Reregistration Eligibility Decision (RED) for PHMB

September 30, 2004

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510C)

EPA739-R-05-003
September 2005

Reregistration Eligibility Decision for PHMB

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

The RED and supporting risk assessments for PHMB are available to the public in EPA's Pesticide Docket **OPP-2004-0305** at: http://www.epa.gov/edockets.

The PHMB RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the PHMB risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to PHMB 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 PHMB will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measure outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary to implement this mitigation measure. 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 PHMB. 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 relevant to this reregistration decision, please contact the Chemical Review Manager, Jennifer Slotnick, at (703) 305-0601. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
PHMB
List C
CASE 3122

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September 29, 2005

Attachment

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for PHMB and is issuing its risk management decision. The Agency has decided PHMB is eligible for reregistration provided all measures outlined in this document are implemented. PHMB is used as a fungicide, algicide, and sanitizer in swimming pools; preservative for cut flowers; materials preservative; bacteriostat in industrial processes and water systems; and hard surface disinfectant (food and non-food contact surfaces). End-use products are formulated as soluble concentrates, as solids, as ready-to-use solutions, and in water-soluble packaging. The product with the impregnated wipe formulation was cancelled in July 2005.

Overall Risk Summary

The Agency's human heath risk assessment indicates only one risk of concern for occupational handlers. An acute dietary risk estimate was completed for females 13-50 years old, the only population subgroup with an acute toxicity endpoint, and is below the Agency's level of concern. Chronic dietary risk estimates were provided for the general U.S. population and all population subgroups. All chronic dietary risk estimates are below the Agency's level of concern. As none of the uses associated with PHMB are expected to impact either surface or ground water resources, no drinking water assessment was performed. When considering aggregate risk from dietary and residential exposures, risk estimates are below the Agency's level of concern.

To address occupational exposure, dermal and inhalation risks were assessed for handlers. Scenarios involving pour liquid for drilling muds and workover fluids showed a risk above the Agency's level of concern. In order to achieve MOEs above the target level, these scenarios must use mitigation measures such as metering pump systems. In addition, since the inhalation MOE for this scenario falls below the MOE of 1,000, when the additional route-to-route extrapolation uncertainty factor is applied, an inhalation study will be required to confirm these findings.

An environmental risk assessment was also conducted for PHMB. Due to limited potential for environmental exposure, environmental risks are below the Agency's level of concern.

Dietary Risk

Acute and chronic dietary (food) risks are below EPA's level of concern for the general U.S. population and all population subgroups. A screening-level acute dietary risk assessment was conducted for PHMB food uses. Risk estimates are provided for females 13-50 years old, the only population subgroup with an acute toxicity endpoint of concern. Risk estimates for the use with the highest exposures were 9% of the aPAD and, therefore, were not of concern.

The chronic dietary risk assessment concludes that for all included use sites, the chronic risk estimates are below the Agency's level of concern for the general U.S. population (<10% of the cPAD) and all population subgroups (37% of the cPAD for children). Risks, therefore, are not of concern and no mitigation measures are necessary.

Drinking Water Risk

None of the uses associated with PHMB are expected to impact either surface or ground water resources. Therefore, no drinking water assessment was performed.

Residential Risk

Residential handler and post-application exposure scenarios were assessed using surrogate exposure data, maximum label rates, and standard assumptions. All margins of exposure (MOEs) from dermal and inhalation exposure for residential handlers are above the target MOE of 100 and, therefore, not of concern. For post-application dermal and incidental ingestion (oral) exposures, MOEs were below the Agency's level of concern. No residential risk mitigation is necessary.

Aggregate Risk

The aggregate risk assessment integrates the assessments conducted for dietary and residential exposure. Using the Aggregate Risk Index (ARI) method, aggregate calculations were performed for adults and children. The ARIs are greater than 1.2 for children and 5.4 for adults. These risks are below the Agency's level of concern (ARI<1), and no mitigation measures are necessary to reduce risks from aggregate exposures.

Occupational Risk

To address occupational exposure, dermal and inhalation risks were assessed for handlers. Only one scenario for occupational handlers showed a risk above the Agency's level of concern. The dermal MOE of 74 for scenarios involving pour liquid for drilling muds and workover fluids is below the target MOE of 100 and, therefore, is of concern. In order to achieve MOEs above the target level (i.e., greater than 100), scenarios involving drilling muds and workover fluids must use mitigation measures such as metering pump systems. In addition, since the inhalation MOE for this scenario falls below the MOE of 1,000, when the additional route-to-route extrapolation uncertainty factor is applied, an inhalation study will be required to confirm these findings. At this time, EPA does not foresee post-application exposures for the occupational uses of PHMB.

Ecological Risk

The Agency conducted an environmental risk assessment to determine the potential impact of PHMB use on non-target terrestrial and aquatic organisms. Environmental exposure modeling was not conducted for PHMB because its uses are not likely to result in significant outdoor exposure. The uses of PHMB make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. The Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for PHMB. However, the high toxicity of PHMB to fish and aquatic invertebrates is of concern in the event of a spill or misuse of the product.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing PHMB. The Agency is issuing this RED for PHMB, as announced in a Notice of Availability published in the *Federal Register*. The RED and supporting risk assessment for PHMB are available to the public in EPA's Pesticide Docket OPP-2004-0305 at http://www.epa.gov/edockets. This RED document includes guidance and time frames for making any necessary label changes for products containing PHMB.

Summary of Mitigation Measures

The Agency has determined that PHMB is eligible for reregistration provided the mitigation measure described in this document and the label changes included in Table 12 in Section V of the RED are implemented.

Occupational Risk

EPA determined that the greatest potential for exposure appears to be the inhalation and dermal occupational scenarios involving pour liquid for drilling muds and workover fluids. Using an open pour scenario, these risks are of concern to the Agency. In order for risks to drop below the Agency's level of concern, scenarios involving drilling muds and workover fluids must use mitigation measures such as metering pump systems.

Data Requirements

Additional confirmatory data is required to complete the reregistration of PHMB. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing PHMB as described in Section V of this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the 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 poly(hexamethylenebiguanide) hydrochloride (PHMB).

PHMB is an antimicrobial used in several types of applications, including as a fungicide, algicide, and sanitizer in swimming pools; preservative for cut flowers; materials preservative; bacteriostat in industrial processes and water systems; and hard surface disinfectant. The registrant for PHMB has indicated that about 95 percent of the use of this chemical is for pools and spas. The hard surface disinfectant use may be on food and non-food contact surfaces in or on agricultural premises and equipment; commercial, industrial, and institutional premises and equipment; residential contents and premises; and medical premises and equipment.

The Agency has concluded that the FQPA Safety Factor for PHMB should be removed (equivalent to 1X) based on: (1) there is no concern for developmental neurotoxicity resulting from exposure to PHMB because there is no evidence PHMB will induce neurotoxic effects; (2) there is no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (3) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredients PHMB. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances

individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for PHMB and any other substances. PHMB does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that PHMB 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 PHMB. 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 PHMB referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket.

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

II. Chemical Overview

A. Regulatory History

PHMB was first registered in the United States in 1982 as an active ingredient. Currently, there are 17 products containing PHMB (two technical products and 15 end-use products) registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use as algaecides, bacteriocides/ bacteriostats, fungicides/fungistats, microbicides/microbiostats, disinfectants, regulators, and sanitizers.

B. Chemical Identification

Technical PHMB

$$X - ((CH_2)_3 - NH - C - NH - C - NH - (CH_2)_3)_n - X$$

$$NH \qquad NH \;.\; HCl$$

where $X = HCl.\ NH_2 - (CH_2)_3$

OR

$$X = - (CH_2)_3 - NH - C - NH - CN$$

$$NH$$

OR

$$X = - (CH_2)_3 - NH - C - NH_2 \;.\; HCl$$

$$NH$$

Figure 1. Molecular Structure of PHMB

Common name:	Poly(hexamethylenebiguanide) hydrochloride
Chemical name:	Poly(iminoimidocarbonyliminoimidocarbonyl-iminohexamethylene) hydrochloride
Chemical family:	Guanidine
Empirical formula:	$C_8 H_{17} N_5 HCl$
CAS Registry No.:	32289-58-0
Case number:	3122
OPP Chemical Code:	111801

Molecular weight: 219.5

Other names: PHMB, Vantocil 1B, Baquacil, Baquacil SB, Cosmoquil CQ

Basic manufacturers: Arch Chemicals, Inc.
Mareva, Inc.

Chemical properties: PHMB is a very faint yellow, mobile liquid. Since PHMB is a liquid, it has no melting point. It has a boiling point of 100.2^{0}C, and decomposition begins at 205 - 210^{0}C. PHMB has a specific gravity of 1.04 at 20^{o}C.

C. Use Profile

The following is information on the uses of PHMB products, currently registered as of September 30, 2004[1], and an overview of use sites and application methods. A detailed table of the uses of PHMB eligible for reregistration is contained in Appendix A.

Type of Pesticide: Algicide, bacteriostat/bacteriocide, fungistat/fungicide, microbiostat/microbiocide, disinfectant, regulator, and sanitizer

Summary of Use:

Food: Hard surface disinfectant uses on kitchen countertops, high chairs, refrigerators, and microwave ovens are indirect food uses, as there surfaces have the potential to come into contact with food.

Public Health:

Hard surface disinfectant:
For use in residential, healthcare, industrial and institutional settings such as hospitals, nursing homes, day care centers, nurseries, hotels, schools, airplanes, boats, buses, campers, cars, railroad trains, taxicabs, campgrounds, restaurants, animal laboratories, veterinary offices, kennels, dental offices, health clubs, farm and livestock premises and mushroom house premises. May be used on hard, non-porous surfaces such as tables, countertops, stovetops, sinks, cabinets, refrigerators, microwave ovens, high chairs, tubs, floors, glazed tiles, urinals, diaper pails and other bathroom surfaces, garbage cans, walls, floors, stainless steel surfaces, kennel runs, pet areas, sealed stones, glazed ceramics, playground equipment, picnic tables and the coils of air conditioning units.

Aquatic non-food residential sanitizer:
For use in swimming pool, spa and hot tub water systems.

[1] The impregnated wipe disinfectant, EPA Reg. No. 50096-1, was cancelled in July 2005. Its exclusion in the risk assessment would not change the risk levels of concern; therefore, the document was not revised to remove it.

Other Non-food: **Terrestrial non-food microbiostat and preservative:**
For use on ornamental flowering plants (cuttings or stored).

Indoor non-food materials preservative:
For use in the preservation of electrocoat resins in addition to aqueous industrial chemicals such as reagents, oil-in-water emulsions, water-in-oil emulsions, cellulose solutions, silicone emulsions and silicone dispersions, aqueous mineral slurries such as calcium carbonate and titanium dioxide as well as polymer latices such as polyvinyl acetate and polyvinyl alcohol.

For the preservation of textiles and cellulosic materials such as carpet, curtains, mops, dishcloths, wipes, sponges, tissues and non-food contact paper products.

For the preservation of leather, fresh animal hides and skins prior to or during processing.

For the control of microorganisms in aqueous adhesives such as animal glues, latex adhesives and other synthetic and protein based glues.

Terrestrial non-food bacteriostat:
For the control of microorganisms and bacteria in drilling muds and packer fluids in addition to workover fluids.

Indoor non-food bacteriostat:
For the control of microorganisms and bacteria in oil field injection water and tunnel pasteurization water.

Target Pests: Slime-forming bacteria, deterioration/spoilage bacteria, animal pathogenic bacteria (G-and G+ vegetative), pseudomonas spp, animal pathogenic fungi, mold/mildew, algae.

Formulation Types: Soluble concentrate/solid, impregnated wipes, ready-to-use solution, and water-soluble packaging.

Method and Rates of Application:

Equipment: The end-use products are added during the manufacturing process of treated articles and materials. Poly(hexamethylenebiguanide) hydrochloride formulations are added directly to water in swimming pools, spas, and cut flower applications, as well as in oil field injection waters and workover fluids. Impregnated wipes are dampened with water prior to use.

Application Rates: For details about specific use sites for PHMB, refer to Appendix A.

Use 1 to 50 lbs. of end use formulation to 10,000 lbs. of product to produce a 100 to 5000 ppm solution for the preservation of reagents, oil-in-water emulsions, water-in-oil emulsions, cellulose solutions, silicone emulsions and silicone dispersions.

Use 5 to 50 lbs. of end use formulation to 10,000 lbs. of product to produce a 500 to 5000 ppm solution for the preservation of aqueous mineral slurries such as calcium carbonate and titanium dioxide, as well as polymer latices, such as polyvinyl acetate and polyvinyl alcohol, and adhesives, such as animal glues, latex adhesives and other synthetic and protein based glues.

Use 1 to 30 lbs. of end use formulation to 10,000 lbs. of product to produce a 100 to 3000 ppm solution for the preservation of leather and fresh animal hides and skins prior to or during processing.

Use 13 fl. oz. to 1 gal. of end use formulation to 1000 gals. of water for the preservation of tunnel pasteurization waters.

For non-porous surface disinfection, spray end use product on surface until wet. Surface must remain wet for 10 minutes before wiping dry. Rinse food-contact surfaces with potable water prior to reuse.

For sanitizing pool water, use enough end-use product to give a concentration of 50 ppm PHMB (58-64 oz. per 10,000 gals.) for freshly filled pools. To maintain or raise level of end use product add at a rate of one pint per 10,000 gals. of water. For pool water sanitizer tablets, add one tablet per approximately 5500 gals. of water.

Use Classification: General use.

III. Summary of PHMB 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 PHMB. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed on the Agency's website at http://epa.gov/dockets. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2004-0220. The OPP public docket is located in Room 119, Crystal Mall II, 1801 Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of PHMB

A brief overview of the toxicity studies used for determining endpoints in the risk assessments are outlined below in Table 1. Further details on the toxicity of PHMB can be found in the "PHMB Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document," dated January 18, 2005; "Poly(hexamethylenebiguanide) Hydrochloride (PHMB) Risk Assessment for the Reregistration Eligibility Decision," dated February 14, 2005; and "PHMB - 2nd Report of the Hazard Identification Assessment Review Committee," dated April 9, 2003. These documents are available on Agency's website in the EPA Docket at http://www/epa.gov/edockets.

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

Table 1. Summary of Acute Toxicity Data for PHMB

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
Acute Toxicity				
870.1100	Acute Oral	00030330	LD_{50} = 2747 mg/kg	III
		44940701	LD_{50} = 1831mg/kg (M) LD_{50} = 1617mg/kg (F)	
		45916505	LD_{50} = 1049mg/kg (F)	
870.1200	Acute Dermal	00065124	LD_{50} > 2.0 ml/kg	III
		44940702	LD_{50} > 2000mg/kg	
		45916506	LD_{50} > 5000mg/kg	IV
870.1300	Acute Inhalation	44970403	LC_{50} = 1.76mg/L	III

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.2400	Primary Eye Irritation	45916508	Corrosive	I
		00046789 00065120 44963902	Moderate irritant	II
870.2500	Primary Skin Irritation	00046789 00065120	Moderate irritant	II
		44949704 45916509	Slight irritant	IV
870.2600	Dermal Sensitization	42674201	Moderate sensitizer	NA
		44940705	Mild sensitizer	

Notes: LC = Lethal Concentration; LD = Lethal Dose; NA = Not Applicable

The doses and toxicological endpoints selected for various exposure scenarios are summarized in Table 2 below.

Table 2. Dietary Toxicological Endpoints for PHMB

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 20 mg/kg/day UF = 100 Acute RfD = 0.2 mg/kg/day	FQPA SF = 1 aPAD = acute RfD / FQPA SF = 0.2 mg/kg/day	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day based on reduced number of litters and skeletal abnormalities.
Acute Dietary (General population including infants and children)	No Appropriate single dose effects can be selected for general population		
Chronic Dietary (All populations)	NOAEL=20 mg/kg/day UF =100 Chronic RfD = 0.2 mg/kg/day	FQPA SF =1 cPAD = chronic RfD / FQPA SF =0.2 mg/kg/day	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day Based on the increased mortality, reduced food consumption, and clinical toxicity; Mouse Developmental Study (Report No. CTL/P/335, 1977 (cited in Report No. 003810, 1978. Section C-9)) LOAEL = 40 mg/kg/day; Based on reduced body weight gain; and Rat Developmental Study (Report No. CTL/P/1262, 1976 (cited in Report No. 003810, 1978. Section C-11)) LOAEL = 50 mg/kg/day Based on reduced food consumption.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (Oral, dermal, inhalation)	The HED Cancer Assessment Review Committee (CARC) classified PHMB as "Suggestive Evidence of Carcinogenicity, but not sufficient to Assess Human Carcinogenic Potential" by the oral and dermal routes. Quantification of human cancer risk is not required.		

Notes: UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose

General Toxicity Observations

Dietary

The acute RfD is 0.2 mg/kg/day for females (13-50 years), based on adverse developmental effects (reduced number of litters and skeletal abnormalities) at 40 mg/kg/day in a rabbit developmental study. The chronic RfD is 0.2 mg/kg/day based on increased mortality, reduced food consumption, and clinical toxicity at 40 mg/kg/day in a rabbit developmental study; reduced body weight gain in a mouse developmental study at 40 mg/kg/day; and reduced food consumption in a rat developmental study at 50 mg/kg/day. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variability) was applied to the NOAEL to obtain the acute and chronic RfDs.

Incidental Oral

The short- and intermediate-term incidental oral NOAEL is 20 mg/kg/day from the rabbit, mouse, and rat developmental toxicity studies that noted increased mortality, reduced food consumption, clinical toxicity, and/or reduced body weight gain. The target margin of exposure (MOE) is 100.

Short-, Intermediate-, and Long-term Dermal

The short-, intermediate-, and long-term dermal NOAEL is 150 mg/kg/day, which is based on decreased body weight and liver tumors identified at a dose of 750 mg/kg/day in an 80-week dermal painting study in mice. The uncertainty factor or "target" MOE for PHMB dermal exposures are 100 for occupational and residential scenarios.

Short- and Intermediate-term Inhalation

The short- and intermediate-term inhalation NOAEL is 20 mg/kg/day based on the oral endpoint. In the absence of route-specific data, it was conservatively assumed that inhalation absorption is equivalent to oral absorption (i.e., 100%). For inhalation exposures, the uncertainty factor is 100 for occupational and residential scenarios. An additional 10x route-to-route extrapolation is used to determine if a confirmatory inhalation toxicity study is warranted.

Carcinogenicity Classification

The Agency classified PHMB as "Suggestive Evidence of Carcinogenicity, but not sufficient to Assess Human Carcinogenic Potential" by the oral and dermal routes. Quantification of human cancer risk is not required.

Mutagenicity Potential

The data base for mutagenicity is considered adequate based on EPA's mutagenic guidelines and indicates that PHMB is not mutagenic or genotoxic.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, PHMB may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for PHMB based on: (1) a lack of evidence that PHMB will induce neurotoxic effects, (2) no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies, and (3) no quantitative or qualitative evidence of increased susceptibility to the offspring when adults are exposed in the two-generation reproductive study. The FQPA Safety Factor assumes that the exposure databases (food, drinking water, and residential) are complete and that the risk assessment does not underestimate the potential risk for infants and children. These criteria have been met for PHMB. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor was needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

Acute dietary risk for PHMB is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose (0.2 mg/kg/day) modified by the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rabbits in which both the NOAEL (20 mg/kg/day) and the LOAEL (40 mg/kg/day) were determined. Acute dietary exposure was estimated only for females ages 13-50 because available studies did not show a toxicity endpoint attributable to a single exposure for the general

population. The PHMB aPAD is 0.2 mg/kg/day based on a reference dose of 0.2 mg/kg/day, and the FQPA safety factor of 1X.

b. Chronic PAD

Chronic dietary risk for PHMB is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.2 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from developmental studies in rats, rabbits, and mice, in which both the NOAELs (20 mg/kg/day) and the LOAELs (40 mg/kg/day in rats and rabbits and 50 mg/kg/day in mice) were determined. The PHMB cPAD is 0.2 mg/kg/day based on a reference dose of 0.2 mg/kg/day, which incorporates the FQPA safety factor (1X) for the overall U.S. population or any population subgroups.

4. Exposure Assumptions

Acute and chronic dietary exposure assessments from PHMB use as a disinfectant on indirect food-contact surfaces were conducted using an equation that considers application rates, surface area, pesticide migration fraction, and body weight. This approach differs from the FDA approach. However, in assessing dietary exposures from PHMB in latex adhesives, a number of assumptions were made based on the FDA guidelines (FDA, 2003b) for the migration level, consumption factor, total food intake, and amount of packaging required for food. As a conservative assumption, it is assumed that latex adhesive represents 10% of the packaging. Also, it is assumed that paper used in food packaging weighs 50 mg/in^2.

5. Dietary Risk Assessment

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Table 4. Based on a review of product labels containing PHMB, four uses have been identified as having the potential to cause indirect dietary exposure due to indirect food contact:

1. Tunnel Pasteurization
2. Disinfectant on Countertops (representative of food-contact hard surfaces)
3. Latex Adhesives on Food Packaging
4. Disinfectant Cloths

Although tunnel pasteurization has the potential for causing indirect dietary exposure to PHMB, an Estimated Daily Intake (EDI) has not been calculated for this use because the bottles or cans are already sealed, and the possibility of infiltration of this product from tunnel pasteurization water into the food appears to be minimal.

a. Dietary Risk from Food

A screening-level acute dietary risk assessment was conducted for three of the four PHMB food uses, excluding tunnel pasteurization. Acute dietary risk estimates are provided for females 13-49 years old, the only population subgroup for which an endpoint was selected. The results showed risk estimates to be <10% of the aPAD for each use site and therefore were not of concern. The chronic dietary assessment concluded that for all included uses, the chronic risk

estimates are below the Agency's level of concern for the general U.S. population (<10% of the cPAD) and all population subgroups (<40% of the cPAD for children, the most highly exposed subgroup). Because the exposure associated with latex adhesives is several orders of magnitude less than the exposure associated with the countertop disinfectant use, the combined dietary exposure amounts are, for all practical purposes, the same as the exposure to the countertop disinfectant, with the liquid disinfectant as a worst-case scenario.

Table 3. Summary of Dietary Exposure and Risk for PHMB

Population Subgroup	Acute Dietary		Chronic Dietary	
	Dietary Exposure (mg/kg/day) [a]	% aPAD [b]	Dietary Exposure (mg/kg/day) [a]	% cPAD [b]
Liquid Disinfectant				
Adult Male	0.016	--	0.016	8
Adult Female	0.018	9	0.018	9
Child	0.074	--	0.074	37
Wipe Disinfectant				
Adult Male	0.0045	--	0.0045	2
Adult Female	0.0053	3	0.0053	3
Child	0.021	--	0.021	11
Latex Adhesive				
Adult Male	$7.4x10^{-10}$	--	$7.4x10^{-10}$	$5.69x10^{-7}$
Adult Female	$8.6x10^{-10}$	$4.3x10^{-7}$	$8.6x10^{-10}$	$6.62x10^{-7}$
Child	$3.4x10^{-10}$	--	$3.4x10^{-10}$	$2.62x10^{-6}$

[a] acute and chronic exposure analysis based on daily consumption associated with use of a liquid disinfectant on counter tops and exposure to food packages using treated latex adhesive.
[b] %PAD = dietary exposure (mg/kg/day) / aPAD or cPAD, where aPAD= 0.2 mg/kg/day (for adult females only) and cPAD=0.2 mg/kg/day (for all populations)

b. Dietary Risk from Drinking Water

None of the uses associated with PHMB are expected to impact either surface or ground water resources. Therefore, no drinking water assessment was performed.

6. Residential Risk Assessment

a. Residential Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential risks for PHMB are listed in Table 4.

Table 4. Residential Toxicological Endpoints for PHMB

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Incidental Oral (1-30 days)	NOAEL=20 mg/kg/day UF = 100	Residential LOC for MOE = 100 Occupational = NA	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day Based on the increased mortality, reduced food consumption, and clinical toxicity; Mouse Developmental Study (Report No. CTL/P/335, 1977 (cited in Report No. 003810, 1978. Section C-9)) LOAEL = 40 mg/kg/day; Based on reduced body weight gain; and Rat Developmental Study (Report No. CTL/P/1262, 1976 (cited in Report No. 003810, 1978. Section C-11)) LOAEL = 50 mg/kg/day Based on reduced food consumption.
Intermediate-Term Incidental Oral (1- 6 months)	NOAEL=20 mg/kg/day UF = 100	Residential LOC for MOE = 100 Occupational = NA	See Short-Term Incidental Oral Endpoint
Short-Term, Intermediate-Term, and Long-Term Dermal Exposure	Dermal (or oral) study NOAEL= 150 mg/kg/day UF = 100	Residential LOC for MOE =100 Occupational LOC for MOE =100	80-Week Dermal Painting Study (MRIDs 00066475 and 00104796) LOAEL = 750 mg/kg/day based on decreased body weight and liver tumors.
Short-Term and Intermediate-Term Inhalation Exposure	No appropriate route-specific study was available. The oral endpoint of 20 mg/kg with a Margin of Exposure of 100 (10x inter-species extrapolation, 10x intra-species variation) is used. An additional 10x route-to-route extrapolation is used to determine if a confirmatory inhalation toxicity study is warranted.		
Cancer (Oral, dermal, inhalation)	The HED Cancer Assessment Review Committee (CARC) classified PHMB as "Suggestive Evidence of Carcinogenicity, but not sufficient to Assess Human Carcinogenic Potential" by the oral and dermal routes. Quantification of human cancer risk is not required.		

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

b. Residential Handlers

i. Exposure Assessment

Based on the use patterns of PHMB, EPA has identified the four major exposure scenarios for residential handlers including:

- Open pouring for swimming pools/spas;
- Spraying (aerosol and/or trigger pump sprays) disinfectants;
- Mopping with disinfectants; and

- Wiping with disinfectants.

Using surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED) and the Chemical Manufacturers Association (CMA) database, maximum application rates from labels, and EPA estimates of daily amount handled, exposure to residential handlers were assessed. PHMB is assessed using a typical residential swimming pool capacity of 20,000 gallons. For mopping, it is assumed that a 1-gallon bucket of solution is used by a homeowner to mop the floor.

ii. Risk Assessment

All of the inhalation and dermal MOEs for residential handlers are above the target MOE of 100 and, therefore, not of concern. In addition, the inhalation MOEs for each use are above the MOE of 1,000, when the additional route-to-route extrapolation uncertainty factor is applied. An inhalation study is not being required for the residential uses at this time. The MOEs for handlers are summarized in Tables 5.

Table 5. Residential Handler Risk Summary

Exposure Scenario	Use site	Label Application Rate (lb a.i./day)	Baseline Dermal MOE	Baseline Inhalation MOE
Open Pouring	Residential Pool	2.2	35,000	180,000
Spraying	Household Premises (hard surfaces)	0.006	8,000	180,000
Mopping	Household Floors (hard surfaces)	0.023	6,400	26,000
Wiping	Household Premises (hard surfaces)	0.006	610	3,400

c. Residential Post-Application

i. Exposure Assessment

Based on the use patterns, EPA has identified residential post-application exposure scenarios for the swimming pool/spa use along with the hard surface cleaners. The exposure scenarios (and assumptions used in the assessment) that are considered representative of the high-end exposures associated with PHMB include:

- Dermal exposure and ingestion of PHMB via swimming in treated pools for adults and children, both competitive and non-competitive. The SWIMODEL 3.0 default values and chemical-specific values (MRIDs 44051301 and 44046301) were used in the calculations for the assessment. Exposure time for non-competitive swimmers is based on data provided in EPA's Exposure Factors Handbook (1997) whereas competitive swimmer exposure time data are based on the Agency's review of the American Chemistry Council (ACC) study "An Analysis of the Training Patterns and Practices of Competitive Swimmers" (ACC, 2002).

- Dermal contact and incidental ingestion (i.e., hand-to-mouth residue transfer) resulting

from toddlers crawling on treated floors after mopping. While other hard surfaces may be treated (e.g., wiping counter tops/sinks), it is believed that the floor represents the high end exposure scenario for children's contact. Residential SOP assumptions are used for this assessment. Toddlers (3 years old) are used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers (USEPA, 2000b). A body surface area of 0.657 m^2 has been assumed, which is the median value. It was also assumed that the diluted treatment solution is applied at a rate of 1000 sq. ft. per gallon, as this was not provided on the label. As a conservative measure, it has been assumed that 25% of the mop solution remains after the final mop. The Residential SOPs estimate of 10% of the amount on the floor/hard surface available for dermal transfer is used.

ii. Risk Assessment

The residential post-application risk assessment identifies short-term (1-30 days) and intermediate-term (1-6 month) exposure doses based on the reported toxicology endpoints for PHMB. Because of the shorter exposure durations of these toxicological endpoints, conservative event-based exposure assumptions are used to calculate upper bound daily dose estimates. Doses are not amortized over a lifetime. Additionally, since the permeability constant provides estimates of an internal dose from the dermal route of exposure, the oral toxicity endpoint rather than the dermal toxicity endpoint is used to assess the risks from the dermal swimming route.

Table 6 presents the estimated doses from the dermal and ingestion routes of exposure and the corresponding MOEs based on the oral endpoint for the swimming scenarios for each age group. The calculated results for short-, intermediate-, and long-term exposures and risks indicate that the risks from the dermal and ingestion routes of exposure are not of concern (MOE>100) for the post-application scenarios developed in this assessment.

Table 6. Residential Post-Application Risk Summary

Use Type	Scenario Description	Dermal Dose (mg/kg/day)	Incidental Ingestion Dose (mg/kg/day)	Dermal MOE[a]	Inhalation MOE[a]
Swimming Pool	Adult Competitive	4.06E-5	0.0056	490,000	3600
	Adult Non-Competitive	6.76E-5	0.019	300,000	1100
	Child (7-10 yrs) Competitive	1.80E-5	0.017	1,100,000	1200
	Child (7-10 yrs) Non-Competitive	9.01E-5	0.087	220,000	230
	Child (11-14 yrs) Competitive	3.08E-5	0.011	650,000	1800
	Child (11-14 yrs) Non-Competitive	4.62E-5	0.033	430,000	620
Floors	Child, Short-Term Duration	150	0.031	600	660
Floors	Child, Intermediate-Term Duration	150	0.014	600	1,400

[a]MOE = NOAEL (mg/kg/day)/Dose (mg/kg/day). The same oral NOAEL is used for dermal and ingestion risks.
Target MOE = 100; NA = Not Applicable

7. Aggregate Risk

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

In the case of PHMB, a cancer aggregate assessment is not needed, as the chemical has been classified by the Agency's Cancer Assessment Review Committee as having "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential." For the non-cancer aggregate assessment, there is no need for an acute and chronic dietary aggregate assessment, as the uses of PHMB have been determined to have no impact on surface or ground water and the dietary risk calculations estimated will characterize the total dietary risk of PHMB. In the case of short-, intermediate-, and long-term aggregate assessments, the following exposure scenarios were aggregated for adults exposed to PHMB: dietary exposure, dermal and inhalation exposure from liquid pouring of PHMB swimming pool product, and dermal and incidental oral exposure from swimming. Aggregate exposures for children and toddlers included food exposure and dermal and incidental oral exposure from swimming. Cleaning activities were not included in the aggregate assessment as these activities were not felt to reasonably occur together with the other exposure scenarios. As about 95% of PHMB is used in swimming pool products, it is unlikely that residential users will be using PHMB both to sanitize their swimming pools and clean their homes.

a. Short- and Intermediate-Term Aggregate Risk

The Agency has concluded that, although an oral toxicity study was selected for dietary, inhalation, and incidental oral risk assessments and a dermal toxicity study was selected for dermal risk assessments, the non-cancer effects occurring by the oral and dermal routes were similar and that these exposures should be aggregated. The report describing this decision can be found in OPP-2004-0305 at http://www.epa.gov/edockets. Inhalation exposures are currently included in the aggregate assessment based on the use of the oral endpoint. Aggregate MOE calculations for adults and children were performed using the Aggregate Risk Index method (USEPA, 2001a). As shown in Table 7, no aggregate risks of concern were identified for either adults or children.

Table 7. Short- and Intermediate-Term Aggregate Risks

Population Subgroup	Chronic Food Exp mg/kg/day/ (MOE)	ST/IT Incidental Oral Swimming Exposure (mg/kg/day) (MOE)	ST/IT Dermal Swimming Exposure (mg/kg/day) (MOE)	Liquid Pouring Dermal Exposure (mg/kg/day) (MOE)	Liquid Pouring Inhalation Exposure (mg/kg/day) (MOE)	Aggregate Risk Index
Males	0.016/ (1250)	0.0056 (comp.) (3600)	0.000044 (comp.) (450000)	0.00424 (35,000)	0.000113 (180,000)	9.0
		0.019 (non-comp.) (1100)	0.000015 (non-comp.) (1,300000)			5.7
Females 13-50 years	0.018/ (1111)	0.0056 (comp.) (3600)	0.000044 (comp.) (450000)	0.00491 (31,000)	0.000131 (153,000)	8.2
		0.019 (non-comp.) (1100)	0.000015 (non-comp.) (1,300000)			5.4
Children 7-10 years	0.074/ (270)	0.017 (comp.) (1200)	0.000018 (comp.) (1,100,000)	N/A	N/A	2.2
		0.087 (non-comp.) (230)	0.00009 (non-comp.) (220000)			1.2
Children 11-14 years	0.074 (270)	0.011 (comp.) (1800)	0.00003 (comp.) (650000)	N/A	N/A	2.3
		0.033 (non-comp.) (620)	0.000046 (non-comp.) (430000)			1.9

MOE = NOEL (mg/kg/day)/Dose(mg/kg/day). Oral NOAEL is 20 mg/kg/day for short- and intermediate-term. Dermal NOAEL is 150 mg/kg/day for short- and intermediate-term. Inhalation NOAEL is 20 mg/kg/day for short-term. The target Margins of Exposure for all exposures are 100.
Aggregation was performed using the Aggregate Risk Index method. ARI = $1/ ((UF_1/MOE_1) + (UF_2/MOE_2) + (UF_3/MOE_3) + \ldots)$. ARIs greater than 1 are not of concern.

b. Chronic Aggregate Risk

A long-term aggregate risk assessment was not performed in this assessment. None of the residential exposure scenarios are considered to be long-term and were, therefore, not aggregated with the chronic dietary exposure.

8. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites (post-application exposure). Occupational handlers of PHMB include workers pouring or pumping PHMB preservatives into vats or tanks for several uses (materials preservatives, tunnel pasteurization, and industrial processes and water systems); pouring PHMB products into swimming pools and spas; and spraying, wiping, and moping PHMB disinfectants on medical premises and equipment. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of PHMB, MOEs greater than 100 are not of concern to the Agency. This MOE includes the standard safety factors of 10X for intraspecies variability (i.e. differences among humans) and 10X for interspecies variability (differences between humans and animals). An additional 10x route-to-route extrapolation is used to determine if a confirmatory inhalation toxicity study is warranted. At this time, EPA does not foresee post-application exposures for the occupational uses of PHMB.

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. Occupational risks were assessed for exposures from pouring liquid formulations, as well as spraying, wiping, and mopping applications.

For more information on the assumptions and calculations of potential risk of PHMB to workers, see the Occupational Exposure Assessment (Section 7.0) in the "Poly(hexamethylenebiguanide) hydrochloride (PHMB): Risk Assessment for the Reregistration Eligibility Decision," dated February 14, 2005 and the "PHMB Occupational/Residential Exposure Assessment," dated February 3, 2005.

a. Occupational Toxicity

The toxicological endpoints used in the assessment can be found in Table 8 below.

Table 8. Occupational Toxicological Endpoints for PHMB

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term, Intermediate-Term, and Long-Term Dermal Exposure	Dermal (or oral) study NOAEL= 150 mg/kg/day UF = 100	Residential LOC for MOE =100 Occupational LOC for MOE =100	80-Week Dermal Painting Study (MRIDs 00066475 and 00104796) LOAEL = 750 mg/kg/day based on decreased body weight and liver tumors.
Short-Term and Intermediate-Term Inhalation Exposure	No appropriate route-specific study was available. The oral endpoint of 20 mg/kg with a Margin of Exposure of 100 (10x inter-species extrapolation, 10x intra-species variation) is used. An additional 10x route-to-route extrapolation is used to determine if a confirmatory inhalation toxicity study is warranted.		
Cancer (Oral, dermal, inhalation)	The HED Cancer Assessment Review Committee (CARC) classified PHMB as "Suggestive Evidence of Carcinogenicity, but not sufficient to Assess Human Carcinogenic Potential" by the oral and dermal routes. Quantification of human cancer risk is not required.		

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

b. Occupational Handler Exposure

Inhalation and dermal exposures to PHMB were addressed for occupational populations using surrogate data from the Pesticide Handlers Exposure Database (PHED) (USEPA, 1997c), the Chemical Manufacturers Association (MRID 42587501), and several studies which relate to the use patterns of PHMB. Using surrogate dermal and inhalation unit exposure data, application rates from labels, and EPA estimates of daily amount handled, exposure and risks to handlers were assessed. A description of the surrogate data and calculations used are included in the Occupational Exposure Assessment (Section 7.0) in the "Poly(hexamethylenebiguanide) hydrochloride (PHMB): Risk Assessment for the Reregistration Eligibility Decision," dated February 14, 2005 and the "PHMB Occupational/Residential Exposure Assessment," dated February 3, 2005.

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle PHMB during the usual use patterns associated with the pesticide's use. Based on the use patterns, the exposure scenarios in Table 9 were assessed.

Table 9. PHMB Handler Scenarios

Category	Scenario
Material Preservatives	Pouring PHMB industrial preservative into vats or tanks of slurry containing leather processing fluids, silicones, adhesives, mineral slurries, textiles, etc.
Food Handling/Storage Establishments Premises and Equipment	Pouring PHMB preservative into vats or tanks for tunnel pasteurization.
Industrial Processes and Water Systems	Pouring or pumping PHMB preservative into vats or tanks for preservation of oil well injection fluids, mud packer solutions, and workover solutions.
Swimming Pools	Pouring PHMB preservatives into pools or spas by commercial treaters.
Medical Premises and Equipment	PHMB is used in a spray, wipe and mop to sterilize surfaces as a hospital cleaner disinfectant and medical equipment. Disinfectants are applied by spray, mopping and wiping.

c. Occupational Handler Risk Summary

The occupational handler risk assessment included both inhalation and dermal exposures. The target MOE for both is 100. Scenarios with an MOE less than 100 indicate a risk of concern. After performing the exposure assessment, EPA determined that the greatest potential for exposure appears to be the inhalation and dermal occupational scenarios involving pour liquid for drilling muds and workover fluids, based on application rates of 1,052 lbs. of active ingredient per day (dermal MOE = 74 and inhalation MOE = 370, target MOEs of 100). In order to achieve MOEs above the target level (i.e., greater than 100), scenarios involving drilling muds and workover fluids must use mitigation measures such as metering pump systems. Calculated MOEs using the pump liquid scenario (i.e., dermal MOE=1,600 and inhalation MOE 3,300) are greater than the target MOE. As the mitigation measure brings the inhalation MOE above 1,000 (which includes the additional 10x route-to-route extrapolation), no confirmatory inhalation toxicity study is needed.

Dermal and inhalation MOEs for the commercial exposure scenarios involving commercial pool operators pouring PHMB liquid into multiple residential swimming pools and spas are greater than the target MOE and, therefore, are not of concern. The commercial handlers for the medical premises uses did not trigger risks of concern for the spray/mop/wipe applications.

9. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network (NPTN). Incident reports were only found in IDS and PCC. Those found in PCC were also in IDS. Therefore, all incidents are reported as found in IDS.

A total of 118 individual incident cases submitted to the EPA Office of Pesticide Programs involving use of PHMB-containing swimming pool products were reviewed to determine the effects of exposure to PHMB. All of the incident reports reviewed were for residential use of the products by consumers. In 17 (14%) out of the 118 individual incident

cases reviewed, it was determined that the exposure effects were the result of not using the product as intended by the manufacturer. They included not following the instructions on the label, accidental ingestion of the product, or splashing the concentrated product onto the skin or into the eyes.

The reported routes for exposure of the 118 incident cases were dermal (58%), ocular (30%), ingestion (9%), inhalation (7%), and unknown (<1%). In some cases more than one route of exposure applied for an individual incident case (e.g., both dermal and ocular exposure). The most common symptoms reported for each exposure route are as follows:

- Dermal exposure: skin irritation/burning, rash, hives/welts, itching, skin discoloration/redness, allergic reaction, and blistering
- Ocular exposure: eye irritation/burning, eye pain, loss of vision, swelling of eyes, and allergic reactions.
- Ingestion/oral exposure: vomiting/nausea/abdominal pain, irritation to the mouth/throat, respiratory irritation including coughing/choking, and diarrhea
- Inhalation exposure: respiratory irritation and coughing/choking

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. PHMB has several registered use sites: swimming pools, cut flowers, materials preservatives, industrial processes and water systems, and hard surfaces. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for PHMB use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Risk Assessment (Section 8.0) in the "Poly(hexamethylenebiguanide) hydrochloride (PHMB): Risk Assessment for the Reregistration Eligibility Decision," dated February 14, 2005, the "Environmental Fate Assessment of PHMB for the Reregistration Eligibility Decision (RED)," dated August 18, 2004, and the "Ecological Hazard and Environmental Risk Assessment: Poly(hexamethlenebiguanide) hydrochloride (PHMB)," dated August 4, 2004.

1. Environmental Fate and Transport

PHMB is stable hydrolytically in the environment and has a half-life of more than thirty days. This may be of environmental concern for surface water contamination, in the event of exposure to surface water. Studies for other fate processes are not required by and have not been submitted to the Agency.

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. Toxicity (Hazard) Assessment

PHMB demonstrates low toxicity to birds and mammals and high toxicity to freshwater aquatic organisms. All submitted ecological toxicity studies were conducted with a 20% a.i. solution of PHMB, which is the technical formulation, and values were adjusted to 100% a.i. to classify the studies according to relative toxicity. Submission of data regarding toxicity to marine/estuarine organisms, plants, or chronic effects was not required for the indoor uses of PHMB. Limited additional data was found using EPA's ECOTOX database. A summary of submitted data is provided in the table below.

Table 10. Summary of Submitted Acute Ecological Effects Toxicity Data for PHMB

Species	LD50/ LC50	NOAEL/ NOAEC	Toxicity category (based on 100% AI)
Birds			
Northern bobwhite (*Colinus virginianus*)	LC50 > 5620 (>1124 ppm ai)	NOEC 5620 ppm (1124 ppm ai)	Slightly toxic
Mallard duck (*Anas platyrhynchos*)	LC50 > 5620 (>1124 ppm ai)	NOEC 5620 (1124 ppm ai)	Slightly toxic
Mallard (*Anas platyrhynchos*)	LD50 > 2510 (>502 mg ai/kg)	NOEL = 2510 (502 mg ai/kg)	Slightly toxic
Mammals			
Laboratory rat *(Rattus norvegicus)*	LD50 = 2747 mg/kg	N/A	
Freshwater Fish			
Rainbow trout *(Oncorhynchus mykiss)*	96-hr. LC50 = 0.02545 ppm ai	NOEC = 0.0098 ppm ai	Very highly toxic
Bluegill sunfish *(Lepomis macrochirus*)	96-hr. LC50 = 0.57 (0.114 ppm ai);	NOEC = 0.17 (0.034 ppm ai)	Highly toxic
Freshwater Invertebrate			
Waterflea *(Daphnia magna)*	48-hr. EC50 = 0.18(0.12 - 0.30) (0.036 ppm ai)	NOEC = 0.7 (0.14 ppm ai)	Highly toxic

N/A = not available
NOAEC= No-observable adverse effect concentration

b. Exposure and Risk

Environmental exposure modeling was not conducted for PHMB. The only use pattern likely to result in significant outdoor exposure is the oil recovery use; however, there is a label statement prohibiting use over or near marine/estuarine (e.g., offshore) oil fields. The uses of

PHMB considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using PHMB for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

c. Risk to Listed Species

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

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether 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 PHMB 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 PHMB.

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

Based on its evaluation of PHMB, the Agency has determined that PHMB products, 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 PHMB. If all changes outlined in this document are incorporated into the product labels, then all current risks for PHMB will be substantially mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for PHMB. During the public comment period on the risk assessments, which closed on September 27, 2004, the Agency received numerous comments that addressed human health and ecological concerns from one of the technical registrants (Arch Chemicals, Inc.); state and local regulatory agencies (California Regional Water Quality Control Board and San Francisco Department of the Environment); an environmental group (Natural Resources Defense Council [NRDC]); water advocacy groups (Sanitation Districts of Los Angeles County and California Stormwater Quality Association); and one private citizen. Comments were received on the following topics:

- Toxicology and Mode of Action of PHMB and Endpoints Chosen;
- Ecological Risks of PHMB;
- Exposure to PHMB;
- Occupational and Residential Exposure to and Risk from PHMB;
- Dietary Exposure and Risk Assessment;
- Efficacy of PHMB as a Swimming Pool Sanitizer; and
- Abbreviated Length of Public Comment Period.

These comments have been addressed and the assessments refined, as appropriate, by the Agency. Response to Comments documents addressing these comments, and those received by the registrants during Phase I of the RED process, are available in the public docket at http://www.epa.gov/edockets (OPP-2004-0305).

Comments that were received comments from the California Regional Water Quality Control Board, San Francisco Department of the Environment, Sanitation Districts of Los Angeles County, and California Stormwater Quality Association on the possible release of PHMB to surface waters are being addressed in the RED as follows:

Comment: Two governmental and two advocacy groups submitted comments in late September 2004 stating the following (exact language differed slightly among comments): Despite uses that will inevitably discharge PHMB to surface waters, the U.S. EPA re-registration risk assessment does not estimate surface water concentrations. U.S. EPA incorrectly assumes that environmental exposure to PHMB will not occur. Whether discharged to a storm drain or a wastewater treatment plant, PHMB will flow to surface water. It provides no chronic toxicity data for aquatic organisms and presents no estimates of PHMB's environmental fate. *The risk assessment provides no scientific basis for evaluating PHMB risks to aquatic organisms*. These risks must be assessed prior to reregistration.

Response: For certain use categories, such as indoor sanitizers or contained outdoor uses, such as swimming pools, the environmental exposure will be limited in most cases, due either to treatment of wastewaters discharged through municipal sewers and/or Federal or Local restrictions on how wastewaters are to be handled. For such uses, environmental modeling is not currently performed, 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 currently undergo a full screening-level risk assessment and are considered to fall under a "no effect" determination. The indoor uses of PHMB, as well as the swimming pool use, fall into this category.

While unauthorized discharges into storm sewers, into surrounding waters, or onto the ground could occur, this would be considered a misuse of the pesticide. Illegal uses, or "misuses," of pesticides are not considered in Office of Pesticide

Program risk assessments; the assessments are based on the correct, labeled use of the pesticide products. In addition, AD recognizes the possibility of some of these pesticides entering into US waterways, which may pose exposure and hazard concerns. We are in the process of developing and validating various modeling programs, which will help us to ascertain that pesticides entering into U.S. water ways, as well as into the municipal waste treatment plants, are not at levels of concern.

As stated in the 40CFR§158, the Agency requires a standard set of environmental fate and aquatic toxicity studies to be submitted for indoor uses, including hydrolysis, acute avian oral toxicity, acute freshwater fish toxicity, and acute freshwater invertebrate toxicity. These data requirements have been fulfilled for PHMB, and the database is considered adequate for the purposes of this risk assessment.

Due to the abbreviated nature of the comment period held on the risk assessments in 2004, the Agency is providing a 60-day public comment period on this RED. While all comments are welcome, those with specific data or information bearing on the risk assessments are most useful.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with PHMB. The Agency has concluded that the risk from dietary exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food and residential uses. Dietary exposure from drinking water was not assessed, as the uses of PHMB have been determined to have no impact on surface or ground water. The Agency has determined that the human health risks from these combined exposures 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 aggregate exposure from food and residential uses.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with PHMB. The Agency has determined that food uses of PHMB, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of PHMB. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of PHMB.

Dietary risk assessments were conducted for adults and children, with the highest risk (9% aPAD for adult females and 37%cPAD for children) being below the Agency's level of concern. Aggregate assessments from dietary and residential exposures were also conducted.

The Aggregate Risk Index was 1.2 for children ages 7-10 years, the subpopulation with the greatest risk, which is above the Agency's level of concern (ARI 1).

c. Determination of Safety to Infants and Children

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

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from PHMB residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for PHMB based on: (1) there is no concern for developmental neurotoxicity resulting from exposure to PHMB because there is no evidence PHMB will induce neurotoxic effects; (2) there is no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (3) the risk assessment does not underestimate the potential exposure for infants and children.

d. Endocrine Disruptor Effects

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

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

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of PHMB. 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 PHMB. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Summary

There are no tolerances or exemptions from the requirement of a tolerance established for residues of PHMB.

D. Regulatory Rationale

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

The following is a summary of the rationale for managing risks associated with the use of PHMB. 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

The acute and chronic dietary risks from PHMB residues on food, estimated using conservative measures, are below the Agency's level of concern. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

As none of the uses associated with PHMB are expected to impact either surface or ground water resources, no drinking water mitigation measures are necessary at this time.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler risks were considered for pouring PHMB into a single swimming pool, spraying an all-purpose cleaner, mopping floors with an all-purpose cleaner, and wiping hard surfaces with an all-purpose cleaner. No mitigation measures are needed at this time for these uses, as none present a risk of concern.

ii. Post-Application Risk Mitigation

High-end exposures were assessed for residential exposure after application of PHMB products in swimming pools and spas, as well as on hard surfaces. All risks were below the Agency's level of concern, and no mitigation measures are presently required.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

EPA determined that the greatest potential for exposure appears to be the inhalation and dermal occupational scenarios involving pour liquid for drilling muds and workover fluids. Using an open pour scenario, these risks are of concern to the Agency. In order for risks to drop below the Agency's level of concern, scenarios involving drilling muds and workover fluids must use mitigation measures such as metering pump systems.

ii. Post-Application Risk Mitigation

At this time, EPA does not foresee post-application exposures for the occupational uses of PHMB; therefore, no mitigation measures are necessary.

2. Environmental Risk Management

As the Agency considers the uses of PHMB assessed in this RED to be unlikely to result in any appreciable exposure to terrestrial or aquatic organisms, no environmental risk mitigation is required.

3. Other Labeling Requirements

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

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and

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

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

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

b. General Risk Mitigation

PHMB end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing PHMB 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 PHMB is 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 (Table 13). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For PHMB 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 Jennifer Slotnick at (703) 305-0601 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Jennifer Slotnick
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Jennifer Slotnick
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end-use products containing the active ingredient PHMB, 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 (PDCI/PRB)
Adam Heyward
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Adam Heyward
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

The Agency has established an interim two-tiered system for toxicology testing requirements. Tier I toxicology data requirements would apply to all indirect food additives that result in residue concentrations ranging from 0-200ppb which applies to PHMB. The requirements would consist of an acute toxicity testing battery, subchronic toxicity study in the rodent, a developmental toxicity study in the rat, and a mutagenicity testing battery. Each of these data requirements has been fulfilled for PHMB. The Agency also conducts a literature search and can also conduct a Structural Activity Relationship analysis (SAR) if appropriate. The Agency also will hold in reserve a two-generation reproduction toxicity study in the rat and a subchronic toxicity study in a non-rodent which would become data requirements if the Agency's evaluation of the Tier 1 data warranted. A 2-generation reproduction study and a subchronic toxicity study in a non-rodent species are available for PHMB.

Tier II studies would be triggered by the presence of significant (i.e. >200ppb) residues in food or evidence of significant toxicity from the Tier I data set, which may include developmental / reproductive, or other systemic toxicity such as presence of neoplastic growth or significant target organ toxicity. In such cases, chronic toxicity and carcinogenicity testing would be required.

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

Table 11. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Dermal Indoor Exposure	875.1200, 875.1600	233, 236
Inhalation Indoor Exposure	875.1400, 875.1600	234, 236
Descriptions of Human Activity	875.2800	133-1
Dietary-Residues in Food from Treating Countertops with PHMB (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Non-Guideline	Non-Guideline

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 13, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

A product-specific data call-in, outlining specific data requirements, will be sent to registrants at a later date. The efficacy studies the Agency intends to call-in are listed in Table 12 below.

Table 12. Efficacy Data Requirements for Reregistration

Claim	Use Pattern	EPA Reg. Nos.	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Disinfectant	Hard inanimate surfaces	71661-1	AOAC Use Dilution Test (Hard water and organic soil) **or** AOAC Germicidal Spray Test **or** AOAC Hard Surface Carrier Test (Distilled water only)	810.2100 (c), (d), (e)	91-2 (b), (c), (d)
Sanitizer	Non-food contact surfaces (non-residual)	5813-75	Sanitizer Test for Hard Inanimate Non-Food Contact Surfaces	810.2100 (l)	91-2 (j)
Sanitizer	Swimming Pools/Spas	1258-1263 1258-1265 1258-1275 7124-105 69461-1 71864-2 81002-2	AOAC Method for Water Disinfectants for Swimming Pools	810.2700 (d)	91-8 (c)

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 13.

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

a. Label Changes Summary Table

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

Table 13. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into algicides, bacteriostats/bacteriocides, fungistats/fungicides, microbiostats/microbiocides, disinfectants, regulators, and sanitizers for the following uses: hard surfaces (food-contact and non food-contact); swimming pools and spas; cut ornamental plants; materials preservatives; drilling muds, packer fluids, and workover fluids; oil field injection water; and tunnel pasteurization water."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish and aquatic invertebrates. 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 Occupational Use		
PPE Requirements[1]	"Wear goggles or face shield when handling concentrate."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls for Formulations Used in Drilling Muds and Workover Fluids	"Scenarios involving drilling muds and workover fluids must use metering pump systems."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately Following User Safety Requirements.)

User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls (Must be placed in a box.)
Environmental Hazards -for Labels with Oil Recovery Uses	"Not for use in oil recovery systems which employ holding ponds for spent liquids. Do not apply in, over, or near marine and/or estuarine oil fields."	Directions for Use
End Use Products Intended for Residential Use		
PPE Requirements[1]	"Wear goggles or face shield when handling concentrate."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Application Restrictions-For Products Used in Swimming Pools/Spas	"Do not use with chlorine- or bromine-based pool products."	Directions for Use under General Precautions and Restrictions
Application Restrictions-For Products Used on Food-Contact Surfaces	"Rinse food-contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils."	Directions for Use under General Precautions and Restrictions

Application Restrictions-For Products Used in Animal/Pet Areas	"Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food-contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces."	Directions for Use under General Precautions and Restrictions
Application Restrictions-For Products Used in Mushroom Houses	"Do not apply directly to the mushroom crop, compost, or casing. Rinse treated surfaces with potable water before they contact the crop, compost, or casing."	Directions for Use under General Precautions and Restrictions
Entry Restrictions-For Products Used in Animal/Pet Areas, Veterinary Offices, and Pet Kennels	"Wait for treatment to have dried to house animals or employ equipment."	Directions for use under General Precautions and Restrictions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

VI. APPENDICES

Appendix A. Table of Use Patterns for PHMB

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Agricultural premises and equipment				
Hog Barns/Houses/Parlors/ Pens (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Farm Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Farrowing Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.

[1] Application rate is given in terms of end-use product, not active ingredient.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Livestock Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Livestock Feeding Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Livestock Premises (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Livestock Watering Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Mushroom House Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Do not apply directly to the mushroom crop, compost, or casing. Rinse treated surfaces with potable water before they contact the crop, compost, or casing.
Poultry Feeding Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Poultry House Premises (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Poultry Watering Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove all animals/feed. Remove all litter and manure. Empty feeding/watering appliances. Ventilate buildings, vehicles, and other enclosed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all feeding/watering appliances with soap or detergent and rinse with potable water before reuse.
Food handling/storage establishments premises and equipment				
Tunnel Pasteurization/Cooling (Bottle/Can Wash) Water	Aqueous Solution (Reg. 1258-1253)	100-1,000 ppm		
Eating Establishments (Non-Food Contact Surfaces, Premises, Food-Contact Surfaces)	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Commercial, institutional and industrial premises and equipment				
Commercial Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Commercial Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Commercial Transportation Facilities	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Industrial Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Industrial Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Institutional Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Institutional Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Athletic Facilities	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Barber and Beauty Shop Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Aircraft (NonFeed/Food)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Buses (Nonfeed/Nonfood)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Railroad Trains	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Ships	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Trucks	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Animal Cages	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Animal Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Animal Feeding/Watering Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Catteries (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Horse Stables (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Research Animal Facilities (Enclosed Premise Treatment)/ Animal Laboratories	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Veterinary Hospital Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Zoo Premises (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Laundry Premises (Commercial)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Urinals	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Coils/Drain Pans (Air Conditioning/ Refrigeration Equipment and Heat Pumps) (Commercial/ Institutional/Industrial)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Playground Equipment (Institutional)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Residential and public access premises				
Automobiles	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Boat Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Pet Kennels (Enclosed Premise Treatment)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Pet Sleeping Quarters	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.
Pet Areas	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Remove animals and feeds. Remove litter, droppings, and manure from all floors and other surfaces. Empty all feeding/watering appliances. Rinse all food contact surfaces with potable water prior to reuse. Ventilate buildings/closed spaces. Wait for treatment to have dried to house animals or employ equipment.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Campers	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Garbage Containers	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Laundry Premises (Residential)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Sinks	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Stovetops	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse.
Residential Food-Contact Surfaces (Microwave Ovens/Refrigerators/ High Chairs/Tables)	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Bathroom Premises	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Whirlpool Bath Surfaces	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Diaper Pails	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
Domestic Dwellings (House Trailer)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Household Contents	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Household Contents (Nursery)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Household Floors	Ready-to-Use Solution (Mopping System) (Reg. 5813-75)	24 fl.oz. lasts about 2-3 months under "normal use"–mop has trigger to dispense solution		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Household Premises	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Mobile Homes (Indoor)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Coils/Drain Pans (Air Conditioning/ Refrigeration Equipment and Heat Pumps) (Residential)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Ornamental Flowering Plants (Cut)	Powder (Water Soluble Packaging) (Reg. 72992-2; 72992-8)	10g per 2.6 quarts of water 0.17 oz (5g) per pint (½ qt) of water[2]		
	Soluble Concentrate (Reg. 72992-3; 72992-7)	10,000 -15,000 ppm solution[3]		
Furniture (Outdoor)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Campgrounds	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Playground Equipment (Residential)	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

[2]Although the application rate of product is different, the application rate of active ingredient (as calculated by multiplying the product application rate by the concentration of active ingredient in the product) is approximately 0.96g PHMB per quart of water.

[3]The application rate for both products is 900 ppm of active ingredient due to differences in the concentration of the active ingredient in the product formulations.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Medical premises and equipment				
Hospital Materials	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Hospital Premises	Impregnated Wipe (Reg. 50096-1)	1 wipe lasts 20 uses		
	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Human Nursery Equipment	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Human Nursery Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Nursing Home Premises	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Dental Offices	Ready-to-Use Solution (Reg. 71661-1)	Thoroughly wet (saturate) all surfaces for 10 minutes.		Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes, or utensils.
Materials preservatives				
Adhesives/Glues (Aqueous-Based) (Indirect Food Contact)	Aqueous Solution (Reg. 1258-1253)	500-5,000 ppm		
Aqueous Industrial Chemicals (Reagents/Oil-in-Water Emulsions/Water-in-Oil Emulsions/Textile Spin Finish Lubricants/Wash Water/Cellulose Solutions	Aqueous Solution (Reg. 1258-1253)	100-5,000 ppm		

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Cellulosic Materials	Aqueous Solution (Apply by padding, spraying, soaking, or exhaustion) (Reg. 1258-1253)	0.025-2% on dry weight of substrate		
Industrial Electrocoats (Resins and Deposition Systems)	Aqueous Solution (Reg. 1258-1253)	1,000-5,000 ppm		
Household Consumer Products	Aqueous Solution (Reg. 1258-1253)	250-2,500 ppm		
Leather Products and Hides/Skins (Fresh Animal)	Aqueous Solution (Reg. 1258-1253)	15 fl oz.-3 gal [1.0-2.6 lbs product per 1,000 lbs hides/skins]		Use prior to or during processing
Polymer Latices (Aqueous-Based) (i.e. Polyvinyl Acetate/Alcohol)	Aqueous Solution (Reg. 1258-1253)	500-5,000 ppm		

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Silicone Emulsions/Dispersions	Aqueous Solution (Reg. 1258-1253)	100-5,000 ppm		
Slurries (Aqueous) (Indirect Food Contact)	Aqueous Solution (Reg. 1258-1253)	500-5,000 ppm		
Textiles	Aqueous Solution (Apply by padding, spraying, soaking, or exhaustion) (Reg. 1258-1253)	0.025-2% on dry weight of substrate		
(8) **Industrial processes and water systems**				
Leather Processing Liquors/Solutions	Aqueous Solution (Reg. 1258-1253)	100-3,000 ppm		

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
Oil Recovery Drilling Muds/Packer Fluids	Aqueous Solution (Reg. 1258-1253)	3,000 ppm		Not for use in oil recovery systems which employ holding ponds for spent liquids. Do not apply in, over, or near marine and/or estuarine oil fields.
Workover Fluids	Aqueous Solution (Reg. 1258-1253)	3,000 ppm		Not for use in oil recovery systems which employ holding ponds for spent liquids. Do not apply in, over, or near marine and/or estuarine oil fields.
Secondary Oil Recovery Injection Water	Aqueous Solution (Reg. 1258-1253)	95 ppm	Slug	Not for use in oil recovery systems which employ holding ponds for spent liquids. Do not apply in, over, or near marine and/or estuarine oil fields. Apply slug treatment to a point where system will be uniformly mixed. Weekly follows slug treatment when microbial control is evident. Before continuous treatment, apply a slug treatment.
		47 ppm	Weekly	
		4-20 ppm	Continuous	
Swimming pools				
Swimming Pool Water Systems	Ready-to-Use Solution (Reg. 1258-1263; 1258-1265; 7124-105; 69461-1; 71864-2; 81002-2)	Maintain Concentration of 30-50 ppm	Weekly/As Necessary	Cannot use with chlorine or bromine based pool products.

Use Site	Formulation	Application Rate (Range)[1]	No. of Applications	Use Limitations
	Tablets (Soluble Concentrate) (Reg. 1258-1275)	Maintain Concentration of 6-10 ppm	Weekly/As Necessary	Cannot use with chlorine or bromine based pool products.
Hot Tubs/Spas (Water Treatment)	Ready-to-Use Solution (Reg. 1258-1263; 1258-1265; 69461-1; 71864-2)	Maintain Concentration of 30-50 ppm	Weekly/As Necessary	Cannot use with chlorine or bromine based pool products.

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

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #3144 (PHMB) covered by this RED. It contains generic data requirements that apply to PHMB in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

(1) Agricultural premises and equipment
(2) Food handling/ storage establishments premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming pools
(12) Aquatic areas

3. Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

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	All	41965401, 42728901
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	All	41894001, 41930701
830.1670	61-2b	Formation of Impurities	All	41965401, 42728903
830.1700	62-1	Preliminary Analysis	All	41965401
830.1750	62-2	Certification of Limits	All	42728902, 41965401
830.1800	62-3	Analytical Method	All	42728902, 41965401
830.6302	63-2	Color	All	41966401
830.6303	63-3	Physical State	All	41966401
830.6304	63-4	Odor	All	41966401
830.7050	None	UV/Visible Absorption	All	Waived[1]
830.7200	63-5	Melting Point	All	41966401
830.7220	63-6	Boiling Point	All	41966401
830.7300	63-7	Density	All	41966401
830.7840 830.7860	63-8	Solubility	All	41966401
830.7950	63-9	Vapor Pressure	All	41966401
830.7370	63-10	Dissociation Constant in Water	All	41966401

[1] Study waived because the chemical structure shows that it will not absorb in the UV spectral region.

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)	All	41687001
830.7000	63-12	pH	All	41966401
830.6313	63-13	Stability	All	42728902
830.6314	63-14	Oxidizing/Reducing Action	All	Not Applicable
830.6315	63-15	Flammability	All	Not Applicable
830.6316	63-16	Explodability	All	Not Applicable
830.6317	63-17	Storage Stability	All	42728902
830.7100	63-18	Viscosity	All	Not Applicable
830.6319	63-19	Miscibility	All	Not Applicable
830.6320	63-20	Corrosion Characteristics	All	Not Applicable
830.6321	63-21	Dielectric breakdown voltage	All	Not Applicable
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test	All	27491 (93191001)
850.2200	71-2	Avian Dietary Toxicity	All	41382 (93191002)
850.1075	72-1	Fish Acute Toxicity - Freshwater	All	ACC 234289 (MRID 77928 and 77929), 43949001
850.1010	72-2	Acute Aquatic Invertebrate Toxicity	All	ACC 234289 (MRID 77929)
850.1075	72-3a	Acute Estuarine/Marine Toxicity - Fish	8	Waived[2]

[2] Label precludes use in, over, or near marine and/or estuarine environments. Therefore, Guidelines 850.1075 and 850.1025 are waived.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1025	72-3b	Acute Estuarine/Marine Toxicity - Invertebrate (Mollusk)	8	Waived[2]
	72-3c	Estuarine/Marine Toxicity - Invertebrate (Shrimp)	8	Waived[2]
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	All	30330 (93191005), 44940701, 45916505
870.1200	81-2	Acute Dermal - Rabbit	All	65124, 44940702, 45916506
870.1300	81-3	Acute Inhalation - Rat	All	44970403
870.2400	81-4	Primary Eye Irritation - Rabbit	All	46789, 65120, 44963902, 45916508
870.2500	81-5	Primary Dermal Irritation - Rabbit	All	46789, 65120, 44949704, 45916509
870.2600	81-6	Dermal Sensitization	All	42674201, 44940705
870.3100	82-1a	90-Day Feeding-Rodent	All	Waived[3]
	82-1b	90-Day Feeding-Non-Rodent	All	53461
870.3200	82-2	21/28-Day Dermal Toxicity - Rat	All	43047701
870.3250	82-3	90-day Dermal Toxicity - Rodent	All	Waived[4]
870.3465	82-4	90-Day Inhalation - Rat	All	Data gap
870.3700	83-3	Developmental Toxicity	All	65131 (rodent), 42992101[5] (rodent), 42865901 (non-rodent)
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro	All	43617401

[3] Study waived because Guideline 83-1a (Chronic Toxicity-Rodent) satisfies this data requirement.

[4] Study waived because 80-week dermal cancer study in mice submitted under Guideline 83-2b satisfies requirement.

[5] MRID 42992101 is an upgrade to the original study, MRID 65131.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	2,3,4,5,7,11	44059301, 44042801
	83-1b	Chronic Feeding Toxicity - Non-Rodent (dog)	2,3,4,5,7,11	43620501
870.4200	83-2a	Oncogenicity - Rat	11	44059301, 44042801
	83-2b	Oncogenicity - Mouse	11	44074201(oral), 93191028 (dermal), 66475(dermal), 104796 (dermal)
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity	11	44059301
870.5265	84-2	Bacterial Reverse Mutation Assay	All	41687004
870.5385	84-2	Micronucleus Assay	All	41096901, 41404503
870.5375	84-2	Cytogenic assay with human lymphocytes	All	41404501, 42149905
870.5550	84-2	UDS Assay	All	41404502, 42149903
870.7485	85-1	General Metabolism	2,3,4,5,7,11	43599901, 43567001, 77926, 86363
870.7600	85-2	Dermal Absorption	11	Waived[6]
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2800	133-1	Description of Human Activity	All	Data Gap
875.2400 875.2900	133-3	Dermal Passive Dosimetry	11	44051301
875.2500 875.2900	133-4	Inhalation Passive Dosimetry	11	44051301
875.1200 875.1600	233	Dermal Indoor Exposure	All	Data Gap
875.1400 875.1600	234	Inhalation Indoor Exposure	All	Data Gap

[6] Study waived because 80-week dermal cancer study submitted under Guideline 83-2b in mice satisfies requirement.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	All	43622301
OTHER DATA REQUIREMENTS				
Non-Guideline	Non-Guideline	Dietary-Residues in Food from Treating Countertops with PHMB (FDA Wipe Study Methodology[7])	2,3,4,5	Data Gap

[7] FDA, 2003a. "Guidance For Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations. Final Guidance." US Food and Drug Administration. April, 2003. http://www.cfsan.fda.gov/~dms/opa2pmnc.html.

FDA, 2003b. "Sanitizing Solutions:Chemistry Guidelines for Food Additive Petitions." US Food and Drug Administration. January, 1993. http://www.cfsan.fda.gov/~dms/opa-cg3a.html.

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.

The docket initially contained the August 26, 2004 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following sites:

http://www.epa.gov/pesticides/antimicrobials
http://www.epa.gov/edockets

These documents include:

Poly(hexamethylenebiguanide) hydrochloride Preliminary Risk Assessment; Notice of Availability, 9/10/04.
Poly(hexamethylenebiguanide) hydrochloride (PHMB) Summary, 8/30/04.
Overview of the PHMB Preliminary Risk Assessment, 8/24/04.

Preliminary Risk Assessment and Supporting Science Documents:

Poly(hexamethylenebiguanide) hydrochloride (PHMB): Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Code 111801, Case 3122, Antimicrobials Division, 8/26/04.
Product Chemistry Science Chapter on PHMB (20% Formulations of Vantocil P and Vantocil IB). PC Code 111801, Case 3122, Antimicrobials Division, 8/4/04, A. Najm Shamim, Ph.D.
PHMB - 2nd Report of the Hazard Identification Assessment Review Committee, TXR No. 0051756, Health Effects Division, 4/9/03, Jonathan Chen, Ph.D.
Cancer Assessment Document: Evaluation of the Carcinogenic Potential of PHMB, PC Code 111801, Case 3122, TXR No. 0052040, Health Effects Division, 7/16/03, Jessica Kidwell, Executive Secretary, Cancer Assessment Review Committee.
Poly(hexamethylenebiguanide) hydrochloride (PHMB): Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 111801, Case 3122, Antimicrobials Division, 8/26/04, Jonathan Chen, Ph.D. and Timothy F. McMahon, Ph.D.
PHMB Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 111801, Case 3122, Antimicrobials Division, 8/26/04, A. Najm Shamim, Ph.D.
PHMB Occupational/Residential Exposure Assessment. PC Code 111801, Case 3122, Antimicrobials Division, 8/19/04, Timothy Leighton, Ph.D.
Health Effects of PHMB in Humans. PC Code 111801, Case 3122, Antimicrobials

Division, 8/4/04, Jonathan Chen, Ph.D.

Environmental Fate Assessment of PHMB for the Reregistration Eligibility Decision (RED). PC Code 111801, Case 3122, Antimicrobials Division, 8/18/04, A. Najm Shamim, Ph.D.

Ecological Hazard and Environmental Risk Assessment: Poly(hexamethlenebiguanide) hydrochloride (PHMB). PC Code 111801, Case 3122, Antimicrobials Division, 8/4/04, Kathryn Montague, M.S.

Revised Risk Assessment and Supporting Science Documents (RED Supporting Documents):

Poly(hexamethylenebiguanide) hydrochloride (PHMB): Risk Assessment for the Reregistration Eligibility Decision, PC Code 111801, Case 3122, Antimicrobials Division, 2/14/05.

Product Chemistry Science Chapter on PHMB (20% Formulations of Vantocil P and Vantocil IB). PC Code 111801, Case 3122, Antimicrobials Division, 8/4/04, A. Najm Shamim, Ph.D.

PHMB - 2nd Report of the Hazard Identification Assessment Review Committee, TXR No. 0051756, Health Effects Division, 4/9/03, Jonathan Chen, Ph.D.

Cancer Assessment Document: Evaluation of the Carcinogenic Potential of PHMB, PC Code 111801, Case 3122, TXR No. 0052040, Health Effects Division, 7/16/03, Jessica Kidwell, Executive Secretary, Cancer Assessment Review Committee.

Poly(hexamethylenebiguanide) hydrochloride (PHMB): Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 111801, Case 3122, Antimicrobials Division, 1/18/05, Jonathan Chen, Ph.D. and Timothy F. McMahon, Ph.D.

PHMB Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 111801, Case 3122, Antimicrobials Division, 1/18/05, A. Najm Shamim, Ph.D.

PHMB Occupational/Residential Exposure Assessment. PC Code 111801, Case 3122, Antimicrobials Division, 2/3/05, Timothy Leighton, Ph.D. and Cassi Walls, Ph.D.

Health Effects of PHMB in Humans. PC Code 111801, Case 3122, Antimicrobials Division, 8/4/04, Jonathan Chen, Ph.D.

Environmental Fate Assessment of PHMB for the Reregistration Eligibility Decision (RED). PC Code 111801, Case 3122, Antimicrobials Division, 8/18/04, A. Najm Shamim, Ph.D.

Ecological Hazard and Environmental Risk Assessment: Poly(hexamethlenebiguanide) hydrochloride (PHMB). PC Code 111801, Case 3122, Antimicrobials Division, 11/18/05, Kathryn Montague, M.S.

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

1. MRID Studies

MRID#	Citation
27491	Beavers, J.B.; Fink, R.; Brown, R. (1979) Final Report: Acute Oral LD50--Mallard Duck: Project No. 123-131. (Unpublished study received Feb 14, 1980 under 10182-19; prepared by Wildlife International, Ltd. in cooperation with Washington State College, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:241792-A)
30330	Jackson, S.J. (1979) Acute Oral and Dermal Toxicity: Report No. CTL/T/1361: Vantocil/P. (Unpublished study received Feb 14, 1980 under 10182-19; prepared by Imperial Chemical Industries, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL: 241790-A)
41382	Beavers, J.B.; Fink, R.; Brown, R. (1979) Final Report: Eight-Day Dietary LC50--Bobwhite Quail: Project No. 123-129. (Unpublished study received Feb 14, 1980 under 10182-19; prepared by Wildlife International, Ltd. in cooperation with Washington State College, submitted by ICI Americas, Inc., Wilmington, Del.; CDL: 241792-C)
45698	Brown, D.; Maddock, B.G. (1980) Determination of the Acute Toxicity of Vantocil P to Rainbow Trout (~Salmo gairdneri~): BL/B/2031. (Unpublished study received Aug 21, 1980 under 10182-19; prepared by Imperial Chemical Industries, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:243099-B)
46789	Imperial Chemical Industries, Limited (1966) Antibacterial 9073: Toxicological Properties: Report No. TR/558. (Unpublished study received Feb 6, 1969 under 0H2556; CDL:221701-I)
53460	Griffiths, D.; Hayes, M.J.; McElligott, T.F. (1966) Ninety-Day Oral Toxicity of Antibacterial 9073--Albino Rats: Report No. IHR/199. (Unpublished study received Feb 6, 1969 under 0H2556; submitted by Imperial Chemical Industries, Ltd., London, England; CDL: 2217101-J)
53461	Griffiths, D.; Hayes, M.J.; McElligott, T.F. (1966) Ninety-Day Oral Toxicity of Antibacterial 9073--Beagle Dogs: Report No. IHR/202. (Unpublished study received Feb 6, 1969 under 0H2556; submitted by Imperial Chemical Industries, Ltd., London, England; CDL:221701-K)

65120 Conning, D.N. (1966) Antibacterial 9073: Toxicological Properties: Report No. TR/558. (Unpublished study received Mar 10, 1978 under 10182-EX-11; prepared by Imperial Chemical Industries Ltd., England, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:233267-B)

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77926 Bratt, H. (1977) Vantocil IB: Absorption and Excretion Studies in the Rat: Report No. CTL/P/163B. Interim rept. (Unpublished study received May 30, 1978 under 10182-19; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:234289-B)

77928 Hill, R.W.; Maddock, B.G.; Hart, B. (1975) Vantocil: Determination of the Acute Toxicity to Rainbow Trout of Vantocil 1B in Freshwater: BL/B/1631. (Unpublished study received May 30, 1978 under ACC#234289; prepared by Imperial Chemical Industries, Ltd., England, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:234289-D)

77929 Buccafusco, R.J.; LeBlanc, G.A. (1977) Acute Toxicity of Vantocil^(R)I IB, Mix No. 1857, to Bluegill (~Lepomis macrochirus~) and the Water Flea (~Daphnia magna~). (Unpublished study received May 30, 1978 under ACC#234289; prepared by EG & G, Bionomics, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:234289-E)

86362 Trutter, J.A.; Patterson, D.R. (1977) 26-week Toxicity Study in Dogs: 20% P.H.M.B. Final rept. (Unpublished study received Mar 10, 1978 under 10182-EX-11; prepared by Hazleton Laboratories America, Inc., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:233270-A)

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41404503 Randall, V.; Beck, S. (1989) Vantocil IB: An Evaluation in the Mouse Micronucleus Test--Addendum: Lab Project ID: CTL/P/2436. Unpublished study prepared by ICI Central Toxicology Laboratory. 7 p.

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43567001 Lythgoe, R.; Howard, E.; Prescott, E. (1995) PHMB: Absorption, Distribution, Metabolism and Excretion Following Single Oral Dosing (20mg/kg) in the Rat: Lab Project Number: CTL/P/4537: UR0360. Unpublished study prepared by Zeneca Central Toxicology Lab. 82 p.

43599901 Lythgoe, R.; Howard, E. (1995) PHMB: Bioavailability Following Dietary Administration in the Rat: Lab Project Number: CTL/P/4595: UR0468. Unpublished study prepared by Zeneca Central Toxicology Lab. 41 p.

43617401 Milburn, G. (1995) Polyhexamethylene Biguanide: Multigeneration Study in the Rat: Lab Project Number: CTL/P/4455: RR0621/F0: RR0621/F1. Unpublished study prepared by Zeneca Central Toxicology Lab. 1985 p.

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44051301 Burt, M. (1996) Assessment of Worker and Postapplicator Exposure to PHMB Used in Pools and Spas: Lab Project Number: JCS/1. Unpublished study prepared by Zeneca Specialties. 41 p.

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45710804 Brown, E. (2002) Historical Control Data for Occurrence of Hemangiosarcoma (Angiosarcoma) in C57BL/10J/CD-1 A1pk Mice: Lab Project Number: AP-1. Unpublished study prepared by Syngenta Central Toxicology Laboratory. 7 p.

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93191002 Burt, M. (1990) ICI Americas Inc. Phase 3 Summary of MRID 00041382. Eight Day Dietary LC50 - Bobwhite Quail Baquacil Mix #5889, Final Report: Project No.123-129. Prepared by Wildlife International Ltd. 11 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 PHMB 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 at a later date.

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

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing PHMB as an active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular), and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar," since they may not have similar use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

Seventeen products were found which contain PHMB as an active ingredient. These products have been placed into three batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. The following bridging strategies may be employed:

- Batch 3:
  - For eye irritation and skin sensitization data, Registration Numbers 72992-2 and 72992-8 may only cite their own studies or those of 72992-2.
  - For eye irritation and skin sensitization data, Reg. No. 72992-3 and 72992-7 may cite each other's studies but not 72992-2 or 72992-8 studies.
  - For all other studies, each product must cite its own data or data from Reg. No. 72992-2.

- No Batch: Each product in this batch should generate its own data (or cite its own pre-existing data if it exists and meets current Agency standards).

Table: PHMB Batching, Case 3122

Please note that while products may have the same percent active ingredient as another product, the composition of their inert ingredients may vary greatly.

MINIMUM ACUTE TOXICITY ACCEPTANCE CRITERIA

1	_____	Does the study report clearly identify the test material? That is, is the test material identified by EPA Registration Number, product name, or, is the product listed as technical grade?
2	_____	Does the report state that the study was conducted in concurrence with the (1984) 40 CFR §160.12?
3	_____	Is the test species identified?
4	_____	Are the test animals the proper weight? (Rats approximately 200-300 grams, rabbits approximately 2.0 - 3.0 kg.)
5	_____	Acute oral, dermal and inhalation toxicity: Did the observation period last for 14 days, or, until the test subjects appeared normal?
6	_____	Primary eye irritation: Did the observation period continue for 21 days, or, until all irritation subsided? Studies displaying excessive irritation (toxicity category I) may be stopped before 21 days.
7	_____	Primary skin irritation: Did the observation period continue for 14 days, or, until all irritation subsided? Studies displaying excessive irritation (toxicity category I) may be stopped before 14 days.
8	_____	Acute inhalation toxicity: Were the test subjects exposed to the material for at least 4 hours (if there was no mortality during the exposure)?
9	_____	Acute inhalation toxicity: Was particle size determined at least twice during the exposure? Was the MMAD between 1 and 4 microns (micrometers)?
10	_____	Acute inhalation toxicity: Was the particle concentration determined at least twice during the study?

Studies that do not meet <u>each</u> (1-10) of the criteria listed above will be rejected. Please be informed that EPA's guidelines change from year to year. A study that was accepted 25 or more years ago may not be currently acceptable.

Please refer to the following documents for more information.

1. <u>Health Effects Test Guidelines, Series 870</u>, EPA 712-C-98-189, August 1998.
2. <u>Conduct of Acute Toxicity Studies</u>, EPA 737-R-97-002, September 1997.

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

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

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

    b. EPA Form No. 8570-4, Confidential Statement of Formula

    c. EPA Form No. 8570-27, Formulator's Exemption Statement

    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

    e. EPA Form No. 8570-35, Data Matrix

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

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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

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

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

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

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