United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA739-R-06-008
August 2006

Reregistration Eligibility Decision for Aliphatic Alkyl Quaternaries (DDAC)

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 Didecyl Dimethyl Ammonium Chloride (DDAC). The Reregistration Eligibility Decision (RED) was approved on August 3, 2006. 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 DDAC 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 DDAC are available to the public in EPA's Pesticide Docket **EPA-HQ-OPP-2006-0338** at: http://www.regulations.gov.

The DDAC RED was developed through EPA's public participation process, published in the Federal Register on April 26, 2006, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership 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.

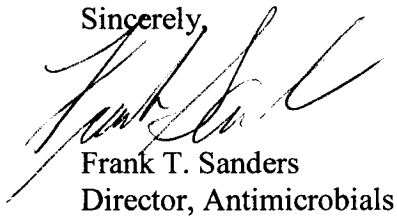
Please note that the DDAC risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, residential, occupational and ecological risks posed by exposure to DDAC alone. This document also contains both generic 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 DDAC will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by DDAC. 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, Tracy Lantz, at (703) 308-6415. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Velma Noble at (703) 308-6233.

Sincerely,



Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
DDAC

CASE 3003

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
August 3, 2006

Attachment

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DDAC Reregistration Team

Health Effects Risk Assessment
Jonathan Chen
Timothy Leighton
Tim McMahon
Najm Shamim
Matthew Lloyd

Chemistry Assessment
Chris Jiang

Ecological Risk Assessment
David Bays
Brian Kiernan
Marietta Echeverria

Environmental Fate Risk Assessment
Srinivas Gowda

Registration Support
Velma Noble
Dennis Edwards

Risk Management
Diane Isbell
Tracy Lantz
Jacqueline Campbell-McFarlane

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

ABSTRACT

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

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

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

DDAC is an antimicrobial used in several types of applications, such as indoor and outdoor hard surfaces (e.g., walls, floors, tables, toilets, and fixtures), eating utensils, laundry, carpets, agricultural tools and vehicles, egg shells, shoes, milking equipment and udders, humidifiers, medical instruments, human remains, ultrasonic tanks, reverse osmosis units, and water storage tanks. There are also DDAC-containing products that are used in residential and commercial swimming pools, in aquatic areas such as decorative ponds and decorative fountains, and in industrial process and water systems such as re-circulating cooling water systems, drilling muds and packer fluids, oil well injection and wastewater systems. Additionally, DDAC-containing products are used for wood preservation.

The Agency has concluded that the FQPA Safety Factor for DDAC should be removed (equivalent to 1X) based on: (1) the existence of a complete developmental and reproductive toxicity database; (2) the lack of evidence for increased susceptibility in these data; and (3) the risk assessment does not underestimate the potential risk for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredients DDAC. 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 DDAC and any other substances. DDAC does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that DDAC 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 DDAC. 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 DDAC referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov.

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

II. Chemical Overview

A. Regulatory History

The aliphatic alkyl quaternary chemical case is comprised of five compounds that are structurally similar quaternary ammonium compounds characterized by having a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C8 or longer) and two methyl substituents. In finished form, these quats are salts with positively charged nitrogen (cation) balanced by a negatively charged molecule (anion.). The anion for the quats in this group is chlorine or bromine. Didecyl dimethyl ammonium chloride (DDAC) compound was the first active ingredient registered in this group in 1962.

The Dialkyl Group Steering Committee/Joint Venture comprised of Lonza Inc, Mason Chemical Company, and Stepan Company, was formed to support the reregistration activities of Alkyl Dimethyl Ethyl Ammonium Bromide (PC 069146), Didecyl Dimethyl Ammonium Chloride (PC 069149), Octyl Decyl Dimethyl Ammonium Chloride (PC 069165), and Dioctyl Dimethyl Ammonium Chloride (PC 069166). These chemicals are formulated into numerous products that are used in residential, commercial, industrial, institutional and agricultural settings.

Oxydiethylenebis (aldyl*dimethyl ammonium chloride) was registered in 1963 (PC 069173). This chemical is registered for use in industrial processes and water systems such as cooling towers, secondary oil recovery, and oil storage tank water. Petrolite Corporation and Buckman Labs have registered five products containing this active ingredient.

In 1988, EPA issued PR Notice 88-2 outlining "Clustering of Quaternary Ammonium Compounds". In this Notice, Quats were clustered into 4 groups as follows:

Group I: The alkyl or hydroxyalkyl (straight chain) substituted Quats

Group II: The non-halogenated benzyl substituted Quats (including hydroxybenzyl, ethylbenzyl, hydroxyethylbenzyl, naphthylmethyl, dodecylbenzyl, and alkyl benzyl)

Group III: The di- and tri-chlorobenzyl substituted Quats

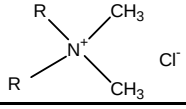
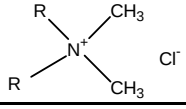
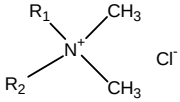
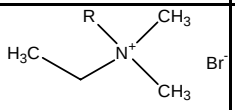
Group IV: Quats with unusual substitutes (charged heterocyclic compounds).

The Agency agreed that for data development purposes DDAC would serve as the model compound.

B. Chemical Identification

Historically, the Agency has registered each distinct aliphatic alkyl quaternary compound as a separate active ingredient. Table 1 below provides the common chemical name, active ingredient code, CAS number, chemical structure and number of registered product for each compound.

Table 1: Active Ingredients in the Group I Quat Cluster

Pesticide Code	CAS RN	Name	Structure	Chain Lengths	Molecular Weight	Est. # Products
69149	7173-51-5	Didecyl Dimethyl Ammonium Chloride (DDAC)		R = C10	332-361	396
69166	5538-94-3	Dioctyl Dimethyl Ammonium Chloride		R = C8	332-361	211
69165	32426-11-2	Octyl Decyl Dimethyl Ammonium Chloride		R1 = C8 (variable %) R2 = C10 (variable %)	332-361	206
69146	84540-07-8	Alkyl Dimethyl Ethyl Ammonium Bromide		R = C12 (5%) C14 (90%) C16 (5%)	350	4
69173	68607-28-3	Oxydiethylenebis (alkyl*) dimethyl ammonium chloride		R=C12 (40%) C14 (50%) C16 (10%)	561-681	5

Common name: DDAC

Chemical name: Didecyl Dimethyl Ammonium Chloride

Chemical family: Quaternary amines

Case number: 3003

Basic manufacturers: Buckman Labs
Lonza, Inc.
Mason Chemical Company
Petrolite Corporation
Stepan Company

Chemical properties: DDAC is a clear yellow liquid with an ethanolic odor which is completely soluble in water. DDAC has a melting point of 228.81°C, a density of 0.9216 g/cm^3 at 25°C with a vapor pressure of 2.33 x 10^{-11} mm Hg.

C. Use Profile

The following is information on the uses of DDAC products, currently registered as of April 26, 2006, and an overview of use sites and application methods. A detailed table of the uses of DDAC eligible for reregistration is contained in Appendix A.

Type of Pesticide: Algaecide, bacteriocide, fungicide, fungistat, microbiocide, microbiostat, disinfectant, viricide, tuberculocide, molluscide, sanitizer, wood preservative, deodorant, and insecticide

Summary of Uses:

Use Category	Use Sites
Industrial Processes and Water Systems	Industrial recirculating water systems, cooling water, disposal water, oil field operations, oil field water flood or salt water disposal
Swimming Pools	Swimming pools, outside spas, whirlpools, and hot tubs
Aquatic Areas	Greenhouses/nurseries, golf courses, recreational parks, amusement parks, universities, and cemeteries
Wood Treatment	Pressure treatment, double vacuum, and dip/spray surface treatment
Agricultural Premise and Equipment	Hatcheries, swine/poultry/turkey farms, dressing plants, farrowing barns, mushroom farm, citrus farm, animal housing facilities, florists/flower shops, greenhouses, and nurseries
Residential and Public Access Premise	Homes, mobile homes, cars, trucks, campgrounds, playgrounds, trailers, campers, boats, and public facilities
Medical Premise and Equipment	Hospitals, health care facilities, medical/dental offices, nursing homes, medical research facilities, autopsy rooms, newborn nurseries, acute care institutions, alternate care institutions, funeral homes, mortuaries, day-care facilities, sick rooms
Commercial Institutional and Industrial Premise and Equipment	Athletic/recreational facilities, exercise facilities, schools, colleges, dressing/locker rooms, transportation terminals, libraries, motel, hotels, barber/beauty salons, health clubs, emergency vehicles, correctional facilities, factories, commercial florists, conveniences stores, offices, commercial and institutional laundry mats,
Food Handling/Storage Establishments Premises and Equipment	Restaurants, food service establishments, food storage, handling, processing plants/facilities, beverage processing plants, bars, cafeterias, supermarkets, dairies, egg processing plants, institutional kitchens, breweries, fast food operations, rendering plants, school lunchrooms, packing plants

Target Pests: Slime-forming bacteria, odor causing/staining bacteria, Gram negative and Gram positive bacteria, *Pseudomonas aeruginosa*, pathogenic fungi (*Trichophyton mentagrophytes*), viruses, mold/mildew, algae.

Formulation Types: Soluble concentrate/tablets, aerosol, impregnated wipes, ready-to-use solution, pressurized liquid, and wettable powder.

Method and Rates of Application:

Method: DDAC formulations are added directly to water in swimming pools, spas, humidifiers, fogging, and cut flower applications, as well as in oil field drilling muds and packing fluids and small process water systems. DDAC formulations are diluted in water to treat hard nonporous surfaces in institutional, commercial, industrial and residential settings by fogging, flood, immersion, wiping, mopping, aerosol/trigger spray, and low and high-pressure spray. Wipes are typically pre-moistened. For treatment of wood, DDAC is applied by a blender spray system, diptank, spray box or pressure treatment.

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

- Use 1 gallon of a 50% end use product per 3000 barrels of water to 1 gallon of a 18% end use product to 100 gallons of water to achieve 32-1800 ppm for treatment of industrial recirculating water systems, cooling water, disposal water and oil field operation.
- Use enough 5 ¼ ounces of a 50% end use product to 10,000 gallon of water to achieve a final concentration of 0.5-2 ppm in swimming pool water.
- Use 1 ounce of a 12 % end use product per 1 gallon of irrigation water to 1 teaspoon of a 12% end use product to 52 gallons of water in decorative fountains, pools, ponds, water displays and standing water to achieve a final concentration of 5-938 ppm.
- Use a 80% end use product to prepare a 3% active ingredient solution to apply 0.6 pounds active ingredient per cubic foot of wood.
- Use 187 ounces of a 4.5% end use solution per 2.5 gallons water to achieve 26,320 ppm for application by fog in hatcheries.
- Use 0.5 of a 7% end use product to 2 ounces of a 15.36% end use solution per gallon water to achieve 234 to 2400 ppm for application to porous and hard non porous surfaces in homes.
- Use 2.67 ounces of a 4.5% end use product per 4 gallons of water to 2 ounces of a 15.36% end use product per 1 gallon of water to achieve a final concentration of 240-2,400 ppm for treatment of hard non-porous surfaces in medical premise and equipment such as hospitals, day care centers, mortuaries and EMS facilities.

- Use 12 ounces of a 13.02% end use product per 1 gallon of water to achieve a final concentration of 12,207 ppm for treatment of carpets in medical premise and commercial settings.
- Use 0.5 ounces of a 50% end use product per 100 pounds of fabric to 1.75 ounces end use product per 100 pounds of fabric to achieve a final concentration of 1935-8789 ppm for treatment of clothing/laundry in commercial and institutional laundry mats.
- Use ready to use end use product, at 0.08% active ingredient or 2 ounces of a 15.36% end use product per 1 gallon of water to achieve a final concentration of 800-2,400 ppm for treatment of hard non-porous surfaces in food handling/storage premise and equipment as well as commercial establishments and a disinfectant/cleaner.
- Use 0.5 ounces of a 7% end use product per 1 gallon of water to achieve a final concentration of 234 ppm to sanitize food contact surfaces in food handling/storage premise and equipment as well as commercial establishments.

Use Classification: General use.

III. Summary of DDAC 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 DDAC. 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://www.regulations.gov. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2006-0338. The OPP public docket is located in: Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

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

A. Human Health Risk Assessment

1. Toxicity of DDAC

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 DDAC can be found in the "Toxicology Disciplinary Chapter for the Re-Registration Eligibility Decision (RED) Risk Assessment on Didecyl Dimethyl Ammonium Chloride (DDAC)," dated February 27, 2006; and "Didecyl Dimethyl Ammonium Chloride (DDAC)-Report of the Antimicrobials Division Toxicity Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee, (HIARC)." dated April 20, 2006. These documents are available in the EPA Docket at http://www.regulations.gov. Revised versions of these documents will be available when the public docket opens.

The Agency has reviewed all toxicity studies submitted for DDAC and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. The acute toxicology data shows that DDAC is toxicity category II by the oral and inhalation routes and toxicity category III via the dermal route. DDAC is also considered to be highly irritating to the eyes and skin (toxicity category I) and is not a dermal sensitizer. Major features of the toxicology profile are presented below.

Table 1. Summary of Acute Toxicity Data for DDAC

Table 4.1 Acute Toxicity Data for DDAC				
Guideline No.	**Study Type**	**MRID #(S).**	**Results**	**Toxicity Category**
81-1	Acute Oral	42296101 41394404	LD_{50} (combined) = 238 mg/kg LD_{50} (combined) = 262 mg/kg	II

Table 4.1 Acute Toxicity Data for DDAC				
Guideline No.	**Study Type**	**MRID #(S).**	**Results**	**Toxicity Category**
81-2	Acute Dermal	42053801	LD_{50} (♂) = 3140mg/kg; LD_{50} (♀) = 2730mg/kg; LD_{50} (combined) = 2930 mg/kg	III
81-3	Acute Inhalation	00145074	LC_{50} = 0.07mg/L	II
81-4	Primary Eye Irritation	42161602 41394404	Severe eye irritant	I
81-5	Primary Skin Irritation	42160601	Severe dermal irritant	I
81-6	Dermal Sensitization	46367601	Not a sensitizer	

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

Table 2. Dietary Toxicological Endpoints for DDAC

Table 2. Summary of Toxicological Endpoints for DDAC (Dietary)			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE/UF, Special FQPA SF for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (Females 13-50)	**NOAEL**(developmental) = 10 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.
	aPAD = 0.1 mg/kg/day (for Females age 13-50)		
Acute Dietary (general population)	An acute dietary endpoint was not identified in the data base.		
Chronic Dietary (general population)	**NOAEL** = 10 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation	Chronic Toxicity Study - Dog MRID 41970401 **LOAEL** = 20 mg/kg/day based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females.
	cPAD = 0.1 mg/kg/day		

UF = uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.

Dietary

The acute RfD is 0.1 mg/kg/day for females (13-50 years). This endpoint is based on a developmental toxicity study in rats with a reported NOAEL of 10 mg/kg/day. This study indicated increased incidence of skeletal variations at the LOAEL of 20 mg/kg/day. The chronic RfD is 0.1 mg/kg/day. This is based on increased incidence of clinical observation signs in males and females and decreased total cholesterol levels in females at 20 mg/kg/day in the chronic toxicity study in dogs. 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 10 mg/kg/day from the dog chronic toxicity study and rat prenatal developmental toxicity studies that noted increased incidence of skeletal variations, increased incidence of clinical signs in males and females and decreased total cholesterol levels in females. The target margin of exposure (MOE) is 100.

Short-term Dermal

The short-term dermal NOAEL is 2 mg/kg/day, which is based on increased clinical and gross findings identified at a dose of 6 mg/kg/day in a 90-day rat dermal toxicity study. The uncertainty factor or "target" MOE for DDAC dermal exposures is 10 for occupational and residential scenarios. The target MOE was chosen because the established endpoint is for dermal irritation, not a systemic toxic effect. In addition, dermal irritation is considered a reversible and short-term effect, thus supporting a 10x uncertainty factor (3x for interspecies extrapolation and 3x for intraspecies variation). It should be noted that the determination to reduce the 100x UF to 10X UF for irritation endpoints is made on a case-by-case basis.

Short- and Intermediate-term Inhalation

The short- intermediate- and long term inhalation NOAEL is 10 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. A 10x inter-species extrapolation and 10x intraspecies variation was used to determine if a confirmatory study is warranted. The target margin of exposure (MOE) is 100.

Carcinogenicity Classification

The Agency classified DDAC as not likely to be a human carcinogen based on the lack of evidence of carcinogenicity in mice or rats.

Mutagenicity Potential

DDAC has been tested for mutagenic activity and the data base for mutagenicity is considered adequate and indicates it is not mutagenic nor genotoxic. However, cytotoxic effects were observed at concentrations as low as 4.0 ug/ml.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruption Screening Program (EDSP) have been developed, DDAC 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 DDAC based on (1) the existence of a complete developmental and reproductive toxicity database, (2) the lack of evidence for increased susceptibility in these data, and (3) the risk assessment does not underestimate the potential risk for infants and children. The FQPA Safety Factor assumes that the exposure databases (food, drinking water, and residential) are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met for DDAC. 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 DDAC 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 (0.1 mg/kg/day) modified by

the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rats in which both the NOAEL (10 mg/kg/day) and the LOAEL (20 mg/kg/day) were determined based on increased incidence of skeletal variations. The DDAC aPAD is 0.1 mg/kg/day for the population subgroup females ages 13+ based on the acute RfD of 0.1 mg/kg/day, which incorporates the uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variability) and which includes the incorporation of the FQPA safety factor (1X).

b. Chronic PAD

Chronic dietary risk for DDAC 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 (0.1 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from the chronic oral toxicity study in the dog in which both the NOAEL (10 mg/kg/day) and the LOAEL (20 mg/kg/day) were determined based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females. The DDAC cPAD is 0.1 mg/kg/day based on a reference dose of 0.1 mg/kg/day, which incorporates the uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variability) and which includes the incorporation of the FQPA safety factor (1X) for the overall U.S. population or any population subgroups.

4. Dietary Exposure Assumptions

The use of DDAC as an antimicrobial product on food contact surfaces, treatment of mushroom houses, and application to food-grade eggs may result in pesticide residues in human food. Residues from the use of DDAC for food contact sanitization on treated surfaces, such as food utensils, countertops, equipment, and appliances, can migrate to food coming into contact with the treated surfaces and can be ingested by humans.

In addition to food contact surface sanitizer uses, this assessment also analyzed residues from hard nonporous surfaces that have been treated with DDAC as a disinfectant after rinsing with potable water. In the absence of transfer residue data on DDAC disinfectants, the Agency assumed that rinsing with potable water cannot remove all residues deposited on the treated surfaces from this use. Therefore, residues from the treated and rinsed surfaces may migrate to food coming into contact with these surfaces and then be ingested by humans.

Exposure to DDAC may result from residues of DDAC on treated food contact surfaces. For this assessment, the Agency estimated residue levels that may occur in food from the application rates on food contact surfaces.

DDAC products may be applied to the shells of food grade eggs. Although it is possible that some of the sanitizer/disinfectant chemicals may penetrate the egg shells, at this time the Agency believes that the amount of chemical transferred into eggs is likely to be minimal. The Agency believes this to be true since the labels of these products state that treated egg shells must be subjected to a potable water rinse if they are to be immediately broken for use in the manufacture of egg products. In addition, consumers generally do not ingest the egg shell. Based on this analysis, the Agency did not assess exposures from this use pattern.

There is no evidence that there will be residues of DDAC in mushrooms following its use as a mushroom house disinfectant. Further, if dietary exposures from mushroom house uses occurred they would be expected to be much lower than the dietary exposures resulting from the surface disinfectant and sanitizing uses. The labels associated with mushroom house use state that the product is not to be applied to the mushroom crop, compost or casing and that treated surfaces are to be rinsed with potable water before contact with the crop, compost or casing. Because any potential exposures would not likely pose risks of concern and the sanitizing uses represent a worst-case scenario, these uses were not assessed.

Food packaging and beverage bottling uses have also been evaluated. For this use, a number of assumptions were made based on the EPA guidelines (2005) for the pesticide migration fraction residual solution, daily food intake rates, application rate, and grams of food per surface area of container.

The Agency assessed the acute and chronic dietary exposure assessment due to DDAC use as a disinfectant and food contact sanitizer on direct and indirect food-contact surfaces. This assessment calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using an FDA model (2003). The assessment considered the following assumptions: application rates, residual solution, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight.

The EDI calculations presented in this assessment assumes that food can contact 2,000 cm^2 or 4,000 cm^2 (50% and 100% respectively of the FDA worst case scenario) of treated surfaces, and that 10% of the pesticide would migrate to food. The use of the 10% transfer rate, instead of the 100% transfer rate was used for all indirect food contact surfaces except for food bottling and packaging surfaces. The 10% migration rate is based on Agency Residential Standard Operation Procedures. These daily estimates were conservatively used to assess both acute (i.e. percent acute population adjusted dose or %aPAD) and chronic dietary risks (i.e. percent chronic population adjusted dose or %cPAD). When assessing the food bottling/packaging use the 100% transfer rate is used because the food is in contact with the treated surfaces for potentially very long periods of time.

A summary of acute and chronic risk estimates are shown in Tables 4a and 4b respectively. Based on a review of product labels containing DDAC, three uses have been identified as having the potential to cause indirect dietary exposure due to indirect food contact: utensils; countertops; and food bottling/packaging. =

a. Acute and Chronic Dietary Risk from Food

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's levels of concern. A summary of antimicrobial indirect food use acute chronic risk estimates are shown below in Tables 4a-1and 4a-2. Risk estimates are below the Agency's level of concern. For adults, the acute, which is specific to adult females of child bearing age (13-15) and chronic dietary risk estimate is 3.32% of the acute and chronic PAD. For children, the most highly exposed population subgroup, the chronic dietary risk estimate is

13.3% of the chronic PAD. Therefore, chronic dietary risk estimates are below the Agency's level of concern for all population subgroups.

Table 4a-1. Calculated EDIs, aPAD, and cPAD for Utensils and Countertops

Exposure Group	Utensils			Countertops			Total		
	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a] (mg/kg/d)
Adult females	0.0959	0.00160	1.60	0.103	0.00172	1.72	0.199	0.00332	3.32

a. % PAD = exposure (DDD) /(aPAD or cPAD) x 100. The acute and chronic population average dose is the same; therefore the % PADs are the same.

EDI is estimated daily intake (mg/kg).
DDD is estimated dietary dose (mg/kg/day).

Table 4a-2. Calculated EDIs, aPAD, and cPAD for Utensils and Countertops

Exposure Group	Utensils			Countertops			Total		
	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD[a] (mg/kg/d)
Adult males	0.0959	0.00137	1.37	0.103	0.00147	1.47	0.199	0.00284	2.84
Adult females	0.0959	0.00160	1.60	0.103	0.00172	1.72	0.199	0.00332	3.32
Children	0.0959	0.00639	6.39	0.103	0.00687	6.87	0.199	0.0133	13.3

a. % PAD = exposure (DDD) /(aPAD or cPAD) x 100. The acute and chronic population average dose is the same; therefore the % PADs are the same.

EDI is estimated daily intake (mg/kg).
DDD is estimated dietary dose (mg/kg/day).

The maximum application rate for DDAC for bottling/packing of food is 0.0020 lbs a.i per gallon of treatment solution. EDI values were calculated using an approach similar to that used for treated food-contact surfaces and food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged with treated material: milk, egg products, and beverages (alcoholic and non-alcoholic). Neither the percent aPad or percent cPad values exceeded 100% and are not of concern.

Table 4b. Calculated EDIs, aPAD, and cPAD for Representative Dairy and Beverage Consumption (Bottling/Packaging)

Food Type	Exposure Group	EDI (mg/p/d)	DDD (mg/kg/d)	% PAD
Acute				
Milk	Adult Female (13-50years)	0.00451	$6.44x10^{-5}$	0.0644
			$7.52x10^{-5}$	0.0752
	Child[a]	0.00290	$1.94x10^{-4}$	0.194
Egg product	Adult Female(13-50years)	0.000034	$4.8x10^{-7}$	$4.8x10^{-4}$
			$5.6x10^{-7}$	$5.6x10^{-4}$
	Child [a]	0.000022	$1.44x10^{-6}$	$1.48x10^{-3}$
Beverages, non-alcoholic	Adult Female(13-50years)	0.00038	$5.6x10^{-6}$	0.0055
			$5.6x10^{-6}$	0.384
	Child[a]	0.00056	$1.60x10^{-5}$	0.990
Beverages, alcoholic, beer	Adult Female(13-50years)	$2.91x10^{-4}$	$4.16x10^{-6}$	0.00416
			$4.85x10^{-6}$	0.00485
Chronic				
Milk	Adults	0.00451	$6.44x10^{-5}$	0.0644
			$7.52x10^{-5}$	0.0752
	Child[a]	0.00290	$1.94x10^{-4}$	0.194
Egg product	Adults	0.000034	$4.8x10^{-7}$	$4.8x10^{-4}$
			$5.6x10^{-7}$	$5.6x10^{-4}$
	Child [a]	0.000022	$1.44x10^{-6}$	$1.48x10^{-3}$
Beverages, non-alcoholic	Adults	0.00038	$5.6x10^{-6}$	0.0055
			$5.6x10^{-6}$	0.384
	Child[a]	0.00056	$1.60x10^{-5}$	0.990
Beverages, alcoholic, beer	Adults	$2.91x10^{-4}$	$4.16x10^{-6}$	0.00416
			$4.85x10^{-6}$	0.00485

a. Child EDI values are multiplied by a modification factor of 0.64

b. Dietary Risk from Drinking Water

The only DDAC outdoor uses are an algaecide in decorative pools, antisapstain wood preservative treatment, once-through cooling tower treatment and oil field uses. The pond and oil field uses are considered to be contained. The other uses are not expected to significantly contaminate drinking water sources. Therefore, the DDAC contributions for drinking water exposure are considered to be negligible and are not quantified.

It should be noted that the Agency estimated concentrations for exposure to aquatic animals resulting from the antisapstain and cooling tower uses. These levels were not considered appropriate for use in the drinking water assessment due to the very conservative nature of the models used, that the model estimates runoff/point source concentrations and not water body concentrations, and the fact that the models does not account for dilution.

5. Residential Risk Assessment

The residential exposure assessment considers all potential non-occupational pesticide exposure, other than exposure due to residues in food or in drinking water. Exposures may occur during and after application as a hard surfaces disinfectant (e.g., walls, floors, tables, fixtures), to textiles (e.g., clothing, diapers) and to carpets. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential risks for DDAC are listed in Table 5a.

MOEs greater than or equal to 100 for inhalation and oral exposures and 10 for dermal exposures are considered protective. The MOE of 100 includes a 10X for interspecies extrapolation, 10X for intraspecies variation. The MOE of 10 includes a 3X for interspecies extrapolation, 3X for intraspecies variation.

Table 5a. Toxicological Endpoints Selected for Assessing Residential and Occupational Risk for DDAC

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term	**NOAEL** (developmental) = 10 mg/kg/day	**Target MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.
Incidental Oral Intermediate-Term	**NOAEL** = 10 mg/kg/day	**Target MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Chronic Toxicity Study - Dog MRID 41970401 **LOAEL** = 20 mg/kg/day based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females.

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Dermal, Short-term	**NOAEL(dermal)** = 2 mg ai/kg/day (8 µg ai/cm^2)[a]	**Target MOE** = 10 (3x inter-species extrapolation, 3x intra-species variation)	90-day Dermal Toxicity - Rat MRID 41305901 **LOAEL** = 6 mg ai/kg/day based on increased clinical and gross findings (erythema, edema, exfoliation, excoriation, and ulceration)
Dermal, Intermediate- and Long-term	No appropriate endpoint identified.		
Inhalation, Short-Term	**NOAEL** [b] = 10 mg/kg/day	**Target MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.
Inhalation, Intermediate- and Long-Term	**NOAEL** [b] = 10 mg/kg/day	**Target MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Chronic Toxicity Study - Dog MRID 41970401 **LOAEL** = 20 mg/kg/day based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females.

UF = uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.
a Short-term dermal endpoint = (2 mg/kg rat x 0.2 kg rat x 1000 ug/mg) / 50 cm^2 area of rat dosed = 8 µg/cm^2.
[b] An additional 10x is necessary for route extrapolation to determine the need for inhalation data. If results are below a MOE of 1,000, a confirmatory inhalation study may be required

b. Residential Handlers

i. Exposure Assessment, Data and Assumptions

Residential exposure may occur during the application of DDAC to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diaper treated during washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were estimated using PHED data and the Chemical Manufactures Association Antimicrobial Exposure Assessment Study (USEPA, 1999). Note that for this assessment, homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The quantities handled/treated were estimated as indicated below.

●For ***mopping*** scenarios, it is assumed that 1 gallon of diluted solution is used.
●For ***wiping and trigger pump spray*** scenarios, it is assumed that 0.5 liter (0.13 gal) of diluted solution is used.
●For ***low pressure hand wand,*** it was assumed that 2 gallons are used in all indoor applications.
●For ***liquid pour*** in ***swimming pool*** scenario, it was assumed that a residential pool contains 20,000 gallons of water.
●For ***liquid pour*** in ***humidifier*** scenario, it was assumed that a humidifier with a 11 gallon tank would be treated, based on Holmes Model# HM4600-U-11. This humidifier releases 11 gallons/1,700 ft^2/24 hours (http://www.holmesproducts.com/estore/product.aspx?CatalogId=3&CategoryId=1120&ProductId=582).

The duration for most homeowner exposures is believed to be best represented by the short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and post-application scenarios are assumed to be performed on an episodic, not daily basis.

ii. Residential Handler Risk Assessment

Based on toxicological criteria and the potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for DDAC residential use. As noted previously, MOEs greater than or equal to 100 for the inhalation route of exposure and 10 for dermal exposure are considered adequately protective for the residential exposure assessment.

A summary of the residential handler inhalation risks are presented in Table 5b. The calculated inhalation MOEs for all scenarios are above the target MOE of 100 and are not of concern.

Table 5b. Short-Term Residential Handler Inhalation Exposures and MOEs

Exposure Scenario Application Method	Application Method	Application Rate[a] (lb ai/gallon)	Quantity Handled/ Treated per day[b] (gallons)	Unit Exposure (mg/lb a.i.)	Daily Dose (mg/kg/day)[c]	MOE[d] (Target MOE = 100)
Application to indoor hard surfaces	Mopping	0.020	1	2.38	0.00079	13,000
	Wiping	0.020	0.13	67.3	0.0029	3,400
	Trigger Spray	0.020	0.13	2.4	0.00010	96,000
Application to Carpets	Low Pressure Spray	0.0088	2	0.681	0.012	50,000
Application to Swimming Pools	Liquid Pour	0.0000244	20,000	0.00346	0.00002	510,000
Application to Humidifiers	Liquid Pour	0.0043	11	1.89	0.0015	6,700

a Application rates are the maximum application rates determined from EPA registered labels for DDAC.
b Amount handled per day values are estimates or label instructions.
c Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x application rate (lb ai/gal) x quantity treated (gal/day) x absorption factor (1.0 for inhalation)]/ Body weight (60 kg for inhalation).

d MOE = NOAEL / Absorbed Daily Dose. [Where short-term NOAEL = 10 mg/kg/day for inhalation]. Target MOE = 100.

A summary of the residential handler risks from dermal exposures are presented in Table 5c. The dermal MOEs were above the target MOE of 10 for all scenarios evaluated except for the spray applications to carpets and the heavy duty cleaning rate (0.02 lb ai/gallon) for mopping and wiping.

Table 5c Short-Term Residential Handler Dermal Risks

Exposure Scenario	Application Method	Application Rate[a] (lb ai/gal)	Quantity Handled/ Treated per day[b] (gallon)	Hand Unit Exposure Adjusted for Surface Area (mg/lb ai/cm^2)[c]	Dermal Skin Irritation Exposure [d] (:g/cm^2)	MOE [e] (Target MOE = 100)
Application to indoor hard surfaces	Mopping	0.0043	1	0.063	0.273	29
		0.02			1.27	**6**
	Wiping	0.0043	0.13	1.341	0.750	11
		0.02			3.49	**2**
	Trigger Spray	0.0043	0.13	0.129	0.072	110
		0.02			0.34	24
Application to Carpets	Low Pressure Spray	0.0088	2	0.161	2.832	**3**
Humidifier	Liquid Pour	0.0043	11	0.000239	0.011	710
Application to swimming pools	Liquid Pour	0.000017	20,000	0.000239	0.08	98

a Application rates are the maximum application rates determined from EPA registered labels for DDAC.
b Amount handled per day values are estimates or label instructions.
c Unit Exposure (mg/lb ai/cm^2) = Hand unit exposure from PHED or CMA (mg/lb ai) / surface area of hand (820 cm^2).
d Dermal Skin Irritation Exposure (:g/lb ai/cm^2) = Unit Exposure (mg/lb ai/cm^2) x Application Rate (lb ai/gal) x Quantity Treated (gal/day) x 1,000 :g/mg
e MOE = NOAEL (:g/cm^2)/ Dermal Skin Irritation Exposure (:g/cm^2). [Where short-term dermal NOAEL = 8 µg/cm^2]. Target MOE = 10.

c. Residential Post-Application

i. Exposure Assessment

Residential post application exposures result when bystanders (adults and children) come in contact with DDAC in areas where pesticide end-use products have recently been applied (e.g. treated hard surfaces/floors), or when children incidentally ingest the pesticide residues through mouthing the treated end products/treated articles (i.e. hand-to-mouth or object-to-mouth contact.)

There is potential for dermal exposure to toddlers crawling on the floor. In addition to dermal exposure, infants crawling on treated floors will also be exposed to DDAC via incidental oral exposure from hand-to-mouth transfer. To calculate incidental ingestion exposure to DDAC due to hand-to-mouth transfer the scenarios established in the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* (USEPA 2000 and 2001) was used.

Post-application scenarios have been developed that encompass multiple products, but still represent high-end exposure scenarios. Post-application scenarios assessed include:

● crawling on treated hard surfaces, carpets, and treated lumber such as decks/play sets (dermal and incidental oral exposure to children)
● wearing treated clothing from wash treatment and from a direct clothing spray treatment (dermal exposure to adults and children and incidental oral exposure to children)
●mouthing/sucking on treated clothing (incidental oral exposure to children) and
●using portable humidifiers (adult and child inhalation exposure), and swimming in treated pools (adult and child incidental ingestion).

Since no toxicological endpoint of concern was identified for dermal systemic adverse effects, post-application dermal risks were assessed using the toxicological endpoint for dermal irritation. The residential post-application dermal risks were assessed by comparing the surface residue on the skin (dermal skin irritation exposure) to the short-term dermal irritation endpoint. It was assumed that during the exposure period, the skin repeatedly contacts the treated surface until a steady-state concentration of residues is achieved on the skin.

ii. Risk Assessment

Based on toxicological criteria and the potential for exposure, the Agency has conducted dermal, inhalation, and incidental ingestion exposure assessments for DDAC. A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the incidental oral and inhalation routes of exposure. The MOE of 100 includes 10X for interspecies extrapolation, 10X for intraspecies variation. A MOE of 10 is considered adequately protective for the dermal route of exposure.

A summary of the residential post-application scenarios are presented in Table 5d. The calculated incidental oral MOEs are above the target MOE of 100 except for incidental ingestion resulting from children mouthing/sucking on treated clothing. The dermal MOEs are above the target MOE for all scenarios except for the adults and children wearing clothing treated with DDAC and children playing on decks and play sets made of wood that has been treated with DDAC. The inhalation MOEs are above the target MOE of 100 for all scenarios, except for the humidifier use. The 24-hour inhalation MOEs for adults and children are 11 and 5, respectively.

Table 5d. Short-term Residential Post Application Risks for Adults and Children

Exposure Scenario	Dermal MOE (Target MOE=10)	Incidental Ingestion (MOE Target MOE=100)	Inhalation MOE (MOE Target MOE=100)
Child playing on floor	**33**	760	NA
Child playing on carpet	**45**	520	NA
Clothing (Laundered – 1% transfer)	690 adults and children	2,600	NA
Clothing (Fabric spray – 5% transfer)	**8**	**150**	N/A

Child playing on decks/play sets	**Range from 3 to 13**	360 (high end)	NA
Swimming	NA	Ranges from 330 to 4,000 for adults and children	NA
Humidifiers	NA	NA	**Adult 11 (24-hrs)**
			Child 5 (24-hrs)

NA = not assessed because negligible exposure is assumed by that route for the exposure scenario of concern.

6. 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 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.

a. Acute and Chronic Aggregate Risks

The acute and chronic aggregate risk assessment includes dietary and drinking water exposures. No drinking water exposures were identified for DDAC. Acute and chronic dietary risk estimates from direct and indirect food uses are presented in Section 5. Table 6a presents a summary of these exposures, including the aggregate indirect and direct dietary exposure (all direct and indirect food contact exposures). Based on the results of the acute and chronic aggregate assessment, the percent of aPAD and percent of the cPAD for adults and children are 3.8% and 14%, respectively. Therefore, the acute and chronic dietary risks are not of concern (i.e., less then 100 percent of the aPAD and cPAD). Please note that for the acute duration of exposure the only adult subpopulation for which a risk estimate was developed was females (13-50).

Table 6a. DDAC Acute and Chronic Aggregate Exposures and Risks (aPAD and cPAD)

Exposure Routes	Acute and Chronic Dietary Exposures (mg/kg/day)			
	Indirect Dietary Exposures[a]	Direct Food Contact Dietary Exposures[a]	Aggregate Dietary Exposures[b]	% aPAD and cPAD (MOE)
Adults				
Oral Ingestion	0.0033	0.00046	0.00376	3.8 (2,700)
Children				
Oral Ingestion	0.013	0.0012	0.0142	14 (700)

a Dietary (indirect + direct food contact) exposures are presented in Tables 5.1 and 5.2.
b Aggregate Dietary Exposures = indirect dietary + direct food contact + drinking water exposures.
c percent aPAD and cPAD (percent acute or chronic population adjusted dose) = aggregate exposures / (a PAD or cPAD) x 100. Where aPAD and cPAD = NOAEL 10 mg/kg/day / 100x uncertainty factor = 0.1 mg/kg/day. MOE = NOAEL of 10 mg/kg/day / aggregate dietary exposures mg/kg/day.

b. Short- and Intermediate-Term Aggregate Risk

Short- and intermediate-term aggregate exposures and risks were assessed for adults and children that could be exposed to DDAC residues from the use of products in non-occupational environments. The following list summarizes all of the potential sources of DDAC exposures for adults and children that have been aggregated in this assessment.

Adult DDAC exposure sources:

- handling of cleaning products containing DDAC as an active ingredient during wiping, mopping, and spraying activities;
- applying DDAC as an air deodorizer using an aerosol spray;
- applying DDAC to carpets using a low pressure sprayer;
- applying DDAC to swimming pools via open pouring;
- applying DDAC to humidifiers via open pouring;
- contacting pressure treated wood;
- wearing treated clothing;
- use of DDAC in humidifiers; and
- eating food having DDAC residues from indirect or direct food contact.

Child DDAC exposure sources:

- post-application exposures to cleaning product residues containing DDAC that are used on hard surfaces (e.g, floors/carpets);
- breathing air treated with a humidifier;
- swimming in treated pools;
- contacting pressure treated wood;
- wearing treated clothing/diapers;
- eating food having DDAC residues from indirect or direct food contact.

The use patterns of the products and probability of co-occurrence must be considered

when selecting scenarios for incorporation in the aggregate assessment. Table 6b summarizes the scenarios included in the short- and intermediate-term aggregate assessments.

Table 6b. Exposure Scenarios Included in the Aggregate Assessments

	Short-term (ST) Aggregate	Intermediate-Term (IT) Aggregate
Adults	▪ chronic dietary (direct and indirect) ▪ handling cleaning products (wipe + trigger pump spray) ▪ wearing treated clothing ▪ humidifier	Oral: ST and IT endpoints are the same for both durations. Dermal: ST endpoint only. Inhalation: All durations same endpoint.
Children	▪ chronic dietary – (direct and indirect) ▪ post-application to cleaning product on carpets (dermal and oral) ▪ wearing treated clothing ▪ humidifier	Oral: ST and IT endpoints are the same for both durations. Dermal: ST endpoint only. Inhalation: All durations same endpoint.

The chronic dietary exposures were used in both the short- and intermediate-term aggregate assessment because chronic dietary exposures occur nearly every day (as opposed to acute dietary exposures occurring on a one-time basis). Therefore, short- or intermediate-term non-dietary exposures have a much higher probability to co-occur with the chronic dietary intake.

Cleaning activities in a residential setting occur on a short-term basis. However, the DDAC-containing cleaning products are also labeled for use in institutional settings such as day-care facilities where cleaning activities can occur on an intermediate-term basis. Therefore, children could have exposure to cleaning product residues on a more continuous basis in a day care facility, thus, these post-application scenarios were included in the intermediate-term aggregate assessment.

The DDAC toxicity endpoints for the chronic dietary and the intermediate-term incidental oral are based on the same toxic effect (and same study), and therefore, these two dietary routes of exposure are aggregated. The dermal and inhalation routes of exposure are based on different toxic effects, and therefore, these two routes of exposure are not aggregated. However, the dermal route of exposure is aggregated among those dermal exposure scenarios that are believed to co-occur. In addition, the inhalation route of exposure is also aggregated among the inhalation exposure scenarios that are believed to co-occur.

Aggregate risks were calculated using the total MOE approach outlined in OPP guidance for aggregate risk assessment (August 1, 1999, Updated "Interim Guidance for Incorporating Drinking Water Exposure into Aggregate Risk Assessments"). Table 6c presents a summary of the short-term aggregate risks (i.e., MOEs). Only the short-term aggregate is presented because the endpoints for incidental oral as well as inhalation are identical for the short- and intermediate-term durations. Only a short-term dermal endpoint was identified (i.e., no intermediate- and/or long-term dermal endpoints were identified).

The aggregate risks are not of concern for adults for the oral and inhalation routes of exposure. The adult dermal MOE for the heavy duty cleaning product rate indicates that the MOE is 1 which is less than the target MOE of 10. The general cleaning rate has an aggregate MOE of 7 for the combined mopping, wiping, and spraying and wearing treated clothing. For children, the oral aggregate (dietary and intermediate-term ingestion for children at day care centers) is 270. The children aggregate MOE for the dermal route is 42 and therefore, not of concern. No children aggregate inhalation scenarios were determined to co-occur. It is important to note, however, that some of the individual risks for scenarios not included in the aggregate are of concern by themselves (e.g., the humidifier use and the fabric spray for clothing).

Table 6c. Short- and Intermediate-term Aggregate Risk (MOE) Assessment for DDAC

Exposure Routes	Chronic Dietary MOE	Cleaning Product MOEs (Adult Applicators & Children Playing)			Humidifier MOE	Wearing Treated Clothing MOE	Route-Specific Aggregate MOE
Adults							
Oral Ingestion	2,700	NA			NA	NA	2,700
Dermal	NA	29 (mop)	11 (wipe)	110 (spray)	NA	690	7
Dermal (Heavy Duty Cleaning)		6 (mop)	2 (wipe)	24 (spray)			1
Inhalation	NA	13,000 (mop)	3,400 (wipe)	96,000 (spray)	Not included, risk of concern	NA	2,600
Children							
Oral Ingestion	700	520 (IT hand-to-mouth carpets)			NA	2,600 (IT Laundered)	270
Dermal	NA	45 (playing on carpets, 5% residue transfer)			NA	690 (Laundered)	42
Inhalation	NA	NA			Not included, risk of concern	NA	No co-occurrence

Aggregate MOE = $1/((1/MOE_{same\ route}) + (1/_{MOE\ same\ route}) + etc)$

7. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Potential occupational handler exposure to DDAC can occur from treatment of the following use sites: agricultural premises, industrial processes and water systems, food handling premises, commercial/institutional/industrial premises, medical premises, swimming pools, and aquatic areas. Additionally, occupational exposure can occur during the preservation of wood. For the preservation of wood, the procedure for treatment can occur in different ways, such that multiple worker functions were analyzed. Due to the complexity of the wood preservative analysis, the results for handler and post-application exposures are presented separately in Section 8.d.e.

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 DDAC, A MOE greater than or equal to 100 is considered adequately protective for the occupational exposure assessment for the inhalation routes of exposure. The MOE of 100 includes 10x for interspecies extrapolation, 10x for intraspecies variation. A MOE of 10 is considered adequately protective for the dermal route of exposure.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application 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.

For more information on the assumptions and calculations of potential risk of DDAC to workers, see the Occupational Exposure Assessment (Section 8.0) in the "Didecyl Dimethyl Ammonium Chloride (DDAC): Risk Assessment," and the "Didecyl Dimethyl Ammonium Chloride (DDAC): Occupational/Residential Exposure Assessment," dated July 27, 2006.

a. Occupational Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, occupational risks for DDAC were listed previously in Table 5a.

b. Occupational Handler Exposure

The Agency has assessed the following occupational exposure scenarios for handlers mixing/loading/applying products containing DDAC. These scenarios represent high-end exposure estimates.

- Agricultural Premises and Equipment: Application to hard surfaces, equipment, and vehicles and Fogging (mix/load only)
- Food Handling/Storage Establishments Premises And Equipment: Application to indoor hard surfaces

- Commercial, Institutional and Industrial Premises and Equipment: Application to indoor hard surfaces and Application to carpets
- Medical Premises and Equipment: Application to hard surfaces
- Industrial Processes and Water Systems: Small process water systems (Recirculating cooling tower) and Oil field operations - drilling mud and packing fluids
- Application to swimming pools

DDAC dermal irritation exposures and risks were not estimated for occupational handler exposures. These risks are addressed using personal protective equipment (PPE) requirements already existing on labels. The level of PPE required is based on the toxicity of the end-use product.

To minimize dermal exposures, the minimum PPE required for mixers, loaders, and applicators who use products containing concentrations of DDAC that result in classification of category I, II, or III for skin irritation potential will be long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of DDAC in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential. These changes to product labels, if necessary, will occur during the product reregistration process.

Inhalation exposures and risks were assessed based on the oral toxicity endpoint (i.e., route-specific inhalation study not available). The surrogate unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure data (use actual title) (USEPA, 1999b: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998). The specific inhalation unit exposures and quantity of DDAC handled are provided in the Occupational and Residential Exposure assessment for DDAC dated July 27, 2006.

The inhalation MOEs were calculated for the short- and intermediate-term durations for occupational handlers using the oral endpoint.

c. Occupational Handler Risk Summary

The inhalation exposures and MOEs for the representative occupational handler scenarios are presented in Table 8.a. The calculated MOEs were above the target MOE of 100 for all scenarios, except for once-through cooling water, metering pump: using the average flow rate for high flow streams (153 MGD) the ST inhalation MOE= 91 for initial applications.

Table 7a. Short- , Intermediate- and Long-Term Inhalation Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application	Inhalation Unit Exposure (mg/lb a.i.)	Application Rate	Quantity Handled/ Treated per day	Inhalation Daily Dose (mg/kg/day)[a]	Inhalation MOE[b, c] (Target MOE = 100)
Agricultural Premises and Equipment (Use Site Category I)						
Application to hard surfaces, equipment, and vehicles	Mop	2.38	0.0094 lb ai/gal	2 gallons	0.0075	13,000
	High pressure/high volume spray	0.12	0.0094 lb ai/gal	40 gallons	0.00075	13,000
	Low pressure handwand	0.681	0.0094 lb ai/gal	40 gallons	0.0043	2,300
	Trigger pump sprayer	1.3	0.0094 lb ai/gal	0.26 gallons	0.000052	190,000
	Wipe	67.3	0.0094 lb ai/gal	0.26 gallons	0.0027	3,600
Fogging (mix/load only)	Liquid pour	1.89	1.88E-05 lb/ft^3	150,000 ft^3	0.089	110
Food Handling/Storage Establishments Premises And Equipment (Use Site Category II)						
Application to indoor hard surfaces	Low pressure handwand	0.681	0.0200 lb ai/gal	2 gallons	0.00045	22,000
	Mop	2.38	0.0200 lb ai/gal	2 gallons	0.0016	6,300
	Wipe	67.3	0.0200 lb ai/gal	0.26 gallons	0.0058	1,700
	Trigger pump sprayer	1.3	0.0200 lb ai/gal	0.26 gallons	0.00011	89,000
	Immersion, Flooding, Circulation	1.89	0.00196 lb ai/gal	2 gallons	0.00012	81,000
Commercial, Institutional and Industrial Premises and Equipment (Use Site Category III)						
Application to indoor hard surfaces	Low pressure handwand	0.681	0.0200 lb ai/gal	2 gallons	0.00045	22,000
	Mop	2.38	0.0200 lb ai/gal	2 gallons	0.0016	6,300
	Wipe	67.3	0.0200 lb ai/gal	0.26 gallons	0.0058	1,700
	Trigger pump sprayer	1.3	0.0200 lb ai/gal	0.26 gallons	0.00011	89,000
	Liquid pour	1.89	0.0043 lb ai/gal	2 gallons	0.00027	37,000
Application to carpets	Liquid pour	0.00346	0.102 lb ai/gal	32 gallons	0.00019	53,000
Medical Premises and Equipment (Use Site Category V)						
Application to hard surfaces	Mop	2.38	0.0200 lb ai/gal	45 gallons	0.036	280
Industrial Processes and Water Systems (Use Site Category VIII)						
Small process water systems: Recirculation cooling tower	Liquid pour	0.45	4.17 lb ai/gal product	2.5 gallons	0.078	130
	Metering pump	0.00432	Initial Dose (ST): 1.50E-03lb ai/gal water	20,000 gallons	0.0022	ST = 4,600
			Maintenance Dose (IT): 1.50E-04lb ai/gal water	20,000 gallons	0.00022	IT =46,000

Exposure Scenario	Method of Application	Inhalation Unit Exposure (mg/lb a.i.)	Application Rate	Quantity Handled/ Treated per day	Inhalation Daily Dose (mg/kg/day)[a]	Inhalation MOE[b, c] (Target MOE = 100)
Oil field operations - drilling mud and packing fluids	Liquid pour	0.00346	1.50 lb ai/gal product	5.6 gallons	0.00048	ST = 21,000
				2.8 gallons	0.00024	IT = 41,000
Once-through Cooling Water System - Power plant	Metering pump	0.000265	Slug Dose (ST): 4.89E-5 lb ai/gal water	5,900,000 gallons	0.0013	ST=2300
			Initial Dose (ST): 4.89 E-5 lb ia/gal water	153,000,000	0.033	ST=91
Swimming Pools (Use Category X)[d]						
Application to swimming pools	Liquid pour	0.00346	Heavy algae Dose (ST): 0.000017 lb ai/gal	200,000 gallons	0.00020	ST= 15,000
			Maintenance Dose (IT/LT): 0.00000417 lb ai/gal	200,000 gallons	0.000048	IT=210,000

ST = short-term, IT = intermediate-term, LT = long-term, N/A= No data available

a Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x absorption factor (1.0 for inhalation) x application rate x quantity treated / Body weight (60 kg for inhalation).

b MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where NOAEL = 10 mg/kg/day for all inhalation exposure durations]. Target MOE = 100.

c The MOEs refer to short-term and intermediate-term duration unless indicated otherwise.

d. The swimming pool scenario also represents the decorative pond/fountain scenario in the aquatic area use site category because the application rates are very similar.

d. Occupational Post-application Exposure

Post-Application exposure may occur from entering food processing plants, hatcheries, wood treatment facilities, or from handling treated wood. Except for the post-application scenarios assessed for fogging (food processing plant and hatchery) and wood preservatives (Section 8.d.ii), occupational post-application dermal and inhalation exposures are assumed to be negligible.

i. Fogging (Food Processing Plant and Hatchery)

There is potential for post-application exposure for workers reentering treated hatcheries and food processing plants. Dermal post-application exposure is presumed to be negligible for hatchery workers; therefore, these risks were not assessed. The inhalation exposure assessment was conducted using the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). MCCEM estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences. MCCEM has the capability to estimate inhalation exposures to chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses. All dose estimates are potential doses; the model does not account for actual absorption into the body.

The fogging application in a food processing plant was assessed using a maximum application rate of 0.0065 lb ai/gal, assuming one quart of the diluted product was used per 1,000 cubic feet of treated area. For fogging applications, a two hour restricted entry interval is required on current labels. The MOE for fogging in the food processing plant with a 2-hr re-entry interval MOE is 7, well below the target MOE of 100. The risks of concern for the food processing plant are attributed to the low air changes per hour assumed (i.e., 0.18 ACH as a default parameter in MCCEM to represent low air flow) in the assessment. This assessment can be refined with additional information on air flows in food processing plants.

The fogging application in a hatchery was assessed using a maximum application rate of 0.181 lb ai/gal, assuming 0.42 gallons of the diluted product was used per 4000 cubic feet of treated area. Fogging in hatcheries is not of concern since the 8-hr MOE is well over 100 after a 2 hour REI.

ii. Wood Preservation

DDAC is used in products that are intended to preserve wood through both non-pressure treatment methods and pressure treatment methods. Section 8.ii.1 presents the exposure analysis for the handler and post-application scenarios for non-pressure treatment scenarios and Section 8.ii.2 presents the exposure analysis for the handler and post-application scenarios for pressure treatment scenarios.

DDAC dermal irritation exposures and risks were not estimated for occupational handler exposures. These risks are addressed using PPE requirements already existing on labels. The level of PPE required is based on the toxicity of the end-use product.

1. Non-Pressure Treatment Scenarios (Handler and Post-application)

There is potential for post- application exposure from DDAC for workers. A proprietary study, "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)"* (Bestari et al., 1999, MRID 455243-04) identified various worker functions/positions for individuals that handle DDAC-containing wood preservatives for non-pressure treatment application methods and for individuals that could then come into contact with the preserved wood. The worker functions/positions identified in the DDAC study are presented below.

Handler:

- ***Blender/spray operators*** are workers that add the wood preservative into a blender/sprayer system for composite wood via closed-liquid pumping.
- ***Diptank Operators*** can be in reference to wood being lowered into the treating solution through an automated process (i.e., elevator diptank, forklift diptank). This scenario can also occur in a smaller scale treatment facility in which the worker can manually dip the wood into the treatment solution.

- ***Chemical operators*** for a spray box system consist of chemical operators, chemical assistants, chemical supervisors, and chemical captains. These individuals maintain a chemical supply balance along with flushing and cleaning spray nozzles.

Post-application:

- ***Graders,*** positioned right after the spray box, grade dry lumber by hand (i.e. detect faults). In the DDAC study, graders graded wet lumber; therefore, the exposures to graders using DDAC are worst-case scenarios.
- ***Millwrights*** repair all conveyer chains and general up-keep of the mill.
- ***Clean-up crews*** perform general cleaning duties at the mill.
- ***Trim saw operators*** operate the hula trim saw and consist of operators and strappers. In the DDAC study, hula trim saw operators handled dry lumber.
- ***Construction workers*** install treated plywood, oriented strand board, medium density fiberboard, and others.

The blender/spray operator position was assessed using CMA unit exposure data and the remaining handler and post-application positions were assessed using data from the DDAC study (Bestari et al., 1999).

Blender/Spray Operators

Table 7.b provides the inhalation doses and MOEs for the workers adding the preservative to the wood slurry. The inhalation MOE is above the target MOE of 100 for short-, intermediate-, and long-term inhalation exposures.

Table 7.b Short-, Intermediate-, and Long-Term Inhalation Exposures and MOEs for Blender/Spray Operator

Exposure Scenario	Inhalation Unit Exposure[a] (mg/lb ai)	Application Rate (% ai in solution/ day)	Wood Slurry Treated[b] (lb/day)	Daily Dose[c] (mg/kg/day)	ST/IT/LT MOE[d] (Target MOE = 100)
Occupational Handler					
Blender/spray operator	0.000403	3	178,000	0.036	280

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term.

a. Inhalation unit exposure: Baseline.

b. Wood slurry treated = (8 batches/day x 7,000 gallons/batch x 0.003785 m^3/gallon x 380 kg/m^3 x 2.2 lb/kg)

c. Daily Dose = unit exposure (mg/lb ai) x App Rate (% ai/day) x Quantity treated (lb/day) x absorption factor (100% for inhalation) / BW (60 kg)

d. MOE = NOAEL (mg/kg/day)/ Daily dose [Where ST/IT/LT NOAEL = 10 mg/kg/day for inhalation. Target MOE = 100.

Chemical Operators (post application): Graders, Millwrights, Clean-up Crews, and Trim Saw Operators

Table 7.c provides the short-, intermediate-, and long-term inhalation doses and MOEs for chemical operators, graders, millwrights, clean-up crews, and trim saw operators. The inhalation MOEs are above the target MOE of 100 for all worker functions. Any dermal irritation

exposures from post-application activities will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product.

Table 7.c Short-, Intermediate, and Long-Term Inhalation Exposures and MOEs for Wood Preservative Chemical Operators, Graders, Trim Saw Operators, and Clean-Up Crews (Handler and Post-application Activities)

Exposure Scenario[a] (number of volunteers)	Inhalation UE[b] (mg/day)	Conversion Ratio[c]	Daily Dose[d] (mg/kg/day)	MOE[e] (Target MOE = 100)
Occupational Handlers				
Chemical Operator (n=11)	0.0281	NA	0.000468	21,000
Occupational Post-Application				
Grader (n=13)	0.0295	NA	0.000491	20,000
Trim Saw (n=2)	0.061	NA	0.00101	9,900
Millwright (n=3)	0.057	NA	0.00095	11,000
Clean-Up (n=6)	0.60	NA	0.0101	990

ST = Short-term duration, IT = Intermediate-term duration, LT = Long-term duration

a. The exposure scenario represents a worker wearing short-sleeved shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves. Volunteers were grouped according to tasks they conducted at the mill.

b. Inhalation unit exposures are from Bestari et. al. (1999). Refer to the Occupational and Residential Exposure Assessment for inhalation exposures. Inhalation exposure (mg/day) was calculated using the following equation: Air concentration (μg/m^3) x Inhalation rate (1.0 m^3/hr) x Sample duration (8 hr/day) x Unit conversion (1 mg/1000 μg). The inhalation rate is from USEPA, 1997.

c. A conversion ratio is not needed because the maximum % active ingredient in the product is the same as the % active ingredient in the DDAC study.

d. Daily dose (mg/kg/day) = exposure (mg/day) x absorption factor (100% for inhalation)/body weight (60 kg).

e. MOE = NOAEL (mg/kg/day)/ Daily dose [Where inhalation NOAEL = 10 mg/kg/day]. Target MOE = 100.

Diptank Operators

These workers are exposed through automatic or manual dip of wood into treatment tanks. Risk resulting form diptank use were assessed using the data from the DDAC study (Bestari et al., 1999). The exposure data for diptank operators were converted into unit exposures in terms of active ingredient. for each 1% of concentration of the product. Table 8.d provides the short-, intermediate- and long-term inhalation dose and MOEs for diptank operators. The inhalation MOE is above the target MOE of 100 and, therefore, is not of concern.

Table 7.d Short-, Intermediate-, and Long-Term Inhalation Exposures and MOEs for Diptank Operator (Handler Activity)

Exposure Scenario[a] (number of replicates)	Inhalation Unit Exposure[b] (mg DDAC/1% solution)	App Rate (% a.i. in solution/ day)	Daily Dose[c] (mg/kg/day)	MOE[d]
Occupational Handler				

Exposure Scenario[a] (number of replicates)	Inhalation Unit Exposure[b] (mg DDAC/1% solution)	App Rate (% a.i. in solution/ day)	Daily Dose[c] (mg/kg/day)	MOE[d]
Dipping, with gloves (n=7)	0.046	3	0.0023	4,300

a The exposure scenario represents a worker not wearing a respirator.

b Inhalation unit exposures are from DDAC study (MRID 455243-04). Refer to Table E-2 in Appendix E for inhalation unit exposure calculations. Inhalation exposure (mg) was calculated using the following equation: Air concentration (mg/m^3) x Inhalation rate (1.0 m^3/hr) x Sample Duration (8 hr). The inhalation rate is from USEPA, 1997.

c Daily dose (mg/kg/day) = unit exposure (mg/1% ai solution) x percent active ingredient in solution (3% ai) x absorption factor (100% for inhalation) / body weight (60 kg).

d MOE = NOAEL (mg/kg/day) / Daily dose [Where inhalation NOAEL = 10 mg/kg/day.] Target MOE = 100.

2. Pressure Treatment Scenarios (Handler and Post-Application)

DDAC may be used to treat wood and wood products using pressurized application methods such as double vacuum. According to the product labels, the maximum retention rate is 0.6 lb/ft^3. An application rate of 3% ai solution was used in this assessment, based on the master label. DDAC-specific exposure data are not available for assessment of pressure treatment exposure. Therefore, the assessment relies on surrogate chromated copper arsenate (CCA) data (ACC, 2002b).

The estimated inhalation exposures and risks for DDAC are presented in Table 8.e. The calculated inhalation MOEs are above the target MOE of 100 for all scenarios and are not of concern.

Table 8e Short-, Intermediate-, and Long-Term Inhalation Exposures and MOEs for Pressure Treatment Handler and Post-application Scenarios

Exposure Scenario	Inhalation Unit Exposure[a] (µg As/ppm)	Application Rate (% ai solution)	Absorbed Daily Doses[b] (mg/kg/day)	Inhalation MOEs[c] (Target MOE = 100)
Occupational Handler				
Treatment Operator (TO)	0.00257	3	0.0013	7,800
Treatment Assistant (TA)	0.000802	3	0.00040	25,000
Occupational Post-application				
All (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman)	0.00160	3	0.00080	13,000

a. Unit exposure values taken from CCA study and are shown in Table 6.11.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) x [% DDAC in solution (3) x 10,000 (parts per million conversion)] x (0.001 mg/µg) x absorption factor (100% for inhalation) / Body weight (60 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where inhalation NOAEL = 10 mg/kg/day for all durations. Target MOE = 100.

8. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to DDAC. The quaternary ammonium compounds (Quats) are clustered into four categories; however, for the available incident information, it is difficult to differentiate the specific members quaternary ammonium compounds associated with each incident. Therefore, all incidents related to the these compounds are discussed together in this section.

The Agency consulted the following sources of information for human poisoning incidents related to DDAC use:

(1) **OPP Incident Data System (IDS)** - The Office of Pesticide Programs (OPP) **Incident Data System** contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.
2) **California Department of Pesticide Regulation (1982-2004)** – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982.
(3) **National Pesticide Information Center (NPIC)** - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991.
(4) Published Incident Reports - Some incident reports associated with Quat related human health hazards are published in the scientific literature.

There have been nearly 2700 incidents reported to the OPP Incident Data System (IDS and the California Department of Pesticide Regulation (1982-2004) associated with exposure to end-use products containing Quats. Most of the incidents are related to dermal, ocular and inhalation irritation. Allergic type reaction is also been reported in some incidents. Although risk associated with eye exposure is not assessed in the risk assessment process, symptoms associated with eye are the most commonly reported associated with Quat exposure.

Incidents Associated with Quat Use	
Type of Incident Reported	**Most Common Symptom**
Inhalation	respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, chest pain, disorientation, dizziness, shortness of breath
Dermal	irritation/burning, rash, itching, and blistering
Allergic	hives and allergic contact dermatitis

Oral	irritation to mouth/throat/nose, vomiting/nausea/abdominal pain, dizziness, and headache
Ocular	irritation/burning, eye pain, conjunctivitis, swelling eye and swelling of eyelid

B. Environmental Risk Assessment

The Agency's ecological assessment compares toxicity endpoints from ecological toxicity studies to estimate environmental concentrations based on environmental fate characteristics and pesticide use data. A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the potential for estimated environmental risks for DDAC use sites and any associated uncertainties. For detailed information on the environmental risk assessment for DDAC please see the following documents: "Environmental Fate Assessment for Didecyl Dimethyl Ammonium Chloride (DDAC) for the Reregistration Eligibility Decision (RED) Document" ;"Ecological Hazard and Environmental Risk Assessment Chapter on Didecyl Dimethyl Ammonium Chloride (DDAC)-Antimicrobial Uses"; and Ecological Risk Assessment in Support of the Antimicrobials Division's Reregistration of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC)-Agricultural Uses" .

1. Environmental Fate and Transport

The environmental fate assessment for DDAC is based on the available data submitted to fulfill the reregistration data requirements. The available data indicates that DDAC is hydrolytically stable under abiotic and buffered conditions over the pH 5-9 range. The calculated half-lives for DDAC were 368 days at pH 5, 194 days at pH 7 (TRIS), 175 days at pH 7 (HEPES), and 506 days at pH 9. DDAC is stable to photodegradation in pH 7 buffered aqueous solutions; even in the presence of a photosensitizer (acetone), degradation is minimal with a calculated half-life of 227 days. DDAC is photolytically stable in soil with a calculated half-life of 132 days.

Aquatic metabolism studies under aerobic and anaerobic conditions indicate that DDAC is stable to microbial degradation. The calculated aerobic and anaerobic half-lives of ^{14}C-DDAC in flooded river water are 180 days and 261 days, respectively. Similarly, DDAC was found to be stable with very little degradation in aerobic soils during a year-long metabolism study. The calculated half-life for aerobic soil degradation was 1,048 days. DDAC is not considered to be degradable since it did not exhibit greater that 60% degredation within a ten-day window.

DDAC is immobile in soil. A soil mobility study reviewed by the Agency shows that DDAC has a strong tendency to bind to sediment/soil with Freundlich K_{ads} values ranging from 1,095 to 30,851 depending on the soil type. Because of its strong adsorption to soils, DDAC is not expected to contaminate surface and ground waters.

Because DDAC is immobile in soil, and not subject to runoff contamination of water bodies, bioaccumulation of DDAC in freshwater fish or aquatic organisms is not likely to occur.

Information on the aqueous availability of DDAC from wood indicates that the use of DDAC as a wood preservative may result in minimal releases to the environment.

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

DDAC Indoor Uses

The majority of DDAC uses are spray applications to indoor surfaces, truck interiors, kennels, institutional areas, household areas, recirculating cooling towers, evaporative condensers, swimming pools and spas, and oil field mud treatments. For the indoor uses of DDAC, it is unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. However, facilities using DDAC for indoor applications are required to have NPDES permits prior to discharging effluents into receiving waters.

Once Through Cooling Tower Use:

Once through cooling tower use will result in a significant release of DDAC into the nearby waterways. Tier I once-through cooling tower modeling indicates that DDAC use will result in acute and chronic risk to all non-endangered and endangered/threatened aquatic organisms at all dosages modeled: 32 ppm and 63 ppm for continuous dosing and 1000 ppm and 1800 ppm for intermittent dosing.

This scenario models a worst-case 10-year. Variables such as stream flow rate and DDAC dissipation, degradation, and half-life were not considered in this Tier I model.

Wood Treatment Use:

DDAC wood treatment uses that have potential for direct release into the environment or runoff to surface waters. The DDAC wood treatment use was modeled (Krahn and Strub, 1990) to estimate the amount of DDAC that will runoff from treated wood when stored outdoors. Modeled estimates range from 18.97ppb to 113ppb. Non-endangered/threatened aquatic species (fish and invertebrates) are not expected to be adversely affected, all estimates are above the LOC.

Endangered/threatened fish (freshwater warm water species) are not expected to be adversely affected by the wood treatment use. However, endangered species LOCs are exceeded based on Tier 1 modeling for many other aquatic organisms.

b. Exposure and Risk

The Agency has evaluated the outdoor use of the DDAC, being considered for reregistration. Although primarily used as antimicrobial agents, DDAC is labeled for use in puddles and decorative pools to control algae. This use is intended for waterbodies generally

disconnected from the greater watershed and will not likely result in exposure to nontarget aquatic species. It is possible these uses will result in exposure to amphibians utilizing these waterbodies for some portion of their lifecycle (e.g. reproduction) and to birds and mammals utilizing these waterbodies for drinking water. At the maximum label rate, 3 ppm initially followed by weekly 1.5 ppm treatments, there are no LOC exceedances, assuming the toxicity of DDAC is similar to that of ADBAC, another Quat compound. However, due to the persistence of DDAC, it is possible that concentrations of DDAC in some waterbodies treated over time could become harmful to animals utilizing these waterbodies.

Non-target Pests

Honeybees could potentially be exposed to pesticide residues if treated wood is used to construct hives or hive components. These residues may be toxic to the bees or result in residues in honey or other hive products intended for human use/consumption. Therefore, a special honeybee study is required for all wood preservative uses unless a statement prohibiting the use of treated wood in hive construction is added to the label such as, "Wood treated with TCMTB shall not be used in the construction of beehives." This study is a combination of Guidelines 171-4 and 850.3030 (see information regarding residue data requirements for uses in beehives in the residue chemistry section of 40 CFR part 158). Numbers of bees used in this study and methods for collection/introduction of bees into hives, feeding, and observations for toxicity and mortality should be consistent with those described in OPPTS Guideline 850.3030, "Honey Bee Toxicity of Residues on Foliage." The toxicity portion of this study is in lieu of the honeybee contact LD50 test.

c. Risk to Listed Species

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

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The active ingredient uses of DDAC, with the exception of the cooling tower and antisapstain wood preservation uses, fall into this category. Using Tier I screening modeling to assess potential exposure from the cooling tower and antisapstain wood preservation uses of DDAC risks to Listed Species are indicated. Since the models are only intended as a screening-level model, and, as such, have inherent uncertainties and limitations which may result in inaccurate exposure estimations, further refinement of the model is recommended before any regulatory action is taken regarding the cooling tower and antisapstain uses of DDAC. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors and impacts from the cooling tower use could potentially be mitigated by the reduction of risk mitigation. Due to these circumstances, the Agency defers making a determination for the cooling tower and antisapstain uses of DDAC until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the cooling tower and antisapstain use of DDAC will be revised, and the risks to Listed Species will be reconsidered.

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 DDAC 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 DDAC.

The Agency has completed its assessment of the dietary, residential, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient DDAC. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient DDAC, the Agency has sufficient information on the human health and ecological effects of DDAC 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 DDAC-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of DDAC 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 DDAC 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 DDAC, the Agency has determined that DDAC 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 DDAC. If all changes outlined in this document are incorporated into the product labels, then all current risks for DDAC will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for DDAC. During the public comment period on the risk assessments, which closed on June 26, 2006, the Agency received comments from the DDAC Consortium, Reckitt Benckiser, and The Clorox Company regarding the risk assessment assumptions. These comments in their entirety are available in the public docket at http://www.regulations.gov (OPP-2006-0338).

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 DDAC. 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. The DDAC contributions for drinking water exposure are considered to be negligible; therefore, Dietary exposure from drinking water was not assessed, as the uses of DDAC 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 DDAC. The Agency has determined that provided a safety finding can be made for DDAC, the established tolerance exemptions for DDAC, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of DDAC. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of DDAC. As discussed in Section III, the acute and chronic dietary (food and drinking water) risks from DDAC are below the Agency's level of concern, provided that mitigation measures outlined in this document are adopted and labels are amended.

The chronic dietary aggregate risks from direct and indirect food contact exposures for adults and children are 3.8 % and 14 % respectively. Therefore, the acute and chronic dietary aggregate risks are not of concern.

The DDAC toxicity endpoints for the chronic dietary and the intermediate-term incidental oral are based on the same toxic effect (and same study), and therefore, these two dietary routes of exposure are aggregated. On the other hand, the dermal and inhalation routes of exposure are based on different toxic effects, and therefore, these two routes of exposure are not aggregated. In addition, the inhalation route of exposure is also aggregated among the inhalation exposure scenarios that are believed to co-occur. The aggregate risks are not of concern for adults for the oral and inhalation routes. However, the adult dermal MOE for the cleaning products are all of concern by themselves. As an aggregate, the adult dermal MOE is less than the target MOE of 10. The aggregate risks for children are above the target MOE.

c. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of DDAC, 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 DDAC 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 DDAC 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 DDAC based on (1) the existence of a complete developmental and reproductive database (2) the lack of evidence for increased susceptibility in the data 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, DDAC 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 DDAC. 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 DDAC. 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 Reassessment Summary

Didecyl Dimethyl Ammonium Chloride, DDAC has a tolerance exemption in 40 CFR 180.940 (a) as a food contact sanitizer for use in public eating places, in dairy processing equipment, and in food processing plants on equipment and utensils and (c) as a food contact sanitizer for use in food processing plants on equipment and utensils.

Table 9: Tolerance Reassessment Summary for DDAC

Tolerance Exemption Listed Under 40 CFR 180.940 (a)			
Use Site	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
public eating places, dairy processing equipment, and food processing plants on equipment and utensils	Total Quat concentration does not exceed 200	Total Quat concentration does not exceed 200 ppm	No change in current definition
Tolerance Exemption Listed Under 40 CFR 180.940 (c)			
Use Site	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
food processing plants on equipment and utensils	Specific Quat concentration does not exceed 200 while total Quat concentration does not exceed 400	Specific Quat concentration does not exceed 200 while total Quat concentration does not exceed 400	No change in current definition

D. Regulatory Rationale

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

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

The DDAC contributions for drinking water exposure are considered to be negligible, thus 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 DDAC into swimming pools and humidifiers, mopping, wiping and trigger pump spray, and low pressure hand wand. All exposure scenarios except carpet treatment by low pressure spray and indoor hard surface mopping and wiping are below the level of Agency concern to residential handlers.

Mitigation of the treatment of carpet by low pressure spray is accomplished via labeling and container size restrictions such that products with this use are not available to residential applicators. Products with label directions for application by low pressure spray are only to be marketed in 5 gallon or larger containers and will include the statement: "For Professional Use Only" with appropriate PPE label statements.

The individual dermal MOEs at the treatment solution concentration of 0.0043 lb ai/gallon for hard surface cleaning includes mopping (MOE = 29), wipes (MOE = 11), and spraying (MOE = 110). The dermal aggregate MOE for the 0.0043 lb ai/gallon hard surface cleaning rate is 7 with a target MOE of 10. The aggregate MOE includes the three cleaning scenarios plus the exposure to adults wearing treated laundered clothing (MOE = 690). The individual dermal MOEs for all four scenarios are not of concern. Once aggregated, the MOE of 7 is less than the target MOE of 10. The assumption of the four scenarios co-occurring at the highend assumptions used in the assessment for amount of treatment solution applied is very conservative. Therefore, the dermal aggregate MOE of 7, based on a NOAEL for dermal irritation, achieves a reasonable certainty of no harm.

However, the heavy duty cleaning rate of 0.02 lb ai/gallon results in an aggregate dermal MOE of 1. Mitigation of the treatment of indoor hard surfaces by mopping and wiping is accomplished by reducing the application rate to 0.0066 lb ai/gallon which results in individual dermal MOEs for mopping, wiping, and spraying of 19, 7, and 72, respectively. The dermal

aggregate MOE using these three individual MOEs plus the treated laundered clothing is 5. While this rate does not result in an acceptable MOE, the Agency believes that the assessment is conservative and that the actual exposures would not be of concern. The Agency recently received extensive use and activity pattern information from industry. A preliminary review of this data suggests that the assumptions used in the wiping and mopping scenarios may overestimate actual use. Again, this rate (0.0066 lb ai/gallon) and a dermal aggregate MOE of 5 based on a NOAEL for dermal irritation, achieves a reasonable certainty of no harm.

ii. Post-Application Risk Mitigation

Post-application scenarios have been developed that encompass multiple products, but still represent a high end exposure scenario for all products represented. Post-application scenarios assessed include crawling on treated hard surfaces, carpets, and treated lumber such as decks/play sets (dermal and incidental oral exposure to children), wearing treated clothing from wash treatment and from a direct clothing spray treatment (dermal exposure to adults and children and incidental oral exposure to children), using portable humidifiers (adult and child inhalation exposure), and swimming in treated pools (adult and child incidental ingestion).

All exposure scenarios except dermal exposure to clothing treated with fabric spray, exposure of children to treated decks/play sets and inhalation exposures due to use in humidifiers are below the level of Agency concern for residential post application exposure.

The assumptions used in developing the risk estimates for the fabric spray scenario are considered to be very conservative. It was assumed that individuals would be exposed via oral mouthing and dermal contact to fabrics that had wetness equivalent to freshly laundered clothing removed from the washer following the final spin cycle. The Agency believes that it is unlikely that people would actually be exposed to treated fabrics with this high level of dampness. Therefore, the Agency has overestimated risks for this scenario.

Based on a screening level assessment, the MOEs for children playing on treated decks and playsets ranged from 3 to 13. The Agency believes that actual exposures are most likely to occur at the upper end of this range and, thus are not of concern. Further, these risk estimates were derived from exposures from a study of workers exposed to DDAC following the antisapstain treatment of freshly cut lumber. This scenario involves workers handling treated wood shortly after a surface spray-on treatment of the lumber for an 8-hour work day where residues on the wood would be relatively high. The residential exposure scenario is considerably different in that children would be exposed to pressure-treated wood for a shorter duration at a time that is much more distant from the actual treatment of the wood (time taken to treat, ship the wood and construct the deck/playset as compared to minutes to hours post treatment.) Therefore, the Agency believes that actual exposures would be at the upper end of the range and not of concern. To confirm this finding the Agency will require confirmatory surface wipe data for DDAC.

At this time, there are no available mitigation measures for the humidifier use. Because of remaining residential exposure concerns, the registrants for DDAC have agreed to conduct a inhalation exposure study that would allow the Agency to refine the risks associated with this uses. However, this study will not be completed in time for inclusion in this RED. Until acceptable data are submitted, the Agency has determined that the residential use of DDAC in

humidifiers is ineligible for reregistration and this use must be deleted. Once the data has been received and determined to be acceptable, and if it is established that the risks are not of concern, the registrants can request that this use be reinstated.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

Occupational risks from handler and applicator exposures were calculated for short-, intermediate- and long-term inhalation exposures. All exposure and risk estimates for occupational handler scenarios are below the Agency's level of concern except for once-through cooling water systems (MOE 91.) Due to the conservative nature of the risk assessment and the proximity of the MOE to the target of 100, the Agency believes that actual exposures do not exceed the Agency's level of concern. Therefore, no risk mitigation measures are required for these handler scenarios.

ii. Post-Application Risk Mitigation

Except for the post-application scenario assessed for fogging in food processing plants and hatcheries, the occupational post-application dermal and inhalation exposures are assumed to be negligible. To mitigate the risk of concern for the fogging use the Agency is requiring that labels to include a 2 hour reentry interval the fogger use in food processing plants and hatcheries. In addition to the REI, food processing plants will be required to have a minimum four (4) ACH (air exchanges) per hour in order to be treated with this chemical.

2. Environmental Risk Management

There is minimal environmental exposure from the indoor uses; such as commercial, institutional, residential hard surfaces, re-circulating cooling water towers, pulp/paper mills, and oil field mud treatments, of products containing DDAC because the amount that actually reaches the environment is negligible and breakdown in the environment via sewage treatment is rapid.

Alternatively, there is the potential for environmental exposure from the outdoor uses from products containing DDAC; once-through cooling water towers and antisapstain wood treatment. In order to reduce the environmental risk, the following mitigation measures must be adopted:

<u>Once-Through Cooling Water Towers:</u>

- Reduce the maximum number of applications to 4 per year.
- Also, all labels supporting this use must carry the NPDES statement per PR Notice 93-10 and 95-5 as well as directions for Bentonite Clay Treatment, a method to treat the water before it is released.
- The Agency will require monitoring data to confirm this decision.

<u>Antisapstain Wood Treatment:</u> All product labels supporting this use must carry the following language:

Treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, stream, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it must consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events.

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 DDAC. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk

Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The active ingredient uses of DDAC, with the exception of the cooling tower and antisapstain wood preservation uses, fall into this category. Using Tier I screening modeling to assess potential exposure from the cooling tower and antisapstain wood preservation uses of DDAC risks to Listed Species are indicated. Since the model is only intended as a screening-level model, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations, further refinement of the model is recommended before any regulatory action is taken regarding the cooling tower and antisapstain uses of DDAC. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors and impacts from the cooling tower use could potentially be mitigated by the reduction of risk mitigation (see General Risk Mitigation, below). Due to these circumstances, the Agency defers making a determination for the cooling tower and antisapstain uses of DDAC until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the cooling tower and antisapstain use of DDAC will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

DDAC end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing DDAC 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 DDAC 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 DDAC 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 Tracy Lantz at (703) 308-6415 with questions regarding generic reregistration.

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

By express or courier service:
Document Processing Desk (DCI/AD)
Tracy Lantz
Office of Pesticide Programs (7510P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

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

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

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

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

Within eight months from the receipt of the PDCI:

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

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

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

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

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 Velma Noble at (703) 308-6233 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/AD)
Velma Noble
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/AD)
Velma Noble
Office of Pesticide Programs (7510P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

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

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 (all uses)	875.2800	133-1
Dietary-Residues in Food from Treating Countertops with DDAC (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Non-Guideline	Non-Guideline
Surface Wood Wipe Study	Non-Guideline	Non-Guideline
Fabric Leaching Study	Non-Guideline	Non-Guideline
Dermal exposure outdoor	875.1100, 875.1600	231
Inhalation Exposure outdoor	875.1300, 875.1600	232
90-Day Inhalation Rat	870.3465	82-4
Non-Target plant phytotoxicity (seedling emergence test using rice)	850.4225	123-1
Aquatic Field Monitoring (once through cooling towers)	Non-Guideline	Non-Guideline
Fish-Early Life Stage	850.1300	72-4A
Aquatic Invertebrate Life Cycle	850.1400	72-4B
Vegetative Vigor using rice	850.4250	123-1
Aquatic plant growth toxicity (*Lemma gibba*)	850.4400	123-2
Aquatic plant growth (3 Algal toxicity species) blue-green cyanobacteria (*Anabeana flos-aquae*), freshwater diatom (*Navicula pelliculosa*), marine diatom (*Skeletonema costatum*)	850.5400	123-2
Honey Bee Toxicity studies	850.3030	141-1

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. Products which include claims for residual sanitizing activity as well as residual claims against certain non-public health organisms, including mold, will be required to submit efficacy data to support these claims. If a product label includes a sanitizing claim such as sanitizing carpets or laundry, the appropriate efficacy data must be submitted to support the claim.

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	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Disinfectant	Hard inanimate surfaces	AOAC Use Dilution Test (Hard water and organic soil) **or** AOAC Germicidal Spray Test **or** AOAC Hard Surface Carrier Test (Distilled water only)	810.2100 (c), (d), (e)	91-2 (b), (c), (d)
Toilet Bowl Disinfection	Toilet bowl and urinal hard surfaces	AOAC Use Dilution Test (Hard water and organic soil) **or** AOAC Germicidal Spray Test **or** AOAC Hard Surface Carrier Test (Distilled water only)	810.2600 (b)(1)	91-7 (a) (1)

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Laundry Additives Disinfection (pre-soak)	Laundry	AOAC Hard Surface Carrier Test (Distilled water only) **or** AOAC Use Dilution Test (Hard water and organic soil)	810.2300 (b)(2)	91-4 (a)(1)
Laundry Additives Disinfection (non-residual)	Laundry	Petrocci and Clarke laundry additives (disinfectant level) or actual in-use study	810.2300 (b)(3)	91-4 (a)(2)
Tuberculocidal	Hard inanimate surfaces	AOAC Tuberculocidal Activity Test method (standard) **or** AOAC Tuberculocidal disinfectants test method (modified) **or** Quantitative Tuberculocidal Activity test method **or** AOAC Germicidal Spray Test (modified for spray products)	810.2100 (h)	91-2 (g)
Virucidal	Hard inanimate surfaces	Virucidal Activity Method used in conjunction with modification of : AOAC Hard surface carrier test (distilled water only) **or** AOAC Germicidal Spray Test	810.2100 (g)	91-2 (f)
Fungicidal	Hard inanimate surfaces	AOAC Fungicidal Test **or** AOAC Hard surface carrier test (distilled water only) **or** AOAC Germicidal Spray Test	810.2100 (f)	91-2 (e)
Sanitizer	Non-food contact surfaces (non-residual)	Sanitizer Test for Hard Inanimate Non-Food Contact Surfaces	810.2100 (l)	91-2 (j)

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Food Contact Sanitizer	Final rinse of previously cleaned food contact surface	AOAC Germicidal and Detergent Sanitizers Method	810.2100 (m)(2)	91-2 (l)(2)
Laundry additive, non residual	Laundry	Petrocci and Clarke laundry additives method (Sanitizing level)	810.2300 (b)(4)	91-4 (a)(3)
Laundry additive, residual self sanitizing	Laundry	Petrocci and Clarke laundry additives method or ATCC Test method 100-1974	810.2300 (b)(5)	91-4 (a)(4)
Laundry Additives, sanitizing pre-soak	Laundry	Sanitizer test for hard inanimate non-food contact surfaces modified to include organic soil	810.2100 (b)(2)	N/A
Residual Self Sanitizing	Hard surfaces (residual self-sanitizing activity of dried chemical residues on hard inanimate surfaces)	Controlled In-Use study or simulated In-Use study	810.2100 (o)	91-2 (m)
Carpet Sanitizer	Carpet	EPA Carpet Sanitizer Protocol	810.2300 (c)	91-4 (b)
Toilet bowl and urinal sanitizing	Toilet bowl and urinal hard surfaces	Sanitizer Test for Hard Inanimate Non-Food Contact Surfaces	810.2600 (b)(2)	91-7 (a)(2)
Presaturated and impregnated towelettes	Hard Inanimate Surfaces	Simulated In-use Study	810.2100 (i)	N/A
Sanitizing Fabric Treatment	Mattresses, upholstered furniture, pillows	Simulated In-use Study	810.2300 (d)	91-4 (c)
Termites	Wood	Pesticide Assessment Guidelines Subdivision G, Product Performance, Preventative treatment-wood impregnation	N/A	Section 95-12(b)(ii)

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

Statements noted with an * are not directly related to risk mitigation but are reflective of Agency labeling requirements.

Description	Amended Labeling Language	Placement on Label
	Manufacturing Use Products	
For all Manufacturing Use Products *	Only for formulation into antimicrobial products for use in: agricultural/farm premises, structures, buildings, and equipment; dairy farm milk handling facilities, equipment, storage rooms, houses, and sheds; food processing plants, food handling, food distribution equipment and premises; eating establishments premises and equipment; commercial, institutional, and industrial premises and equipment (floors, walls, storage areas); domestic dwellings, food handling areas, bathroom premises (hard surfaces), indoor premises; and medical institutional critical care and noncritical care premises and laundry. For Formulation into antimicrobial products for use in golf courses, greenhouses/nurseries, fountains/water displays/decorative ponds/standing water, disposal water, spas, air conditioner/refrigeration condensate water systems, air washer and industrial scrubbing systems, once- through and recirculating industrial/commercial cooling water systems, and swimming pools. Gas/oil drilling muds/packer fluids, mushroom houses/empty premises and equipment, wood preservation, egg handling equipment and rooms, egg washing treatment, poultry processing plant equipment/premises, meat processing plant/equipment, gas/oil recovery injection water systems.	Directions for Use
Precautionary Statements for all Manufacturing Use Products (based on concentration of active ingredients)	Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or inhaled. May be harmful if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number TC-21C) or a NIOSH approved respirator with any N, R, P, or HE filter. Wear goggles or faceshield, rubber gloves, and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.	Precautionary Statements

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Language Required by the RED and PR Notice 93-10 and 95-1	"This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. 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."	Environmental Hazard Statements
End Use Products Intended for Commercial, Institutional, Industrial, and Agricultural Uses		
PPE Requirements[1]	The Precautionary Statements/PPE are dependent on the Acute Toxicity Data submitted to support the end use product registration(s). Refer to Label Manual, 3rd Edition Chapter 7 for labeling.	Precautionary Statements
Hatcheries	2 hour Reentry Interval for fogging applications	Directions for Use
Food Processing Plants	2 hour Reentry Interval for fogging applications and a minimum of 4 air exchanges (ACH) per hour in the facility	Directions for Use
Wood Preservation	Label must include dilution rate and retention chart specific to the type of wood for pressure and dip treatment. If registrant has not supported Honey Bee Data, the following statement must be included on the Agency label as well as the end tag on the treated lumber: Wood treated with DDAC shall not be used in the construction of bee hives.	Directions for Use
Application Restrictions-For Products Used in Swimming Pools/Spas	Do not apply when swimmers are in the immediate vicinity (the Agency recommends a 15 minute reentry interval)	Directions for Use
Environmental Hazards -for Labels for AntiSapstain	Treated lumber must be stored under cover, or indoors, or at least 100 from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the water way. Treated lumber stored outdoors within 100 feet of a pond, lake, stream or river must be either covered with plastic or surrounded by berm to prevent surface water runoff into the nearby waterway. If a berm is used around the site, it must consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events.	Environmental Hazards

Description	Amended Labeling Language	Placement on Label
Environmental Hazards for Once Through Cooling Water Towers	**DO NOT APPLY THIS PRODUCT MORE THAN 4 TIMES PER YEAR.** DEACTIVATION: This product must be deactivated prior to discharge of the NPDES outfall. TO DEACTIVATE: Use Bentonite Clay at minimum ratio 5 ppm clay to 1 ppm product. Deactivation must occur prior to discharge of the NPDES outfall.	Directions for Use
Humidifiers	Delete the Use	Delete all claims and Directions for Use
Pulp and Paper Mill Water Systems	Delete the Use. This use is not supported by this RED. There are no end use products for this use, thus a risk assessment for this use was not completed.	Delete all claims
Hard nonporous surfaces in Institutional/Commercial Food Handling Facilities *	After disinfection, a potable water rinse is required. Do not use on dishes, glasses, and utensils. Do not use to disinfect appliances, refrigerator interiors, and microwave oven interiors.	Directions for Use
Disinfection/Sanitizing Drains/Disposals *	Delete the claim because the Agency believes it is not feasible to disinfect throughout a drain w/ or w/out a disposal system.	Directions for Use
Institutional/Commercial Laundry Treatment *	Dilute ____ oz per _____ gallons of water per 100 lbs of fabric (dry weight). When washing the clothes, a maximum of 60 gallons of water per 100 lbs. of fabric (dry weight) must be in the machine. Add use solution to the wash wheel at the beginning of the final rinse cycle.	Directions for Use
Addition of ATCC number *	All organisms tested to support bactericidal, virucidal, and fungicidal claims must list the ATCC number to identify the specific strain of organism.	Directions for Use
Hand Sanitizer *	Delete the Use. This use is regulated only by the Food and Drug Administration.	Delete all claims and Directions for Use
Udders, Teats and Flanks *	Delete the Uses. These uses are regulated only by the Food and Drug Administration.	Delete all claims and Directions for Use
Treatment of Hatching Eggs *	Delete the Use. This use is regulated only by the Food and Drug Administration.	Delete all claims and Directions for Use

Description	Amended Labeling Language	Placement on Label
Sanitizing Incubators and Hatchers	Label must include the following text: Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs.	Directions for Use
Carpet Restoration Treatment (due to damage from flood, fire, smoke other water damage)	This use only for commercial, industrial and institutional applicators: thus products with this use are only to be marketed in 5 gallon or larger containers with statement: "For Professional Use Only" with appropriate PPE statements listed on label including the use of gloves. Refer to http://www.epa.gov/mold/mold_remediation.html, Table 1 & 2 for Remediation Directions for Use.	Directions for Use and Precautionary Language
Mold Remediation/Prevention (Water/Smoke restoration/Sewer backup/river flood cleanup/clean water source)	**For Professional Use Only:** For use by Mold Remediation Workers, Mold Remediation Contractors, Certified Mold Remediators, Certified Mold Contractors, Certified Mold Remediation Contractors, Applied Microbial Remediation Technicians, Certified Mold Professional, Certified Restorers, and Mold Remediation Companies. Refer to http://www.epa.gov/mold/mold_remediation.html, Table 1 & 2 for Remediation Directions for Use.	Directions for Use and Precautionary Language
Agricultural Premises and Equipment/Animal housing facilities *	All animal viruses claimed on the label must immediately precede directions for agricultural premises and equipment/animal housing facilities.	Directions for Use
Institutional/ Medical premise and equipment *	If the label indicates use in institutions, medical facilities/premises on medical equipment such as wheelchairs, hospital bed frames, or unqualified metal, plastic, and stainless steel surfaces, the following statement, "This product is not for use on medical devices and equipment " must be added or the following MOU language from PR Notice 94-4 must be included in the label text: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Treatment of Eggs in Egg Processing Facilities *	Label must include the following text: Eggs sanitized with this product must be subjected to a potable water rinse if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.	Directions for Use
Treatment of Mushroom Farms	Label must include the following text: DO NOT APPLY TO THE MUSHROOM CROP, COMPOST OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.	Directions for Use
Sanitizing Hatchery Rooms	Label must include the following text: Remove all animals and feed from premise, vehicles and enclosures.	Directions for Use
Algae Treatment for Fountains, Water Displays, Decorative Pool/Ponds and Standing Water	This product is not to be used in open waterways connected to larger watersheds or in waters that serve as natural habitats for aquatic and amphibious organisms. DO NOT use when fish or other wildlife (for example, amphibians) are present.	Direction for Use
Citrus Canker Control	Label must include the following text: After use, all surfaces which come in contact with food or crop must be rinsed with potable water.	
End Use Products Intended for Residential Use		
PPE Requirements[1]	The Precautionary Statements/PPE are dependent on the Acute Toxicity Data submitted to support the end use product registration(s). Refer to Label Manual, 3rd Edition Chapter 7 for labeling.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Cleaning of hard surfaces by Mopping and Wiping	The use of products in this manner is limited to a final concentration (use solution) of no more than 0.0066 lb DDAC per gallon of water. This is equivalent to a final concentration (use solution) of DDAC at no greater than 786 ppm. Revise labels such that this is the maximum rate for any cleaning or heavy duty cleaning in which this product may be applied by mopping or wiping.	Directions for Use
Application Restrictions-For Products Used in Swimming Pools/Spas	Do not apply when swimmers are in the immediate vicinity (the Agency recommends a 15 minute reentry interval)	Directions for Use under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Disinfection/Sanitizing Drains/Disposals *	Delete the claim because the Agency believes it is not feasible to disinfect throughout a drain w/ or w/out a disposal system.	Directions for Use
Addition of ATCC number *	All organisms tested to support bactericidal, virucidal, and fungicidal claims must list the ATCC number to identify the specific strain of organism.	Directions for Use
Carpet Restoration Treatment (due to damage from flood, fire, smoke other water damage)	This use only for commercial, industrial and institutional applicators only. Delete this use from residential products. Refer to http://www.epa.gov/mold/mold_remediation.html, Table 1 & 2 for Remediation Directions for Use.	Directions for Use under General Precautions and Restrictions
Mold Remediation/Prevention (Water/Smoke restoration/Sewer backup/river flood cleanup/clean water source)	**For Professional Use Only:** For use by Mold Remediation Workers, Mold Remediation Contractors, Certified Mold Remediators, Certified Mold Contractors, Certified Mold Remediation Contractors, Applied Microbial Remediation Technicians, Certified Mold Professional, Certified Restorers, and Mold Remediation Companies. Refer to http://www.epa.gov/mold/mold_remediation.html, Table 1 & 2 for Remediation Directions for Use.	Directions for Use and Precautionary Language
Humidifiers	Delete the Use	Delete all claims and Directions for Use
Algae Treatment for Fountains, Water Displays, Decorative Pool/Ponds and Standing Water	This product is not to be used in open waterways connected to larger watersheds or in waters that serve as natural habitats for aquatic and amphibious organisms. DO NOT use when fish or other wildlife (for example, amphibians) are present.	Direction for Use
Hard, non-porous food contact surfaces *	Do not use to disinfect appliances, refrigerator interiors, and microwave oven interiors. Do not use as a disinfectant on dishes, glasses, or utensils.	Directions for Use

[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. Master Label Table for DDAC

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
Industrial processes and water systems					
1839-129	Small Process Water Systems	Cooling Towers (recirculating only) evaporative condensers, dairy sweetwater systems, cooling canals, pasteurizers, tunnel coolers and warmers	Pour		497,000 ppm
1839-129	Small Process Water Systems	Cooling Towers (recirculating only) evaporative condensers, dairy sweetwater systems, cooling canals, pasteurizers, tunnel coolers and warmers	Metered		Initial: 178 ppm Maintenance: 17.9 ppm
6836-235	Industrial Water Systems	Once Through Cooling	Metered	Do Not Apply this Product More Than 4 Times Per Year Labels Must Carry NPDES Statement	5.83 ppm
1839-179	Oil Field Operations-Drilling Mud and Packing Fluids	Oil Field Water Disposal Systems, Injection and Wastewater, Packer Fluids, Drilling Muds	Pour/Metered, Continuous Injection, Batch Treatment		179,000 ppm
Swimming Pools					
10324-69	Swimming Pool	Swimming Pool	pour	Do not apply when swimmers are in the immediate vicinity (the Agency recommends a 15 minute reentry interval)	Initial/Winter Treatment: 2 ppm Maintenance Dose: 0.5 ppm
1839-133	Swimming Pool	Outside Spas/Whirlpools/ Hot Tub Bath	pour	Do not apply when swimmers are in the immediate vicinity (the Agency recommends a 15 minute reentry interval)	2 ppm
Aquatic Areas					
499-482		decorative fountains, decorative pools, ponds, water displays and standing waters associated with greenhouse/ nurseries, golf courses, recreational parks, amusement parks, universities, cemeteries	dribble, spray ring	Refer to Table 13 (Labeling Changes Summary Table) for appropriate label restriction	For Algae control Initial Treatment: 3 ppm Maintenance Dose: 0.5 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
499-482		irrigation system, watering lines, drip lines, emitters, watering nozzles, and hoses associated with greenhouses and nurseries	immersing or running thru system		For Algae and Slime control at 938 ppm
Wood Treatment					
6836-212	Lumber		Pressure Treatment, Double Vacuum, Dip/Spray Surface Treatment	Refer to Table 13 (Labeling Changes Summary Table) for appropriate label restriction	3% AI Solution
10324-92	Lumber		Sapstain	Refer to Table 13 (Labeling Changes Summary Table) for appropriate label restriction	3% AI Solution
Agricultural Premises and Equipment					
10324-80	hatcheries, swine/poultry/turkey farms, egg receiving area, egg holding area, setter room, tray dumping area, chick holding room, poultry buildings, dressing plants, farrowing barns and areas, blocks, creep areas, chick holding area, hatchery room, chick processing area, and chick loading area	toilets, urinals, portable toilets, floors, walls, ceilings, feed racks, mangers, troughs, automatic feeders/fountains/ waterers, other feeding and watering appliances, halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure, blocks, chutes, incubators, hatchers, glazed porcelain, glazed ceramic tile, glass, shoes, gloves	mop, wipe, spray, immersion		1120 ppm
71240-5	Greenhouses	Floors, carpets, walls, ceilings, counters, work surfaces, foundations	Mop, wipe, spray		786 ppm
10324-81	hatchery rooms		fogging	2 hour reentry interval	0.0000188 lb/AI/1000 ft.^{3}
10324-81	incubators and hatchers		fogging	2 hour reentry interval	0.0000188 lb/AI/1000 ft.^{3}

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
10324-108	Mushroom Farm	breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings	mop, wipe, cloth, mop, sponge, spray, immersion		1120 ppm
1839-167	Mushroom Farm	breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds, casing rings, and waterproof footwear (shoe bath)	cloth, mop, sponge, spray, immersion		1120 ppm
1839-167	Citrus Farm	trucks, vehicles, equipment, trailers, field harvesting equipment, cargo area, wheels, tires, under carriage, hood, roof, fenders	spray, dip, brush		1120 ppm
10324-117	Animal housing facilities	boots and shoes	immersion		1120 ppm
1839-167	Florists/flower shops, greenhouses, shippers, packing areas	flower buckets, coolers, floors and walls of coolers, design and packing benches, garbage pails	Mop/wipe, cloth, brush, sponge, sprayer		1120 ppm
499-482	greenhouse/ nursuries	work tables, benches, pots, flats, knives, pruning tools, floors, plant containers, carts, transplant trays, hanging baskets, tray/ pot holders, water collectors, walkways, windows	immersion, spray, brush		1120 ppm
48815-1	farms	fish aquariums, tanks, fish handling equipment, nets, seines, traps, filter boxes, pumps, air diffusers, shipping boxes, feeding equipment, floors, countertops, raceways, garbage pails, other hard nonporous surfaces, holding tanks, lavatories.	immersion, brush, mop or cloth		1120 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
Residential and Public Access Premises					
10324-134	Homes	floors, walls, windows, toilets, bathtubs, shower stalls, shower door/curtain, sinks, mirrors, restroom fixtures, cabinets, tables, chairs, desks, bed frames, doorknobs, garbage cans/pails, outdoor furniture, telephones, glazed porcelain, glazed ceramic tile, glass, Countertops (kitchen/food prep); Internal (external) surfaces of appliances (refrigerator, microwave, freezer); stovetop; table surfaces; sinks, shelves, racks	mop, wipe, (cloth), spray		Disinfection at 512 ppm Heavy Duty Cleaning and all other applications (excluding disinfection, sanitization, carpets and furniture) are limited to 786 ppm
10324-108	homes	Carpets	Rotary Floor Machine, Portable Extraction Units, Truck Mounted Extraction Machines, Metered		1050 ppm
3573-69	home	Furniture upholstery, window treatments, application to clothing without washing, plush toys, shoes/sneakers, children mattresses, pet bed, sports bag/equipment, carpet	Spray (fabric sanitizer)		1311 ppm
10324-117	Homes	cooking utensils; coolers/ice chest; cups; cutlery; dishes; eating utensils; glassware	Immersion		200 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1836-167	campgrounds, playgrounds, Public facilites, mobile homes, cars, campers, trailers, trucks	floors, walls, toilets, urinals, bathrooms, bathtubs, sinks, countertops, shower doors/curtains, toilet seats, shower stalls, tables, chairs, shelves, telephones, cabinets, desks, bed springs, door knobs, linen carts, hampers, exercise equipment, automobile/truck interiors, garbage cans/pails, fixtures, metal, stainless steel. glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, enameled surfaces, painted wood work, Formica, vinyl and plastic upholstery, chrome plated fixtures	cloth, mop, sponge, spray		512 ppm
10324-117	homes	water softners and reverse osmosis units	pour		200 ppm
48815-1	homes	fish aquariums, tanks, fish handling equipment, nets, seines, traps, filter boxes, pumps, air diffusers, shipping boxes, feeding equipment, floors, countertops, raceways, garbage pails, other hard nonporous surfaces, holding tanks, lavatories.	immersion, brush, mop or cloth		512 ppm
1677-109	Homes	Clothing and Diapers treated during the final rinse cycle of wash	Immersion		0.000733 lb AI/lbs dry fabric

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
Medical Premises and Equipment					
1839-167	Hospitals, Health Care facilities, Medical/Dental offices, Nursing homes, operating rooms, patient care facilities, clinics, isolation wards, medical research facilities, autopsy rooms, ICU areas, recovery anesthesia, emergency rooms, X-ray cat labs, newborn nurseries, orthopedics, respiratory therapy, acute care institutions, alternate care institutions, healthcare institutions, Funeral Homes, mortuaries	floors, walls, toilets, urinals, lavatories, bathrooms, bathing areas, bathtubs, sinks, sink tops, shower stalls, shower doors/curtains, mirrors, ultrasonic bath, whirlpools, foot baths, countertops, cabinets, tables, chairs, desks, hospital beds, bed springs, bed frames, traction devices, MRI, CAT, examining tables, scales, paddles, wheelchairs, lifts, door knobs, wheel chairs, telephones, garbage pails/cans, fixtures, metal, stainless steel. glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, enameled surfaces, painted wood work,	Wipe, mop, (cloth), swab, brush, spray, portable extraction units, truck mounted extraction machines, metered		2383 ppm
10324-134	Hospitals, medical/dental offices, nursing homes	Floors, walls, windows, toilets, bathtubs, shower stalls, shower door/curtain, sinks, mirrors, restroom fixtures, cabinets, tables, chairs, desks, bed frames, doorknobs, garbage cans/pails, telephones, glass, glazed porcelain, glazed ceramic tile, table surfaces, sinks, shelves, racks	mop, wipe, spray		2383 ppm
1677-109	Hospitals	Clothing and Diapers treated during the final rinse cycle of wash	pour at final rinse or sour to washweel		0.000733 lb AI/lbs dry fabric

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
71240-5	Nursing Homes	Floors, carpets, walls, ceilings, counters, work surfaces, foundations	Mop, wipe, spray		786 ppm
1839-178	hospitals, day-care facilities, sick rooms	counters, stovetops, sinks, outside microwaves, refrigerator exteriors, walls, appliances, finished wood, cabinets, floors, exterior toilet bowl surfaces, trash cans, tubs, shower walls, bathrooms, door knobs, closets, phones, car interiors, computers, hand rails, switch plates, door frames, urinals, desks, cribs, changing tables	RTU wipe		2383 ppm
1839-173	Morgues and Funeral homes	human remains	sponge, wash cloth, soft brush		2383 ppm
Commercial, Institutional, and Industrial premises and equipment					
10324-134	Athletic/recreational facilities, exercise facilities, schools, colleges, dressing rooms, transportation terminals, institutions	floors, walls, windows, toilets, bathtubs, shower stalls, shower door/curtain, sinks, mirrors, restroom fixtures, cabinets, tables, chairs, desks, bed frames, doorknobs, garbage cans/pails, outdoor furniture, telephones, glass, glazed porcelain, glazed ceramic tile, chrome plated intakes, enameled surfaces, countertops (kitchen/food prep); Internal (external) surfaces of appliances (refrigerator, microwave, freezer); stovetop; table surfaces; sinks, shelves, racks	mop, wipe, (cloth), spray		2383 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-167	Athletic/recreational facilities, exercise facilites, locker rooms, dressing rooms, schools, colleges, transportation terminals,	floors, walls, toilets, urinals, bathrooms, bathtubs, sinks, countertops, shower doors/curtains, toilet seats, shower stalls, tables, chairs, shelves, telephones, cabinets, desks, bed springs, door knobs, garbage cans/pails, fixtures, metal, stainless steel. glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, enameled surfaces, painted wood work,	cloth, mop, sponge, spray		2383 ppm
71240-5	Hotels, restaurants (non-food contact), kennels, veterinary clinics, flower shops, trailer and boat interiors	Floors, carpets, walls, ceilings, counters, work surfaces, foundations	Mop, wipe, spray		786 ppm
1839-167	motels, hotels, schools	carpets	portable extraction units, truck mounted extraction machines, rotary floor machines, metered, spray	Mitigation via labeling and container size restrictions such that product is not available to residential applicators. Products with label directions for low pressure spray are only to be marketed in 5 gallon or larger containers and will include: "For Professional Use Only" with appropriate PPE label statements including gloves.	12,150 ppm
1839-175	Hotels and schools	floors, walls, metal surfaces, stainless steel, glazed porcelain, glazed ceramic tile, shower stalls, bathtubs, cabinets, plastic surfaces	RTU wipe/spray		2383 ppm
6836-78	Barber and Beauty Salons	Barber/ Beauty Instruments and Tools	immersion		2383 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-178	Barber and Beauty Salons, Health clubs, hotels, motels, emergency vehicles, transportation terminals, correctional facilities, factories,	counters, sinks, walls, finished wood, cabinets, floors, exterior toilet bowl surfaces, trash cans, tubs, shower walls, bathrooms, door knobs, closets, phones, car interiors, computers, hand rails, switch plates, door frames, urinals, desks,	RTU wipe		2383 ppm
1839-167	commercial florists	flower buckets, coolers, floors and walls of coolers, design and packing benches, garbage pails	cloth, mop, sponge, spray		2383 ppm
3573-69	Hotels, dorms, convenience stores, recreational centers, offices, motels	floors, walls, toilets, urinals, bathrooms, bathtubs, sinks, countertops, shower doors/curtains, toilet seats, shower stalls, tables, chairs, shelves, telephones, cabinets, desks, bed springs, door knobs, linen carts, hampers, exercise equipment, bidets, fountains, synthetic marble, vinyl, linoleum , sealed granite, glazed porcelain, microwave oven exteriors, marlite, plastic, outdoor furniture, laundry hampers	spray	potable rinse for children's toys and food contact surfaces	2383 ppm
1677-109	Commercial and institutional laundry mats	clothing	pour at final rinse or sour to washweel		0.000733 lb AI/lbs dry fabric
6718-24	industry and schools	bedframes, tables, sinks, walls, countertops, chairs, other hard nonporous surfaces	cloth, mop, spray		2383 ppm
48815-1	Schools, Institutional, and Industrial	fish aquariums, tanks, fish handling equipment, nets, seines, traps, filter boxes, pumps, air diffusers, shipping boxes, feeding equipment, floors,	immersion, brush, mop or cloth		2383 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
		countertops, raceways, garbage pails, other hard nonporous surfaces, holding tanks, lavatories.			
Food Handling/Storage Establishments premises and equipment					
1839-152 including food contact surfaces	Restaurants, food service establishments, food processing plants/facilities, beverage processing plants, Bars, Cafeterias, Convenience stores, supermarkets, Dairies, Egg Processing plants, Federally inspected meat and poultry plants , Food Handling areas, Food preparation areas, Food storage areas, Institutional kitchens, USDA inspected food processing facilities, breweries, fast food operations	floors, walls, countertops, appliances (microwaves, refrigerators, stove tops, freezers, coolers), chairs, tables, shelves, picnic tables, outdoor furniture, racks, carts, telephones, door knobs, storage areas, potato storage areas, food storage areas, garbage storage areas, cutting boards, tanks, exhaust fans, refrigerator bins, refrigerated storage/display equipment, coils and drain pans of air conditioning/refrigeration equipment, heat pumps, storage tanks, coolers, ice chests, garbage cans/pails	cloth, mop, spray, flood, immersion		40 CFR 180.940 (a) 200 ppm Public Eating Places, Dairy Processing Equipment, Food Processing Equipment and Utensils 40 CFR 180.940 (c) 400 ppm Food Processing Equipment and Utensils Disinfection 2383 ppm
1839-175	Restaurants	floors, walls, tables, shelves, garbage disposal areas, metal surfaces, stainless steel, glazed porcelain, glazed ceramic tile, shower stalls, bathtubs, cabinets, plastic surfaces	RTU spray		2383 ppm
10324-81	Dairies and Food Processing Facilities	floors, walls, metal surfaces, stainless steel, glazed porcelain, glazed ceramic tile, cabinets, plastic surfaces	fogging	2 Hour reentry interval Minimum of 4 air exchanges per hour	Need to talk to Tim on rate: 0.0065 lbs AI/gal to ft3

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
10324-134	bottling and beverage plants, breweries, tobacco, egg processing plants, meat/poultry processing plants, rendering plants, fishery/milk/citrus/wine/ice cream/ potato processing plants, restaurants	floors, walls, tables, shelves, garbage cans, garbage disposal areas, glazed porcelain, glazed ceramic tile, glass	mop, wipe, (cloth), spray		2383 ppm
10324-117 including food contact surfaces	bottling and beverage plants, breweries, tobacco, egg processing plants, meat/poultry processing plants, rendering plants, fishery/milk/citrus/wine/ice cream/ potato processing plants, restaurants	ice machines, water coolers, counters, tables, food processing equipment, food utensils, dairy equipment, dishes, silverware, eating utensils, glasses, sinks, counters, refrigerated/storage display equipment	spray, wipe, sponge, immersion		40 CFR 180.940 (a) 200 ppm Public Eating Places, Dairy Processing Equipment, Food Processing Equipment and Utensils 40 CFR 180.940 (c) 400 ppm Food Processing Equipment and Utensils Disinfection 2383 ppm
10324-117	bottling and beverage plants, breweries, tobacco, egg processing plants, meat/poultry processing plants, rendering plants, fishery/milk/citrus/wine/ice cream/ potato processing plants,	water softners and reverse osmosis units	pour		200 ppm
10324-117	bottling and beverage plants, breweries, tobacco, egg processing plants, meat/poultry processing plants, rendering plants, fishery/milk/citrus/wine/ice cream/ potato processing plants,	boots and shoes	immersion		2382 ppm
Clean/Deodorization					
1839-167	Water/Smoke restoration (institutional, industrial, hospital)	carpets, carpet cushion, sub floors, drywall, trim, farm lumber, tackless strip and paneling	Pour, brush, spray	Refer to Table 13 (Labeling Changes Summary Table) for appropriate label restriction	12,154 ppm
1839-167	Sewer backup/river flood cleanup, (clean water source)	carpets, carpet cushion, sub floors, drywall, trim, farm lumber, tackless strip and paneling	spray	Refer to Table 13 (Labeling Changes Summary Table) for appropriate label restriction	12, 154 ppm
1839-167	garbage storage areas, pet areas	garbage bins, cans floors, walls, tables, shelves, glazed	Spray, wipe, sponge, immersion		2383 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
		porcelain, glazed ceramic tile, glass			
71814-1	hospitals	Medical waste	pour		Poured into machine

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 #3003 (DDAC) covered by this RED. It contains generic data requirements that apply to DDAC 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.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
CHEMISTRY				
New Guideline Number	Old Guideline Number			
830.1550	61-1	Product Identity and Composition	All	44520301, 44520302
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	44520302, 44520301
830.1670	61-2B	Formation of Impurities	All	44520302, 44520301
830.1700	62-1	Preliminary Analysis	All	44520302, 44520301

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
830.1750	62-2	Certification of limits	All	44520302, 44520301
830.1800	62-3	Analytical Method	All	44520302, 44520301
830.6302	63-2	Color	All	44520303
830.6303	63-3	Physical State	All	44520303
830.6304	63-4	Odor	All	44520303
830.7050	None	UV/Visable Absorption	All	44520303

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
830.7200	63-5	Melting Point	All	44520303
830.7220	63-6	Boiling Point	All	44520303
830.7300	63-7	Density	All	44520303
830.7840 830.7860	63-8	Solubility	All	44520303
830.7950	63-9	Vapor Pressure	All	44520303
830.7370	63-10	Dissociation Constant	All	44520303

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
830.7550	63-11	Octanol/Water Partition Coefficient	All	44520303
830.7000	63-12	pH	All	44520303
830.6313	63-13	Stability	All	44520303
830.6314	63-14	Oxidizing/Reducing Action	All	44520303
830.6315	63-15	Flammability	All	44520303
830.6316	63-16	Explodability	All	44520303

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
830.6317	63-17	Storage Stability	All	44520303
830.7100	63-18	Viscosity	All	44520303
830.6319	63-19	Miscibility	All	44520303
830.6320	63-20	Corrosion characteristics	All	44520303
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	All	41785803, 258798

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
850.2200	71-2A	Avian Dietary Toxicity - Quail	Wood Preservation, Sapstain, Once Through Cooling Water	41785801, 258798
850.2200	71-2B	Avian Dietary Toxicity - Duck	Wood Preservation, Sapstain, Once Through Cooling Water	41785802, 258798
850.1075	72-1A	Fish Toxicity Bluegill	ALL	41578001, 038901
850.1075	72-1C	Fish Toxicity Rainbow Trout	ALL	038901, 40129801
850.1010	72-2A	Invertebrate Toxicity	ALL	41578002, 038901, 40129801, 40129802, 40129803
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	Wood Preservation, Sapstain, Once Through Cooling Water	43620001

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
850.1025 or 850.1055	72-3B	Estuarine/Marine Toxicity - Mollusk	Wood Preservation, Sapstain, Once Through Cooling Water	249002, 43260003
850.1035 or 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp	Wood Preservation, Sapstain, Once Through Cooling Water	249002, 41578004
850.1300	72-4A	Fish- Early Life Stage	Wood Preservation, Sapstain, Once Through Cooling Water	Data Gap
850.1400	72-4B	Aquatic Invertebrate Life Cycle	Wood Preservation, Sapstain, Once Through Cooling Water	Data Gap
850.1710 850.1730 850.1850	72-6	Aquatic organism bioaccumulation	Wood Preservation, Sapstain, Once Through Cooling Water	45834101
850.4400	123-2	Aquatic Plant Growth	Wood Preservation, Sapstain, Once Through Cooling Water	Data Gap

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
850.5400	123-2	Algal Toxicity	Wood Preservation, Sapstain, Once Through Cooling Water	48596402, Data Gap for remaining species
850.1950	Non-Guideline	Aquatic Field Monitoring	Wood Preservation, Sapstain, Once Through Cooling Water	Data Gap
850.4225	123-1	Non-Target plant phytotoxicity (seedling emergence test using rice)	Once Through Cooling Water & Wood Preservation	Data Gap
850.4250	123-1	Vegetative Vigor using rice	Once Through Cooling Water & Wood Preservation	Data Gap
850.3030	141-1	Honey Bee Toxicity Studies	Wood Preservation	Data Gap

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
	TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity-Rat	All	42296101, 41394494
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	00071158, 42053801
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	00145074
870.2400	81-4	Primary Eye Irritation-Rabbit	All	41394404, 42161602
870.2500	81-5	Primary Skin Irritation	All	42161601

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
870.2600	81-6	Dermal Sensitization	All	42161603, 46367601
870.3100	82-1A	90-Day Feeding - Rodent	All	40966302
870.3150	82-1B	90-Day Feeding - Non-rodent	Indirect Food	40262901
870.3200	82-2	21-Day Dermal - Rabbit/Rat	Domestic dwelling contents	40565301, 41105801, 45656601
870.3465	82-4	90-Day Inhalation Rat	All	Data Gap
870.3250	82-3	90-day Dermal- Rat	All	41305901

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	Swimming Pool, Wood Preservation	41965101
870.4100	83-1B	Chronic Feeding Toxicity – Non-Rodent	Swimming Pool, Wood Preservation	41970401
870.4200	83-2A	Carcinogenicity - Rat	Swimming Pool, Wood Preservation	41965101
870.4200	83-2B	Carcinogenicity - Mouse	Swimming Pool, Wood Preservation	41802301
870.3700	83-3B	Developmental Toxicity - Rabbit	Swimming Pool, Wood Preservation	41018701
870.3800	83-4	2-Generation Reproduction - Rat	Indirect Food	41804501

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity-Rat	Swimming Pool, Wood Preservation	41965101
870.5140	84-2A	Gene Mutation (Ames Test)	All	40282201, 44005801
870.5300	84-2B	Forward Gene Mutation	All	40895202
870.5375	84-4	In vitro chromosome aberration	All	41252601
870.5550	84-4	Unscheduled DNA synthesis	All	40895201
870.7485	85-1	General Metabolism	Indirect Food	41617101

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.1100	Special Studies	Wood Wipe Study		Find MRID
875.1100 875.1200	233, 236	Dermal Indoor /Outdoor Exposure	Handlers	41742601, 42587501
875.1300 875.1400	234, 236	Inhalation Indoor/Outdoor Exposure	Handlers	455021101, 45524304
875.2800	133-1	Descriptions of Human Activity (all uses)	All	Data Gap
	Non-Guideline	Fabric Leaching Study	Domestic dwelling contents	Data Gap

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
	ENVIRONMENTAL FATE			
835.2120	161-1	Hydrolysis	All	41175801
835.2240	161-2	Photodegradation - Water	Wood Preservation	41175802
835.2410	161-3	Photodegradation - Soil	Not Required	42480801
835.4100	162-1	Aerobic Soil Metabolism	Wood Preservation & Once Through Cooling Towers	42253801
835.4400	162-3	Anaerobic Aquatic Metabolism	Wood Preservation & Once Through Cooling Towers	42253801

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
835.4300	162-4	Aerobic Aquatic Metabolism	Wood Preservation & Once Through Cooling Towers	42253803
835.1240	163-1	Leaching/Adsorption/Desorption	Wood Preservation	41385301
None	165-4	Bioaccumulation in Fish	Wood Preservation	45834101
	AWPA E11-97	Leachability of Wood Preservative	Wood Preservation	45524305
	Special Studies	Biodegradability of DDAC	Not Required	46865701

Data Supporting Guideline Requirements for the Reregistration of DDAC

REQUIREMENT			USE PATTERN	CITATION(S)
	RESIDUE CHEMISTRY			
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg	Indirect Food	FDA, 2003. "Sanitizing Solutions: chemistry for food Additives petitions." Http://www.cfsan.fda.gov/-dms/opa-cg3a.html. Last accessed June 9, 2003
	Non-Guideline	Dietary-Residues in Food from Treating Countertops with DDAC (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Indirect Food	Data Gap

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained the April 18, 2006 preliminary risk assessment and the related documents. Sixty days later the first public comment period closed. 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 site: http://www/regulations.gov, docket ID # EPA-HQ-OPP-2006-0338

These documents include:

1. Risk Assessment on Didecyl Dimethyl Ammonium Chloride (DDAC), 7/31/06
2. Toxicology Disciplinary Chapter for the Re-Registration Eligibility Decision (RED) Risk Assessment on Didecyl Dimethyl Ammonium Chloride (DDAC), 8/10/06
3. DDAC Dietary Risk Assessment, 7/27/06
4. Ecological Hazard and Environmental Risk Assessment Chapter on Didecyl Dimethyl Ammonium Chloride (DDAC)-Antimicrobial Uses, 8/2/06
5. PDM4 Modeling of Didecyl Dimethyl Ammonium Chloride (DDAC) in Once-Through Industrial Water Systems, 8/2/06
6. Ecological Risk Assessment in Support of the Antimicrobials Division's Reregistration of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC)-Agricultural Uses, 2/3/06
7. Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC), 1/23/06
8. Environmental Fate Assessment of Didecyl Dimethyl Ammonium Chloride (DDAC) for the Reregistration Eligibility Decision (RED) Document, 7/31/06
9. Incident Reports Associated with Quaternary Ammonium Compounds (Quats), 2/15/06
10. Didecyl Dimethyl Ammonium Chloride (DDAC) Occupational and Residential Exposure Assessment, 8/1/06
11. Product Chemistry Science Chapter for Didecyl Dimethyl Ammonium Chloride (DDAC), 1/11/06
12. Didecyl Dimethyl Ammonium Chloride (DDAC)- Report of the Antimicrobials Division Toxicity Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee (HIARC), 8/10/06

Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE INTERIM REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or MRID number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID#	CITATIONS
40129801	Henck, J.H. (1986) Avian Eight-day dietary toxicity test in bobwhite quail. TRL Study No. 014-064. Toxicity Research Laboratories, Ltd.
40129802	Surprenant, D.C. (1986) Acute toxicity of Maquat MQ 416M: Report No. BW-86-12-2263; Springborn Bionomics, Inc.
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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 DDAC 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. 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 H. 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.