	Required
ECOLOGICAL EFFECTS				
850.1300	72-4	Fish early life-stage testing-freshwater		Data gap
850.1400	72-4b	Invertebrate life-cycle testing - freshwater		Data gap.
	122-2	Aquatic plant growth		42038101
	122-1a	Seed germ/seedling emerg		42038101
	122-1b	Vegetative vigor		42038101
850.4225	123-1	Seedling emergence dose-response in rice		Data gap
850.4250	123-1	Vegetative vigor dose-response in rice		Data gap
	123-1a	Seed germ / seedling emerg		42038101
840.4400	123-2	Aquatic plant growth		42013301, 42013302 , 42013303, 42013304 , 42013305
850.4400	123-2	Aquatic vascular plant dose-response toxicity		Data gap
850.5400	123-2	Acute algal dose-response toxicity - 4 species		Data gap
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		41654801
850.2200	71-2a	Acute avian diet. Quail		159307, 052201020
8502200	71-2b	Acute avian diet. Duck		41411501

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.1075	72-1a	Fish toxicity bluegill		41352002, 41352003
850.1075	72-1c	Fish Acute Toxicity – Freshwater (Rainbow Trout)		41352001, 107207
850.1010	72-2a	Acute Aquatic Invertebrate Toxicity		41352003
850.1025	72-3a	Estu/mari tox. Fish		40139202
850.1025	72-3b	Estu/mari tox. Mollusk		40334201
850.1025	72-3c	Estu/mari tox. Shrimp		40139203
850.1300	72-4a	Early life stage fish		42479601
850.1300	72-4b	Life cycle invertebrate		41108401
TOXICOLOGY*				
870.1100	81-1	Acute Oral - Rat		41373401, 93062009
870.1200	81-2	Acute Dermal - Rabbit		41327101, 93062010
870.1300	81-3	Acute Inhalation - Rat		41877501
870.2400	81-4	Primary Eye Irritation - Rabbit		41361701, 93062011
870.2500	81-5	Primary Dermal Irritation - Rabbit		41298601, 93062012
870.2600	81-6	Dermal Sensitization		40750301, 93062013
870.3050		28-day oral (mice)		40362601
870.3100	82-1a	90-Day Feeding-Rodent		40025001, 93662014
870.3150	82-1b	90 day feeding-nonrodent		Required
870.3200	82-2	21/28-Day Dermal Toxicity - Rat		Data Gap
870.3250	82-3	90-day dermal rodent		40170601/93062015
870.3465	82-4	28/90-Day Inhalation – Rat		Data gap
870.4100		Chronic tox - dog		41234501/93062016
870.4100	83-1a	Chronic tox – rodent		42543801, 41561301, 41809101

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.4100	83-1b	Chronic tox – non rodent		41234501, 93062016
870.4200	83-2a	Oncogenicity – rat		41809101
870.4200	83-2b	Oncogenicity – mouse		41494301/93062017
870.4300		Combined chronic toxicity/carcinogenicity		41809101, 41561301
870.3700	83-3	Developmental Toxicity -Rat		41423001/93062018
870.3700	83-3a	Teratogenicity – rat		40578201, 41423001
870.3700	83-3b	Teratogenicity – rabbit		41248001, 93062019
870.3800	83-4	2 – generation repro. –rat		40578201/ 93062020
870.5265	84-2	Bacterial Reverse Mutation Assay		Data gap
870.5275		Sex – linked recessive lethal test		151205
870.5100		Reverse mutation assay – salmonella typh.		41573701
870.5300	84-2	Detection of gene mutations in somatic cells		Data gap
870.5385	84-2	Micronucleus Assay		151206
870.5300	84-2a	Gene mutation – ames		41573701
870.5380	84-2b	Struct. chrom. aberration		151205, 151206, 93062021
870.6300	84-4	Other genotoxic effects		40978701, 93062022
870.5550		Unscheduled DNA synthesis in mammalian cells in culture - rat		40978701
870.4200	83-2	Carcinogenicity		Data gap.
870.7485	85-1	General Metabolism		40268601
870.7600	85-2	Dermal penetration – rat		40139201
Environmental Fate				
	160-5	Chemical Identity		41898401

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
835.2120	161-1	Hydrolysis of Parent and Degradates		41407401, 159309
835.2240	161-2	Photodegradation – Water		41420901, 159310
835.4400	162-3	Anaerobic Aquatic Metabolism		40165201
835.4300	162-4	Aerobic Aquatic Metabolism		4033410 , 40165202
835.1230	163-1	Leaching and Absorption/desorption		157906, 157907, 159311, 159312
840.1100	164-2	Aquatic Field Dissipation		Waived
850.1730	165-4	Bioaccumulation in Fish		159308
850.1950	165-5	Bioaccumulation in Aquatic non-target organisms		Data Gap.
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity		41898401

Appendix C. Technical Support Documents

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

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

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

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

These documents include:

Preliminary Risk Assessment and Supporting Science Documents:

- Poly(oxyethylene(dimethylminino)ethylene(dimethyliminio) ethylenedichloride): Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Code 069183, Case 3034, Antimicrobials Division, 8/04/07.
- Product Chemistry Science Chapter on Busan 77 . PC Code 069183, Case 3034, Antimicrobials Division, 7/13/07, A. Najm Shamim, Ph.D.
- Environmental Exposure Assessment for Releases of BUSAN 77 from Once-through Cooling Water Systems. PC Code 069183, Case 3034, Antimicrobials Division, July 27, 2007, Siroos Mostaghimi, Senior Scientist
- Poly(oxyethylene (dimethylminino) ethylene(dimethyliminio) ethylenedichloride) Busan 77: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 069183, Case 3034, Antimicrobials Division, 726/07, Timothy F. McMahon, Ph.D.
- Busan 77 Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 069183 , Case 3034, Antimicrobials Division, 7/23/07, A. Najm Shamim, Ph.D.
- Busan 77 Occupational/Residential Exposure Assessment. PC Code 069183, Case 3034, Antimicrobials Division, 7/27/07, Cassi Walls, Ph.D.
- Busan 77 – Incident Report Summary. PC Code 069183, Case 3034, Antimicrobials Division, 8/03/07, Jonathan Chen, Ph.D.
- Environmental Fate Assessment of Busan 77 for the Reregistration Eligibility Decision (RED). PC Code 069183, Case 3034, Antimicrobials Division, 7/27/07, A. Najm Shamim, Ph.D.
- Ecological Hazard and Environmental Risk Assessment: Poly(oxyethylene (dimethylminino) ethylene(dimethyliminio) ethylenedichloride) PC Code 069183, Case 3034, Antimicrobials Division, 7/27/07, Genevieve Angle, Biologist

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision of Busan 77 (Bibliography)

1. MRID Studies

MRID #	Citation
00151205	McCarroll, N. (1985) Drosophila Sex-linked Recessive Lethal Assay [with WSCP (Busan 77)]: Final Report: Project No. 197-183. Un- published study prepared by Hazleton Laboratories. 20 p.
00151206	Cortina, T. (1984) In vivo Micronucleus Assay in Mice: WSCP: Final Report: Project No. 197-182. Unpublished study prepared by Hazleton Laboratories America, Inc. 38 p.
40025001	Tisdel, M. (1986) Busan 77--Thirteen-week Subchronic Toxicity Study in Rats: Project ID: Study No. 6176-106. Unpublished study prepared by Hazleton Laboratories of America, Inc. 285 p.
40139201	Bosch, A. (1987) Dermal Absorption of [Carbon 14]-Busan 77 (WSCP) in Male Rats: HLA Study No. 6176-117: Final Report. Unpublished study prepared by Hazleton Laboratories America, Inc. 52 p.
40170601	Spindler, M. (1987) 13-Week Dermal Toxicity Study with Busan 77 in Rabbits: Laboratory Project ID: HLA 6176-118. Unpublished study prepared by Hazleton Laboratories America, Inc. 290 p.
40268601	Puhl, R. (1987) Metabolism Study with Busan 77 (WSCP) in Rats: Final Report: Laboratory Project ID: HLA 6176-115. Unpublished study prepared by Hazleton Laboratories America, Inc. 98 p.
40578201	MacKenzie, K. (1988) Two-Generation Reproduction Study with Busan 77 in Rats (One Litter per Generation): Project ID: HLA 6176-104. Unpublished study prepared by Hazleton Laboratories America, Inc. 952 p.
40750301	Glaza, S. (1987) Dermal Sensitization Study in Guinea Pigs with WSCP: Proj. ID 70303995. Unpublished study prepared by Hazleton Laboratories America, Inc. 30 p.
40978701	Cifone, M. (1989) Mutagenicity Test on Busan 77 in the in vivo/in vitro Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: Project ID: HLA Study No. 10280-0-494. Unpublished study pre- pared by Hazleton Laboratories America, Inc. 26 p.
41234501	Kehoe, D. (1989) One-Year Chronic Toxicity Study with Busan 77 in Dogs: Laboratory Project ID HLA 6176-111. Unpublished study prepared by Hazleton Laboratories America, Inc. 301 p.

41248001 Rodwell, D. (1989) Teratology Study in rabbits with Buan 77: SLS Study No. 3138.29. Unpublished study prepared by Springborn Life Sciences, Inc. 229 p

41298601 Rush, R. (1989) Primary Skin Irritation Study in Rabbits with Busan 77: SLS Study No. 3138.49. Unpublished study prepared by Springborn Laboratories, Inc. 19 p.

41327101 Rush, R. (1989) Acute Dermal Toxicity Study in Rabbits with Busan 77: Lab Project Number: 3138.50. Unpublished study prepared by Springborn Laboratories, Inc. 26 p.

41361701 Rush, R. (1989) Primary Eye Irritation Study in Rabbits with Busan 77 (EPA-FIFRA): Lab Project Number: 3138/52. Unpublished study prepared by Springborn Laboratories, Inc. 25 p.

41373401 Rush, R. (1990) Acute Oral Toxicity Study in Rats with Busan 77: SLS Study No. 3138.51. Unpublished study prepared by Springborn Laboratories, Inc. 65 p.

41423001 Nemec, M. (1987) A Teratology Study in Rats with Busan 77: Final Report: Lab Project Number: WIL-94020. Unpublished study prepared by WIL Research Laboratories, Inc. 281 p.

41494301 Kehoe, D. (1990) 18-Month Study with Busan 77 in Mice: Lab Project Number: HLA 6176-109. Unpublished study prepared by Hazleton Labs America, Inc. 924 p.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Busan 77 RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In for Busan 77 at a later date.

Appendix G. Batching of Busan 77 Products for Meeting Acute Toxicity Data Requirements for Reregistration