United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510C)

EPA739-R-06-009
August 2006

Reregistration Eligibility Decision for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)

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 Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for ADBAC 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 ADBAC 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 ADBAC are available to the public in EPA's Pesticide Docket **EPA-HQ-OPP-2006-0339** at: http://www.regulations.gov.

The ADBAC 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 USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the ADBAC risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to ADBAC 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

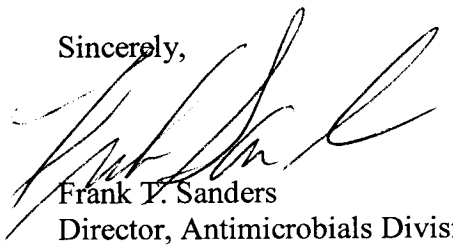
responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

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

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by ADBAC. 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, Jacqueline Campbell-McFarlane, at (703) 308-6416. 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
ADBAC
CASE 0350

Approved By:

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

Attachment

Table of Contents

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Health Effects Risk Assessment
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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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

ABSTRACT

The Environmental Protection Agency (EPA or The Agency) has completed the human health and environmental risk assessments for alkyl dimethyl benzyl ammonium chloride, ADBAC, 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 ADBAC that pose risks of concern. As a result of this review, EPA has determined that ADBAC-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 Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC).

ADBAC is an antimicrobial used in agricultural, food handling, commercial/ institutional/ industrial, residential and public access, and medical settings. Examples of registered uses for ADBAC in these settings include application to indoor and outdoor hard surfaces (e.g., walls, floors, tables, toilets, and fixtures), eating utensils, laundry, carpets, agricultural tools and vehicles, egg shells, hands and gloves, shoes, milking equipment, and udders, humidifiers, RV tanks, medical instruments, human remains, ultrasonic tanks, reverse osmosis units, and water storage tanks. There are also ADBAC end-use products that are used in residential and commercial swimming pools, in aquatic areas such as decorative ponds, decorative fountains, and agricultural watering lines, and in industrial process and water systems such as once-through and re-circulating cooling water systems, cooling towers, evaporative condensers, pasteurizers, drilling mud, packer fluids, oil well injection and wastewater systems, and in pulp and paper products, water, and chemicals. Additionally, ADBAC end-use products are used for wood preservation.

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

Risks summarized in this document are those that result only from the use of the active ingredients ADBAC. 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 ADBAC and any other substances. ADBAC does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that ADBAC 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 ADBAC. In an effort to simplify the RED, the information presented herein is summarized from more detailed information that can be found in the technical supporting documents for ADBAC referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of ADBAC, and its regulatory history. Section III, Summary of ADBAC 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 first product containing ADBAC was registered in 1947. The oldest active product containing an ADBAC was registered in 1956 under chemical code 069105. These pesticides are classified as List A chemicals for which a registration standard was issued by EPA in 1985. When the list of active ingredients undergoing reregistration was published in 1989, 43 additional active ingredients were added to this case. Since issuance of the list, one active ingredient has been placed into a separate chemical case, and 18 active ingredients have been canceled thus resulting in 24 active ingredients in this case.

The ADBAC Quat Steering Committee/Joint Venture comprised of Lonza, Inc., Mason Chemical Company, and Stepan Company was formed to support the reregistgration activities of this chemical case. Along with the Quat Steering Committee/Joint Venture, Albemarle Corporation produces chemicals within the ADBAC case. These chemicals are formulated into countless products that are used in residential, commercial, industrial, institutional, and agricultural settings.

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, hydroxyethylbenzyl, naphylmethyl, dodecyhlbenzhyl, and alkyl benzyl)

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

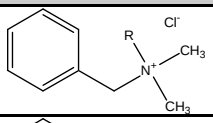
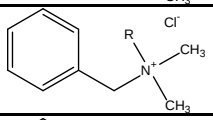
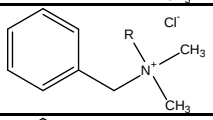
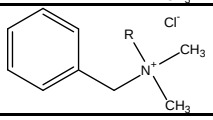
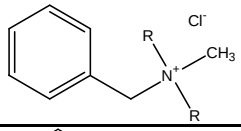
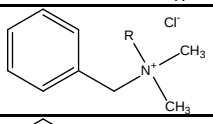
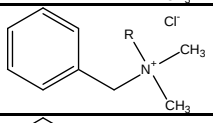
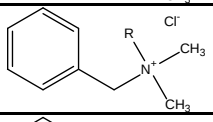
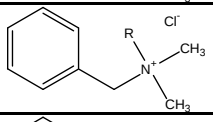
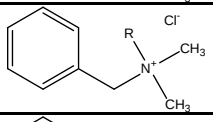
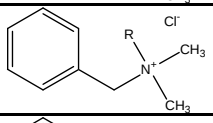
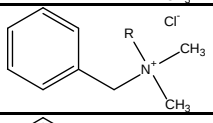
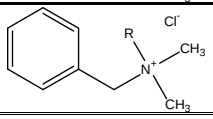
Group IV: Quats with unusual substitutes (charged heterocyclic compounds).

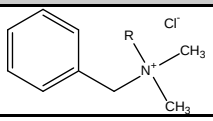
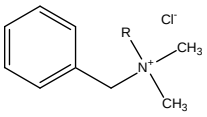
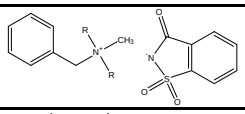
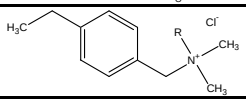
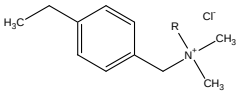
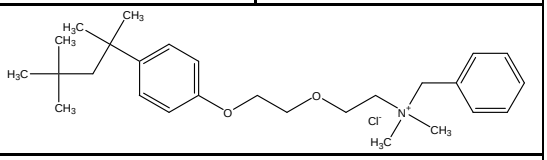
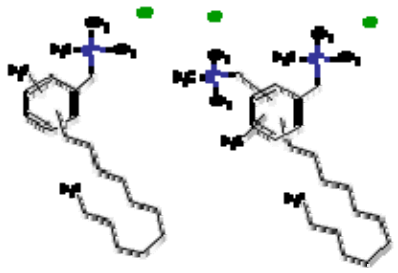
The Agency agreed for data development purposes that the pesticide, alkyl (50%C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride (PC code 069105), would serve as the model compound.

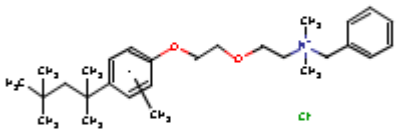
B. Chemical Identification

The alkyl dimethyl benzyl ammonium chloride (ADBAC) chemical case is comprised of 24 compounds that are structurally similar quaternary ammonium compounds (quats) that are characterized by having a positively charged nitrogen covalently bonded to three alkyl group substituents and a benzyl substituent. In finished form, these quats are salts with the positively charged nitrogen (cation) balanced by a negatively charged molecule (anion). The most common anion for the quats in this cluster is chloride. However, other anions, such as saccharine and bromide are also used. Table 1 below provides the common chemical name, active ingredient code, CAS number, and chemical structure.

Table 1: Active Ingredients in Group II Cluster

Pesticide Code	CAS RN	Name	Structure	Chain Lengths
69104	53516-76-0	ADBAC		R = C12 (5%) C14 (60%) C16 (30%) C 18 (5%)
69105	68424-85-1	ADBAC		R = C12 (40%) C14 (50%) C16 (10%)
69106	8001-54-5	ADBAC		R = C12 (50%) C14 (30%) C16 (17%) C18 (3%)
69107	139-08-2	ADBAC		R = C12 (1%) C14 (98%) C16 (1%)
69119	73049-75-9	Dialkyl Methyl BAC		R = C12 (5%) C14 (60%) C16 (30%) C18 (5%)
69137	68424-85-1	ADBAC		R = C12 (25%) C14 (60%) C16 (15%)
69140	61789-71-7	ADBAC		R = C8-10 (2.5%) C14 (61%) C16 (23%) C18 (2.5%)
69141	68424-85-1	ADBAC		R = C12 (14%) C14 (58%) C16 (28%)
69157	68424-85-1	ADBAC		R = C12 (65%) C14 (25%) C16 (10%)
69175	68391-01-5	ADBAC		R = C12 (67%) C14 (25%) C16 (7%) C18 (1%)
69189	68391-01-5	ADBAC		R = C12 (61%) C14 (23%) C16 (11%) C18 (5%)
69184	68424-85-1	ADBAC		R = C12 (3%) C14 (95%) C16 (2%)
69192	85409-22-9	ADBAC		R = C12 (70%) C14 (30%)

Pesticide Code	CAS RN	Name	Structure	Chain Lengths
69194	68424-85-1	ADBAC		R = C12 (5%) C14 (90%) C16 (5%)
128928	63449-41-2	ADBAC		R = C8 – Not specified C10 – Not specified C12 (67%) C14 (25%) C16 (7%) C18 – Not specified
69171	68989-01-5	ADBA Saccharinate		R = C12 (40%) C14 (50%) C16 (10%)
69154	85409-23-0	ADEBAC		R = C12 (68%) C14 (32%)
69111	8045-21-4	ADEBAC		R = C12 (50%) C14 (30%) C16 (17%) C18 (3%)
069112	53516-75-9	n-Alkyl dimethyl 1-naphtylmethyl ammonium chloride		R=C12 (98%) C14 (2%)
069125	1330-85-4	Dodecyl benzyl trimethyl ammonium chloride		
169159	N/A	n-alkyl dimethyl dimethyl ammonium chloride		R= C12 (68%) C14 (32%)
69122	121-54-0	Diisobutylphenoxy-ethyoxyethyl dimethyl benzyl ammonium chloride [Benzethonium Chloride]		
69129	1399-80-0	Methyl dodecyl benzyl tri methyl ammonium chloride - 80% Methyl dodecyl xylene bis tri methyl ammonium chloride – 20%		

Pesticide Code	CAS RN	Name	Structure	Chain Lengths
69134	25155-18-4	Diisobutyl cresoxyethoxyethyl dimethyl benzyl ammonium chloride monohydrate		

Common name: ADBAC

Chemical name: n-Alkyl dimethyl benzyl ammonium chloride

Chemical family: Quaternary amines

Case number: 0350

Basic manufacturers: Albemarle Corporation
Lonza, Inc.
Mason Chemicals Company
Stepan Company

Chemical properties: ADBAC is a clear yellow to straw colored liquid with an amine odor that is soluble in water and alcohols. ADBAC has a melting point of 241.02^{o}C, vapor pressure of 3.53x 10^{-12} mm HG, and a density of 0.9429 g/cm^{2} at 25^{o}C.

C. Use Profile

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

Type of Pesticide: Algicide, bacteriocide, bacteriostat, wood preservative, fungicide, fungistat, virucide, tuberculocide, insecticide, microbiocide, microbiostat, molluscide, deodorant, disinfectant, and sanitizer

Summary of Uses:

Use Category	Use Site
Industrial processes and water systems	Industrial re-circulating water systems, pulp and paper facilities, cooling water towers, disposal water, oil field operations, and oilfield water flood or saltwater disposal.
Swimming Pools	Swimming Pools, Outside Spas, Whirlpools, and hot tubs
Aquatic Areas	Golf courses, recreational parks, amusement parks, universities, cemeteries, and greenhouse/nurseries
Wood Treatment	Pressure Treatment, Double vacuum, and dip/spray surface treatment
Agricultural Premise and Equipment	Hatcheries, swine/poultry/turkey farms, animal housing facilities, farrowing barns, dressing plants, mushroom farms, citrus farm, florist/flower shops, and greenhouses/nurseries
Residential and Public Access Premises	Homes, mobile homes, cars, boats, playgrounds, boats, public facilities, campgrounds, trailers, campers, trailers, and trucks
Medical Premises and Equipment	Hospitals, health care facilities, medical/ dental offices, nursing homes, autopsy rooms, funeral homes, mortuaries, medical research facilities, acute care institutions, alternative care institutions, newborn nurseries, day-care facilities, and sick rooms
Commercial, Institutional, and Industrial Premise and Equipment	Athletic/recreational facilities, exercise facilities, health clubs, dressing/locker rooms, schools, colleges, universities, transportation terminals, libraries, motels, hotels, barber and beauty salons, convenience stores, offices, commercial/ institutional laundry mats, emergency vehicles, factories, commercial florist, and correctional facilities
Food Handling/Storage Establishments Premises and Equipment	Restaurants, food service establishments, food processing/storage/handling plants and facilities, beverage processing plants, supermarkets, breweries, bars, cafeterias, fishery/citrus/wine/ice cream/ potato processing plants, egg processing plants, dairies, institutional kitchens, fast food operations, rendering plants, school lunchrooms, and packing plants

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

Formulation Types: Formulation intermediate, aerosol, soluble concentrate/tablet, impregnated wipes, ready-to-use solution, wettable powder, pressurized liquid, and water-soluble packaging.

Method and Rates of Application:

Methods: ADBAC formulations are added directly to water in swimming pools, decorative ponds/fountains, spas, cooling water towers, oil field drilling muds and packing fluids, small process water systems, humidifiers, and cut flower applications. ADBAC formulations are diluted in water to treat hard nonporous surfaces in institutional, commercial, industrial, and residential settings by fogging, immersion, wiping, mopping, aerosol/trigger spray, and low pressure and high-pressure spray. Some impregnated wipes are dampened with water prior to use while others are pre-moistened. For the treatment of wood, ADBAC is applied by a blender/spray system, diptank, spray box, or pressure treatment.

Application Rates: For details about specific use sites for ADBAC, refer to Appendix A. The following rates are a representation of the maximum rate documented in the label table by use category.

- Use 14 oz of 50% end-use product per 10,000 of water to produce a 5 ppm active solution for treatment of swimming pools and spas.
- Use 1 oz of 20% end-use product per gallon of water to produce a 781.5 ppm active solution for treatment of aquatic areas such as decorative ponds, fountains, and water displays.
- Use 6 pounds of 50% end use product diluted to 3% active ingredient solution per cubic foot of wood for dip, brush, spray, and pressure treatment for wood preservation.
- Use 9 oz of 3.2% end use product per gallon of water to achieve a 2250 ppm active solution for treatment of agricultural premises and equipment such as animal housing facilities, animal life science laboratories, farms, ornamental nurseries, and animal transportation vehicles.
- Use 115 oz of 9.0% end use product per 2.5 gallons of water to achieve 44,000 ppm active solution for treatment in egg processing plants and hatcheries by fogging.
- Use 53.2 grams of 40% end-use product per 2 gallons of water to achieve 2800 ppm active solution for treatment in ornamental nurseries on plants and trees.
- Use 0.5 oz of 20% end-use product per gallon of water every 40 sq. feet to achieve 781 ppm active solution for treatment of lawns, turf, and golf courses greens and tees.
- Use 1 oz of 20% end-use product to one gallon of water to achieve 1532 ppm active solution or use Ready-to-Use formulation for treatment of medical premises and equipment such as hospitals, day-care centers, mortuaries, and EMS facilities.
- Use 9 oz of 3.2% end-use product to one gallon of water to achieve 2250 ppm active solution or use Ready-to-Use formulation for treatment of commercial and industrial premises and equipment such

as barber/beauty salons, athletic facilities, libraries, manufacturing facilities, and hotels. Also, use 155 oz of 9.0% end-use product per 2.5 gallons of water to achieve 44,000 ppm active solution for treatment of commercial and industrial premises by fogging.

- Use 2 oz of 10% end-use product per gallon of water to achieve 3000 ppm active solution or use Ready-to-Use formulation for treatment of residential and public access premises such as homes, campgrounds, and recreational facilities.
- Use 1 oz of 20% end-use product per gallon of water to achieve a 400 ppm active solution for food contact sanitizing treatment in food handling/storage establishments such as restaurants, food storage areas, meat, poultry, and vegetable processing facilities.
- Use 6 oz of 4.5% end-use product per gallon of water to achieve a 2100 ppm active solution for disinfection in food handling/storage establishments such as restaurants, food storages areas, meat, poultry, and vegetable processing facilities.
- Use 24 oz of 9.0% end-use product per gallon of water to achieve 16,875 ppm active solution for treatment of carpets in medical, commercial, and residential settings.
- Use 8 oz of 20% end-use product per 100 pounds of dry laundry to achieve 1154 ppm active solution from treatment of clothing/laundry in medical and commercial settings.

Use Classification: General use.

III. Summary of ADBAC 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 ADBAC. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, http:/www.regulations.gov. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2006-0339. 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.

A. Human Health Risk Assessment

1. Toxicity of ADBAC

The Agency's use of human studies in the ADBAC 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 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 ADBAC can be found in the "Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document on Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)," dated February 27, 2006; "Draft Preliminary Risk Assessment for Alkyl Dimethyl Ammonium Chloride (ADBAC)," dated April 20, 2006; and "ADBAC - 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 at http://www.regulations.gov.

The Agency has reviewed all toxicity studies submitted for ADBAC and has determined that the toxicological database is sufficient for reregistration. The acute toxicology data shows that ADBAC is toxicity category II by the oral and inhalation routes and toxicity category III via the dermal route. ADBAC 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 acute toxicology profile are presented below

Table 1. Summary of Acute Toxicity Data for ADBAC

Guideline Number	Test Substance	MRID	Results	Toxicity Category
870.1100	Acute oral, rat BQ451-8 Biocide (Purity 82.26%)	45109204	LD50 =304.5 mg/kg (combined) LD50 =510.9 mg/kg (males) LD50 =280.8 mg/kg (females)	II

Guideline Number	Test Substance	MRID	Results	Toxicity Category
870.1200	Acute dermal, rat BQ451-8 Biocide (Purity 82.26%)	45109202	LD50 =930 mg/kg (combined) LD50 =1100 mg/kg (males) LD50 =704 mg/kg (females)	III
870.1300	Acute inhalation, rat (Purity 82.26%)	44885201	0.054 < LC50 < 0.51 mg/L	II
870.2400	Primary Eye Irritation	Waived	N/A	I
870.2500	Primary Dermal Irritation, , rabbit BQ451-8 Biocide (Purity 82.26%)	45109201	Corrosive	I
870.2600	Dermal sensitization, guinea pigs BQ451-8 Biocide (Purity 82.26%)	45109201	Not a dermal sensitizer	N/A

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

Table 2. Summary of Toxicological Endpoints for ADBAC (Dietary)

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE or UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population; females 13+)	An acute dietary endpoint was not identified in the data base.		
Chronic Dietary	NOAEL =44 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Chronic toxicity/carcinogenicity –rat MRID 41947501 LOAEL = 88 mg/kg/day, based on decreased body weight and weight gain
		Chronic RfD = 0.44 mg/kg/day	

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.

Dietary

Acute dietary risks were not assessed because an endpoint appropriate for acute dietary assessment was not identified in the available ADBAC database.

For ADBAC, a chronic toxicity/carcinogenicity study was conducted in rats. This study established the RfD of 0.44 mg/kg/day based on decreased body weight and weight gain in male rats at 88 mg/kg/day. An uncertainty factor of 100 (10X for interspecies extrapolation, 10X for intraspecies variation) was applied to the NOAEL to obtain the chronic RfD.

Incidental Oral

The short- and intermediate-term incidental oral NOAEL is 10 mg/kg/day from a rat developmental toxicity study that noted decreased body weight and decreased food consumption at 30 mg/kg/day.

Short-term Dermal

The short-term dermal NOAEL is 20 mg/kg/day based on denuded non-vascularized epidermal layer from a 21-day dermal toxicity study on a 4% active ingredient formulated product. The uncertainty factor or "target" MOE for ADBAC 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.

Intermediate-Term Dermal

The intermediate-term dermal NOAEL is 20 mg/kg/day since it was the highest dose tested before irritation became significant at day 43. The uncertainty factor or "target" MOE for ADBAC dermal exposures are 10 for occupational and residential scenarios. The target MOE was chosen because the established endpoint is for dermal irritation, not a systemic toxic effect. The Agency has reevaluated this value 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,- Intermediate,- and Long-term Inhalation

The short-, intermediate-, and long-term inhalation NOAEL is 3 mg/kg/day based on the hyperactivity and labored breathing at 9 mg/kg/day in an oral developmental study in rabbits. 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 target MOE is 100 for occupational and residential scenarios, (10x interspecies extrapolation and 10x interspecies

variability). However, if the resulting MOE is not at least 100, the Agency can request a repeat dose inhalation study of at least 28 days in duration.

Carcinogenicity Classification

The database for carcinogencity is complete, and ADBAC is not carcinogenic based on studies in rats and mice.

Mutagenicity Potential

The data base for mutagenicity is considered adequate and indicates that ADBAC is not mutagenic or genotoxic.

Endocrine Disruption Potential

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 such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

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

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for ADBAC 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 riks 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 ADBAC. The Agency

determined that no special FQPA Safety Factor was needed since there were no residual uncertainities 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 risks for ADBAC were not assessed because an endpoint appropriate for acute dietary assessment was not for ADBAC.

b. Chronic PAD

Chronic dietary risk for ADBAC 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 (0.44 mg/kg/day) modified by the uncertainty factor. The cPAD was derived from a chronic toxicity/ carcinogencity study in the rat, in which the NOAEL (44 mg/kg/day) and the LOAEL (88 mg/kg/day) were determined based on decreased body weight and weight gain. The ADBAC cPAD is 0.44 mg/kg/day based on a reference dose of 0.44 mg/kg/day and a FQPA safety factor of 1X.

4. Dietary Exposure Assumptions

The antimicrobial use of ADBAC on food contact surfaces, agricultural premises, poultry premises including hatcheries and application to food-grade eggs may result in pesticide residues in human food. Residues from the use of ADBAC 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 ADBAC as a disinfectant after rinsing with potable water. In the absence of transfer residue data for these ADBAC disinfectant uses, the Agency assumed that rinsing with potable water cannot remove all residues deposited on the treated surfaces. Therefore, residues from the treated and rinsed surfaces may migrate to food coming into contact with these surfaces and then be ingested by humans.

In the absence of data for residues of ADBAC on treated food contact surfaces, the Agency estimated residue levels that may occur in food from the application rates on food contact surfaces such as utensils and countertops. In addition, the food packaging and beverage bottling uses have also been evaluated.

ADBAC products may be applied to the shells of food grade-eggs in egg processing plants. Although it is possible that some sanitizer/disinfectant chemicals may penetrate egg

shells, at this time, the Agency believes that the amount of the chemical transferred into eggs is likely to be minimal because the eggs must be subjected to a potable water rinse if they are to be immediately broken for use in the manufacturing of egg products.

There is no evidence that there will be residues of ADBAC 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 because the label states that the product is not be applied to the mushroom crop, compost or casing and treated surfaces are to be rinsed with potable water before contact with the crop, compost, or casing. Since these exposures are not likely to pose risks of concern, and the sanitizing uses represent a "worse-case" scenario, these uses were not assessed.

The Agency assessed the chronic dietary exposure due to ADBAC 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). The assessment considered: application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on FDA guidelines (FDA, 2003). However, in assessing dietary exposures from ADBAC in food packaging and beverage bottling, 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 EDI calculations presented in this assessment assumes that food can contact 2,000cm^2 or 4,000 cm^2 (50% and 100% of the FDA worse 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 use of a 100% transfer rate was used for all indirect food contact surfaces except for food packaging and bottling surfaces. The 10% migration rate is based on Agency Residential Standard Operation Procedures. These daily estimates were conservatively used to assess chronic dietary risks (i.e., percent chronic population adjusted dose or %cPAD).

5. Dietary Risk Assessment

A summary of the chronic risk estimates are shown in Table 4a and b. Based on a review of product labels containing ADBAC, food handling establishments and food processing facilities, have been identified as having the potential to cause indirect dietary exposure due to indirect food contact on the following surfaces:

1. Utensils
2. Countertops
3. Food bottling/Packaging

a. Dietary Risk from Food

A dietary risk assessment was conducted for three of the five direct and indirect food contact surfaces listed above; as explained previously exposures from poultry hatcheries and mushroom houses were not assessed. Acute dietary risks were not assessed because an acute

toxicity value was not identified. However, the chronic dietary assessment concluded that for all included uses, the chronic risk estimates are below the Agency's level of concern for adults and the most highly exposed population subgroup, children (<4% of the cPAD). Any potential additional exposure as the result of the egg and mushroom house uses of ADBAC would not be expected to contribute significantly to overall dietary exposure and would not impact the %cPAD in a significant way.

Table 4a: Calculated EDIs and cPAD for Utensils and Countertops (The Aggregate represents the total chronic population adjusted dose (cPAD) for both surfaces)

Exposure Group	Utensils			Countertops			Aggregate		
	EDI (mg/day)	DDD (mg/kg/d)	% cPAD[a]	EDI (mg/day)	DDD (mg/kg/d)	% cPAD[a]	EDI (mg/day)	DDD (mg/kg/d)	% cPAD[a]
Adult males	0.0815	0.00116	0.265	0.0815	0.00243	0.265	0.252	0.00359	0.530
Adult females	0.0815	0.00136	0.309	0.0815	0.00284	0.309	0.252	0.00419	0.680
Children	0.0815	0.00543	1.23	0.170	0.0113	1.23	0.252	0.0168	2.46

a % PAD = exposure (DDD) /(cPAD) x 100.

EDI is the estimated daily intake (mg/day).

DDD is the dietary daily dose (mg/kg/day).

For food and beverage packaging/bottling, EDI values were calculated using an approach similar to that used for treated food contact surfaces and utensils. The maximum application rate for ADBAC for bottling/packing of beverages and food is 0.0103 lbs a.i. per gallon of treatment solution. 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). None of the calculated % cPad values exceeded 100% are not of concern. The results of the EDI and %cPAD are presented in Table 4b.

Table 4b. Calculated EDIs and cPAD for Representative Dairy and Beverage Consumption

Food Type	Exposure Group	EDI (mg/day)	DDD (mg/kg/d)	% cPAD
Milk	Adult Male	3.8×10^{-3}	5.37×10^{-5}	1.2×10^{-2}
	Adult Female		3.86×10^{-4}	1.4×10^{-2}
	Child[a]	2.4×10^{-3}	1.66×10^{-4}	3.6×10^{-2}
Egg product	Adult Male	2.8×10^{-5}	4.06×10^{-7}	9.1×10^{-5}
	Adult Female		4.69×10^{-7}	1.1×10^{-4}
	Child [a]	1.58×10^{-5}	1.20×10^{-6}	2.7×10^{-4}
Beverages, non-alcoholic	Adult Male	3.2×10^{-4}	4.57×10^{-6}	1.0×10^{-3}
	Adult Female		1.96×10^{-6}	1.2×10^{-3}
	Child[a]	2.0×10^{-4}	1.37×10^{-5}	3.1×10^{-3}
Beverages, alcoholic, beer	Adult Male	2.4×10^{-5}	3.47×10^{-6}	7.9×10^{-4}
	Adult Female		4.04×10^{-6}	9.0×10^{-4}

b. Dietary Risk from Drinking Water

As an outdoor pesticide, ADBAC is applied to nursery ornamentals and turf, and is used for mosquito control in ponds and puddles and as an algaecide in decorative pools. Since the uses are ornamental and periodic in nature, disconnected from the larger watershed, the Agency believes exposures to drinking water sources from these uses are not expected to be significant. For the drinking water assessment, only the turf and nursery uses for ADBAC were considered. Foliar spray, drench and "dribble" applications are allowed.

The Tier 1 surface water and groundwater model was used to assess applications to ornamental plants, this use represents the highest application rate of all labeled uses, of 302 lbs. a.i/Acre, and a maximum of 3 applications per year. Since the tier I models are not dependent on "crop" type, the Estimated Drinking Water Concentrations (EDWCs) determined for the nursery ornamental use are also protective of all other uses with lower application rates. The EDWCs for the human health risk assessment are in Table 5.3 and are based on the nursery ornamental use pattern. There were no major degradates of ADBAC in the laboratory studies (EFED Memo by Marietta Echeverria to Jacqueline Campbell-McFarlane: Tier I Drinking Water Assessment for alkyl*dimehtyl benzyl ammonium chloride (50%C14, 40%C12, 10%C10) (ADBAC) and Didecyl dimethyl ammonium chloride, (DDAC), dated 2006).

An acute oral toxicological endpoint was not established for ADBAC. Therefore, only the chronic drinking water exposure is calculated. The adult chronic drinking water dose is 0.009 mg/kg/day (i.e., average EDWC 331 ug/L x 2 L/day consumption x 1/70 kg BW). The chronic drinking water dose for children is 0.022 mg/kg/day (i.e., average EDWC 331 ug/L x 1 L/day consumption x 1/15 kg BW). There are no drinking water concerns with ADBAC as the concentrations are much lower than level of concern.

Table 5.3. Tier I Estimated Drinking Water Concentrations (EDWCs) Based on Aerial Application of ADBAC on Nursery Ornamentals		
Drinking Water Source (Model)	Use rate (lbs ai/A/year)	EDWC (ppb)
Surface water (FIRST)	906	
Acute (peak)		13,129
- Chronic (annual average)		331
Groundwater (SCIGROW)	906	5.4

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.

6. Residential Risk Assessment

The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Exposure may occur during and after application as a hard surface disinfectant or non-food contact sanitizer (e.g., walls, floors, tables, fixtures), to textiles (e.g. clothing), 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

A MOE of 100 for inhalation exposure and oral exposures and a 10 for dermal exposure are considered protective. The MOE of 100 is based on a 10x interspecies and 10x intraspecies variability while the MOE of 10 is based on a 3x interspecies and 3x intraspecies variability. The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential risks for ADBAC are listed in Table 6a.

Table 6a. Toxicological Endpoints Selected for Residential and Occupational Toxicological Risks for ADBAC

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE or UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Incidental Oral (short-term)	NOAEL = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – Rat, MRID 42351501 LOAEL = 100 mg/kg/day, based on decreased body weight and food consumption

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE or UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Incidental Oral (intermediate-term)	NOAEL = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – Rat, MRID 42351501 LOAEL = 100 mg/kg/day, based on decreased body weight and food consumption
Short-Term Dermal-	NOAEL= 20 mg ai/kg/day (333 µg/cm^2)	FQPA SF = 1 UF = 10 (3x inter-species extrapolation, 3x intra-species variation)	21-day dermal toxicity- guinea pigs MRID 41105801 LOAEL = 1000 mg/kg/day, based on denuded non-vascularized epidermal layer
Intermediate-Term Dermal	NOAEL=20 mg ai/kg/day (80 ug/cm^2)	UF = 10 (3x inter-species extrapolation, 3x intra-species variation)	90-day dermal toxicity in rats MRID 41499601 20 mg/kg/day is the highest dose tested before irritation became significant
Long-Term Dermal (TGAI)	No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical grade that could be tested without irritation effects.		
Inhalationa (Any time point)	NOAEL= 3 mg/kg/day MOE = 100[c]	UF = 100 (10x inter-species extrapolation, 10x intra-species variation) Note: an additional 10x is used for route extrapolation to determine if a confirmatory study is needed	Developmental Toxicity – rabbit, MRID 42392801 LOAEL = 9 mg/kg/day, based on clinical signs of toxicity in maternal rabbits

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, NA = Not Applicable.
aAn additional uncertainty factor of 10x is applied for use of an oral endpoint for rout-to-route extrapolation to determine if confirmatory inhalation toxicity study is warranted.
b Dermal endpoint = (20 mg/kg guinea pig x 0.4 kg guinea pig x 1000 ug/mg) / 25.8µg/cm^2 area of guinea pig dosed = 333 µg/cm^2 .
c TGAI-based dermal endpoint = (20 mg/kg rat x 0.2 kg rat x 1000 ug/mg) / 100µg/cm^2 area of rat dosed = 40 µg/cm^2 .

b. Residential Handlers

i. Exposure Scenarios, Data and Assumptions

For antimicrobial uses, residential exposure may occur during application of ADBAC as a hard surface disinfectant or sanitizer (e.g. walls, floors, tables, fixtures), to textiles, musical instrument mouthpieces, carpets, swimming pools, and humidifiers. In addition to the traditional antimicrobial uses of ADBAC described above, it may also be used outdoors to treat ornamental plants, lawns, and puddles/ponds/swimming pools. For this assessment, homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The following exposure scenarios were assessed for ADBAC:

- Indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays)
- Air deodorizers
- Carpets
- Swimming Pools (e.g., liquid pour)
- RV holding tanks (e.g., liquid pour)
- Textiles (e.g. clothing, treated during washing);
- Musical instrument mouthpieces; and
- Humidifiers
- Ornamental Plants
- Lawns

The antimicrobial residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data, the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (USEPA, 1999), Outdoor Residential Exposure Task Force data (ORETF).

The quantities handled/treated for the handler scenarios were estimated as indicated below: For additional information, please review the Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment (Antimicrobial Uses) dated July 27, 2006.

- 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 ***aerosol sprays***, it is assumed that one can is used. The net weight of the can was not provided on the label; therefore, it was assumed that the can contained 16-oz of product.
- 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 ***RV holding tank*** scenario, it was assumed that one tank would be treated. The product label states a maximum application rate of 4 oz (0.031 gallons) product per tank.
- For mixer/loader/applicators scenarios:

For agricultural exposures, residential exposures may occur during the application of ADBAC to ornamental plants, shrubs, trees as well as seedlings, seeds, and cuttings, residential/commercial turf, golf courses, and fountains/water displays, sewage treatment systems, standing water for mosquito control. As with the antimicrobial use, homeowners are assumed to complete elements of an application (mix/load/apply) without the use of personal protective equipment.

The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios. For additional information, please review the Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment (Agricultural Uses) dated August 1, 2006

Mixer/Loader/Applicators:

(1) Liquid Formulations: Low Pressure Handwand (PHED data for dermal and ORETF data for inhalation)
(2) Dry Flowable Formulations: Low Pressure Handwand (using liquid concentrate PHED data for dermal and liquid concentrate ORETF data for inhalation)
(3) Liquid Concentrates: Hose-End Sprayer (PHED data for dermal and ORETF data for inhalation)
(4) Dry Flowable Formulations: Hose-End Sprayer (no data)
(5) Ready-to-Use Formulations: Hose-End Sprayer (no data)
(6) Liquid Concentrates: Watering Can (using PHED hose-end sprayer data for dermal and ORETF hose-end data for inhalation)
(7) Ready to Use Formulations via Trigger-Pump Sprayer (PHED data for aerosol can for dermal and ORETF data for inhalation), and
(8) Dip or Soak Applications (no data)

Since no toxicological endpoint of concern was identified for dermal systemic adverse effects, both the handler and the post-application dermal risks were assessed using the toxicological endpoint for dermal irritation. The duration of exposure for homeowner handler exposures is believed to be the short-term duration (1 to 30 days). The short term duration was chosen because the handler and post-application scenarios are assumed to be episodic, not a daily occurrence.

ii. Risk Assessment

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

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A summary of the residential handler inhalation risks are presented in Table 6b. The calculated inhalation MOEs for all scenarios are above the target MOE of 100, and not of concern.

Table 6b Short-Term Residential Handler Inhalation Exposures and MOEs

Exposure Scenario Application Method	Application Method	Application Rate[a]	Quantity Handled/ Treated per day[b]	MOE [c] (Target MOE = 100)
Application to indoor hard surfaces	Mopping	0.025 lb ai/gal	1 gallon	3,000
	Wiping	0.025 lb ai/gal	0.13 gallon	820

Exposure Scenario Application Method	Application Method	Application Rate[a]	Quantity Handled/ Treated per day[b]	MOE [c] (Target MOE = 100)
	Trigger Spray	0.025 lb ai/gal	0.13 gallon	23,000
Air deodorization	Aerosol Spray	0.2% ai by weight	1 can (1 lb)	38,000
Application to Carpets	Low Pressure Spray	0.014 lb ai/gal	2 gallons	9,200
Application to Swimming Pools	Liquid Pour	0.000052 lb ai/gal	20,000 gallons	50,000
Application to RV holding tanks	Liquid Pour	0.834 lb ai/gal	0.031 gal (1 tank at 4 oz product/tank)	3,700

a Application rates are the maximum application rates determined from EPA registered labels for ADBAC.
b Amount handled per day values are estimates or label instructions.
c MOE = NOAEL / Absorbed Daily Dose. [Where short-term NOAEL = 3 mg/kg/day for inhalation]. Target MOE = 100.

A summary of the residential handler dermal risks are presented in Table 6c. The dermal MOEs for all formulations assessed are above the target MOE of 10, and therefore, are not of concern.

Table 6c: Short-Term Residential Handler Dermal Risks

Exposure Scenario	Application Method	Application Rate[a] (lb ai/gal)	Quantity Handled/ Treated per day[b]	Hand Unit Exposure Adjusted for Surface Area (mg/lb ai/cm^2)[c]	Dermal Skin Irritation Exposure [d] (µg/cm^2)	MOE [e] (Target MOE = 10)
Application to indoor hard surfaces	Mopping	0.025 lb ai/gal	1 gallon	0.063	1.587	210
		0.0070 lb ai/gal			0.44	760
	Wiping	0.025 lb ai/gal	0.13 gallon	1.341	4.363	76
		0.0070 lb ai/gal			1.22	270
	Trigger Spray	0.025 lb ai/gal	0.13 gallon	0.129	0.420	790
		0.014 lb ai/gal			0.24	1,400
Air deodorization	Aerosol Spray	0.2% ai by weight	1 can (1 lb)	0.129	0.259	1,300
Application to Carpets	Low Pressure Spray	0.014 lb ai/gal	2 gallons	0.161	4.615	72
Application to RV holding tanks	Liquid Pour	0.834 lb ai/gal	0.031 gal (1 tank at 4 oz product/tank)	0.000239	0.0062	54,000
Application to swimming pools	Liquid Pour	0.000052 lb ai/gal	20,000 gallons	0.000239	0.25	1,300

a Application rates are the maximum application rates determined from EPA registered labels for ADBAC.
b Amount handled per day values are estimates or label instructions.
c Unit Exposure (mg/lb ai/cm^2) = Unit Exposure from PHED or CMA (mg/lb ai) / surface area of hand (820 cm^2).
d Dermal Skin Irritation Exposure (µg /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 (µg /cm^2)/ Surface Residue on Skin (µg/cm^2). [Where short-term dermal formulated-based NOAEL = 333 µg/cm^2]. Target MOE = 10.

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A summary of the agricultural residential handler inhalation risks are presented in Table 6d. The calculated inhalation MOEs for all scenarios are above the target MOE of 100, and not of concern.

Table 6d: ADBAC Short-term Inhalation Risks to Residential Handlers

Scenario	Crop/Target	Application Rate [a]	Quantity Handled/ Treated per day[s]	Inhalation Unit Exposure (ug/lb ai)[c]	Inhalation Exposure[d]	Inhalation Dose[e]	Inhalation MOE[f]
M/L/A Liquid Concentrates with LP Handwand (1)	Residential Turf, Ornamental Bulbs and Orchids	0.0065 lb ai/gal water	5 gal/day	30	0.000975	0.000016	180,000
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden), Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	30	0.00065	0.000011	280,000
M/L/A DF with Low Pressure Handwand (liquid concentrate PHED data as surrogate) (3)	Residential Turf, Ornamental Bulbs and Orchids	0.0065 lb ai/gal water	5 gal/day	30	0.000975	0.000016	180,000
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden), Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	30	0.00065	0.000011	280,000
M/L/A Liquid Concentrates with a Hose-end Sprayer (4)	Residential Turf	7 lb ai/A	0.5 acres/day	17	0.06	0.00099	3,000
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden)	0.43 lb ai/A	0.25 acres/day	1.6	0.00017	2.9E-6	1,000,000
M/L/A Liquids with a Watering Can (PHED residential hose-end data as surrogate) (8)	Ornamental Palms	0.013 lb ai/gal water	5 gal/day	1.6	0.001	1.7E-6	1,700,000
	Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	1.6	0.000034	5.7E-7	5,200,000
Applying Ready to Use Formulations via Trigger-Pump Sprayer (9)	Ornamental Shrubs, Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gallon	1 gal/day	19	0.000082	1.4E-6	2,200,000

a Application rates are the maximum application rates determined from EPA registered labels for ADBAC
b Amount handled per day values are based on Exposure SAC SOP #12, and HED estimates.
c Baseline Inhalation: no respirator.
d Baseline inhalation exposure (mg/day) = application rate (lb ai/gal) x amount handled per day (gal/day) x inhalation unit exposure (µg/lb ai) x conversion factor from µg to mg (0.001)
e Baseline inhalation dose (mg/kg/day) = baseline inhalation exposure (mg/day) x inhalation absorption factor (100%) / female bodyweight (kg)

f Inhalation MOE = inhalation NOAEL (3 mg/kg/day) / inhalation dose (mg/kg/day)

A summary of the residential handler dermal risks are presented in Table 6c. The dermal MOEs for all formulations assessed are above the target MOE of 10, and therefore, are not of concern.

Table 6e: ADBAC Short-term Dermal Risks to Residential Handlers

Scenario	Crop/Target	Application Rate[a]	Quantity Handled Per Day[b]	Unit Exposure for Hands[c] (mg/lb ai)	Estimated Residue Transferred to Skin on Hands (ug ai/cm^2/day)[d]	Dermal MOE (UF = 10)[e]
M/L/A Liquid Concentrates with LP Handwand (1)	Residential Turf, Ornamental Bulbs and Orchids	0.0065 lb ai/gal water	5 gal/day	102	4.0	82
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden), Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	102	2.7	120
M/L/A DF with LP Handwand (liquid concentrate PHED data as surrogate) (3)	Residential Turf, Ornamental Bulbs and Orchids	0.0065 lb ai/gal water	5 gal/day	102	4.0	82
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden), Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	102	2.7	120
M/L/A Liquid Concentrates with a Hose-end Sprayer (4)	Residential Turf	0.0063 lb ai/gal water	100 gal/day	27.5	21	16
	Ornamental Herbaceous Plants, Ornamental Shrubs, Ornamental Trees, Seedlings (planted in garden)	0.0043 lb ai/gal water	100 gal/day	27.5	14	23
M/L/A Liquids with a Watering Can (PHED residential hose-end data as surrogate) (8)	Ornamental Palms	0.013 lb ai/gal water	5 gal/day	27.5	0.7	460
	Seedlings, Seeds, Cuttins (preplant or at plant)	0.0043 lb ai/gal water	5 gal/day	27.5	0.1	2,300
Applying Ready to Use Formulations via Trigger-Pump Sprayer (PHED data for aerosol can used as surrogate) (9)	Ornamental Shrubs, Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gallon	1 gal/day	106	2.8	120

Footnotes:

a Application rates are the maximum application rates determined from EPA registered labels for ADBAC

b Amount handled per day values are based on Exposure SAC SOP #12 and HED estimates.

c From residential PHED unit exposures values for hands for the scenarios listed.

d Application rate (lb ai/gal) * amount handled per day (gal/day) * dermal unit exposures value (mg/lb ai) * conversion factor mg to µg (1000) / surface area of adult hands (820 cm^2) from Exposure Factors Handbook.

f Dermal MOE = Estimated Residue transferred to Skin of Hands (μg/cm^2/day)/ Dermal Endpoint (333 μg/cm^2/day)

c. Residential Post-Application

i. Exposure Assessment

Residential post application exposures result when bystanders (adults and children) come in contact with ADBAC in areas where products have been applied (e.g.. treated floors and carpets), or when children inadvertently ingest the pesticide residues through mouthing treated items (e.g., toys and fabric). The post-application scenarios have been developed to represent a high end exposure scenario. Representative post-application scenarios for antimicrobial uses assessed include children crawling on treated hard surfaces, carpets, and treated lumber such as decks/play sets (dermal and incidental oral exposure to children), wearing treated clothing (dermal exposure to adults and children and incidental oral exposure to children), using air deodorizers (adult and child inhalation exposure), using portable humidifiers (adult and child inhalation exposure), swimming in treated pools (adult and child incidental ingestion), and using treated instrument mouthpieces and reeds (child and adult incidental exposure). Dermal post application exposure to swimmers was not assessed because ADBAC is readily mixed in the water to a low concentration that it does not pose any risk. Representative post-application scenarios for agricultural uses assessed include adults contacting treated lawns and ornamental plants (adult derma exposure) and children's incidental oral activities on treated lawns such as hand-to-mouth activity, object to mouth, and soil ingestion. Data sources and methodologies include the HED Residential SOPs (USEPA 2000, 2001), Residential and Residential Exposure Test Guidelines: Group B Post application Exposure Monitoring Test Guidelines (1998), Human and Environmental Risk Assessment (HERA) Guidance Document (2003 and 2005), the DDAC wood preservative task force study (MRID 455243-04), the Multi-Chamber Concentration and Exposure Model (MCCEM), and the SWIMODEL.

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 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 residue is achieved on the skin. Adults and children post application dermal risks were assessed for the antimicrobial uses; however, only adults were assessed for post-application dermal risks for the agricultural uses because the Agency believes these are individuals that are exposed to the chemical by engaging in activities at their residences previously treated with a pesticide.

ii. Risk Assessment

Based on toxicological criteria and the potential for exposure, the Agency has conducted dermal, inhalation, incidental oral exposure assessment for ADBAC. The inhalation and incidental oral target MOE of 100 is based on 10x interspecies and 10x intraspecies variability. The dermal target MOE of 10 is based on 3x interspecies and 3x intraspecies variability.

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The calculated dermal MOEs are above the target MOE of 10 and are, therefore, not of concern. The inhalation and incidental oral MOEs are above the target MOE of 100 for all scenarios, except for the inhalation exposure from the humidifier. The inhalation MOEs for adults and children are 10 and 4, respectively. A summary of the residential post application are presented in Table 6d.

Table 6d. Residential Post-Application Risk Summary

Exposure Scenario	Dermal MOE	Incidental Ingestion MOE	Inhalation MOE
Child playing on floor	1,100	610	NA
Child playing on carpet	1,200	330	NA
Clothing (1% residue transfer)	210 adults and children	1900	NA
Child playing on decks/play sets (maximum exposure)	110	360	NA
Air deodorizer	NA	NA	5,700 adults 1,800 children
Swimming	NA	Ranges from 500 to 5,600 for adults and children	NA
Humidifiers	NA	NA	**Adult 10 (24-hrs)** **Child 4 (24-hrs)**
Instrument mouthpiece/reed	NA	No data	NA

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

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Table 6g presents the postapplication MOE values calculated for adults after home greenhouse, garden or turfglass applications of ADBAC for a short-term exposure duration. The dermal MOEs were not of concern (i.e., MOEs <10) on the day of application for any of the three scenarios with the different application rates. An MOE of less than 10 represents a risk of concern to the Agency.

Table 6g: ADBAC: Adult Residential Short-Term Dermal Risks for Postapplication Exposure

Exposure Scenario	Route of Exposure	Formulation	Application Rate[a] (lb ai/acre)	Residue on Skin[b]	MOE[c] at Day 0
Exposure To Treated Ornamental Plants	Dermal	Spray	0.43	0.96	350
Exposure to Treated Turf			7	3.9	85
			0.9	0.5	660

a Maximum application rate on label (lb ai/A).

b Residue concentration available to be transferred on day 0 = application rate in µg/cm^2 (lb ai/gal * conversion factors (lb to µg and A to cm^2) * fraction of DFR or TTR available on day 0 * percent of DFR or transferrable to skin (100%).
c Short-term Dermal MOE = dermal endpoint (333 ug/cm^2)/ residue concentration on skin

A summary of the combined risks from incidental exposure for toddlers for applications to home lawn for maximum label application rate as well as the lower application rate (i.e. hand-to-mouth activity, object-to-mouth activities, and incidental soil ingestion and for hand-to-mouth activity at the lower application rate) is represented in table 6h. An MOE of less than 100 represents a risk of concern to the Agency. For this scenario, the maximum application rate (7 lb ai/A) resulted in a MOE of 76 while the lower concentration rate (0.9 lb ai/A) was not of concern with a MOE of 590.

Table 6h: ADBAC: Combined Incidental Oral Risk Estimates - Toddlers

Postapplication Exposure Scenario		Margins of Exposure (MOEs) (UF=100)	
		Short-Term Oral (Non-Dietary)	Short-Term Oral: Combined (Non-Dietary)
Turf application at 7 lb ai/acre	Hand to Mouth	**96**	**76**
	Object to Mouth	380	
	Incidental Soil Ingestion	29,000	
Turf application at 0.9 lb ai/acre	Hand to Mouth	740	590
	Object to Mouth	3,000	
	Incidental Soil Ingestion	220,000	

7. Aggregate Risk

The Food Quality Protection Act (FQPA) amendments to the Federal Food, Drug, and Cosmetic Act 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. Chronic Aggregate Risks

An acute toxicological endpoint was not identified for ADBAC. Therefore, an acute aggregate risk assessment was not conducted. The chronic aggregate risk assessment includes only dietary and drinking water exposures because chronic exposures are not expected from residential uses. Chronic dietary risk estimates from direct and indirect food uses are presented in Section 5a, and drinking water exposure estimates are presented in Section 5b. Table 7a presents a summary of these exposures, including the aggregate indirect and direct dietary exposure (i.e., all direct and indirect food contact exposures) as well as a total dietary aggregate

exposure estimate (i.e., drinking water plus direct/indirect dietary exposures). Based on the results of the chronic aggregate assessment, the %cPAD for adults and children are 3.5% and 10.3%, respectively. Therefore, the chronic dietary risks are not of concern (i.e., less then 100 % of cPAD).

Table 7a. ADBAC Chronic Aggregate Exposures and Risks (cPAD)

Exposure Routes	Chronic Dietary Exposures (mg/kg/day)				
	Indirect Dietary Exposures[a]	Direct Food Contact Dietary Exposures[a]	Drinking Water Exposures	Aggregate Dietary Exposures[b]	% cPAD[c] (MOE)
Adults					
Oral Ingestion	0.0042	0.0024	0.009	0.0066	3.5% (2,800)
Children					
Oral Ingestion	0.017	0.0061	0.022	0.023	10.3 (980)

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 %cPAD (percent chronic population adjusted dose) = (aggregate exposures / cPAD) x 100. Where cPAD = NOAEL 44 mg/kg/day / 100x uncertainty factor = 0.44 mg/kg/day. MOE = NOAEL of 44 mg/kg/day / aggregate dietary exposures mg/kg/day.

b. Short- and Intermediate-Term Aggregate Risk

The short- and intermediate-term aggregate risks include pesticide exposures from dietary, drinking water, and residential sources. The following list summarizes all of the potential sources of ADBAC exposures for adults and children.

Adult ADBAC exposure sources:

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

Child ADBAC exposure sources:

- post-application exposures to cleaning product residues containing ADBAC that are used on hard surfaces (e.g, floors/carpets);
- breathing air treated with an air deodorizer or humidifier;
- swimming in treated pools;

- contacting pressure treated wood;
- wearing treated clothing/diapers;
- eating food having ADBAC 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 6-2 summarizes the scenarios included in the short- and intermediate-term aggregate assessments.

Table 7b. 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 ADBAC-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.

Since the ADBAC toxicity endpoints for the oral, dermal, and inhalation routes of exposure are based on different toxic effects, these three routes of exposure are not aggregated together. Instead, the aggregate assessment is based solely on the co-occurrence of the same route of exposure. 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 7c presents a summary of the short- and intermediate-term aggregate risks (i.e., MOEs). The short- and intermediate-term aggregate is identical 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 any of the three routes of exposure as the total aggregate MOE is 2,800 for oral, 42 dermal, and 630 for inhalation which are greater than the target MOE. For children, the aggregate risk estimate for each of the routes of exposure are also above the target MOE (MOE=220 for the oral route, 180 for the dermal route) and thus are not of concern. It is important to note, however, that some of the individual risks are of concern by themselves (e.g., the humidifier use).

Table 7c. Short- and Intermediate-term Aggregate Risk (MOE) Assessment

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	2,800	NA			NA	NA	2,800
Dermal	NA	210 (mop)	76 (wipe)	790 (spray)	NA	2,500	42
Inhalation	NA	3,000 (mop)	820 (wipe)	23,000 (spray)	Not included, risk of concern	NA	630
Children							
Oral Ingestion	980	330 (hand-to-mouth carpets)			NA	1,900	220
Dermal (ST only)	NA	1,200 (playing on carpets)			NA	210 (1% residue transfer)	180
Inhalation	NA	NA			Not included, risk of concern	NA	No co-occurrence

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

8. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide or by entering treated sites. For ADBAC, potential occupational handler exposure can occur from treatment of the following uses: agricultural premises, industrial processes and water systems, food handling premises, commercial/institutional/industrial premises, medical premises, swimming pools, and aquatic areas. In addition to the "antimicrobial" exposures scenarios, ADBAC is used to treat ornamental plants in nurseries and greenhouses, commercial turf and golf courses. 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.e.

Occupational risk for all potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a NO Observed Adverse Effect Level (NOAEL) from toxicity studies. In the case of ADAC, A MOE greater than or equal to 100 is considerably adequately protective for the occupational exposure assessment for inhalation routes of exposure. The MOE of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variation. A MOE of 10 is considered adequately protective for the dermal route of concern; it includes 3x interspecies extrapolation and 3x intraspecies variation.

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 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 ADBAC to workers, see the Occupational Exposure Assessment (Section 8.0) in the Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC): Risk Assessment for the Reregistration Eligibility Decision," dated July 27,2006 and the "Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational/Residential Exposure Assessment," dated August 3, 2006.

a. Occupational Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential risks for ADBAC were listed previously in Table 6a.

b. Occupational Handler Exposure

Potential occupational handler exposure can occur in various antimicrobial and agricultural use sites which include: agricultural premises, industrial processes and water systems, food handling premises, commercial/institutional/industrial premises, medical premises, swimming pools, ornamental greenhouses/nurseries, golf courses, 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 preservation analysis, the handler and post-application exposures are presented separately in section e.

The Agency has assessed exposures to handlers mixing/loading/applying antimicrobial and agricultural use products containing ADBAC. The following handler exposure scenarios represent high end exposure estimates.

Antimicrobial Use - Mixer/Loader/Applicators:

- For the ***liquid pour*** scenarios, the unit exposure depends on the material being treated. The following CMA unit exposures were available and used for the assessment of the risk associated with the treatment of the specified materials.
    - *Swimming pools, carpets, and oilfield operations (drilling muds and packer fluids):* CMA preservative data (gloved). The inhalation unit exposure is 0.00346 mg/lb a.i. and is based on 2 replicates. Although this unit exposure is based on minimal replicates, the exposure value is similar to the one found in PHED for a similar scenarios.
    - *Indoor hard surfaces (immersion, flooding and circulation) and medical instruments in Use Site Categories II and V*: The inhalation unit exposure value for disinfectant liquid pour (1.89 mg/lb a.i.) was used.
    - *Small process water systems:* CMA cooling tower data (gloved). The inhalation unit exposure is 0.450 mg/lb a.i. and is based on 5 replicates.
- For the ***mopping*** scenarios, the CMA inhalation unit exposure value for ungloved mopping was used (2.38 mg/lb a.i.). This value is based on data collected from six replicates in which the applicator mopped the floor and received exposure via contact with the mop or with the bucket.
- For the ***wiping*** scenarios, the CMA inhalation unit exposure value for ungloved wiping was used (67.3 mg/lb a.i.). This value is based on data collected from six replicates (dental technicians) who used a finger pump sprayer to apply the product and then wiped the surfaces with a paper towel
- For the ***low pressure hand wand*** scenario, the CMA inhalation unit exposure value for low pressure spray was used (0.681 mg/lb a.i.). This value is based on data collected from eight replicates in which the applicator hand sprayed carpet using 200 psi, then used a push broom rake to raise the carpet nap
- For the ***aerosol spray and trigger pump spray*** scenarios, the PHED inhalation unit exposure value for aerosol applications (PHED scenario 10) was used. The inhalation unit exposure is 1.3 mg/lb a.i.
- For the ***liquid/metering pump*** scenarios, the unit exposure depends on the material being treated. The following CMA unit exposures were available and used for the assessment of the risk associated with the treatment of the specified materials.
    - *Pulp and paper, Papermaking chemicals, and Once-through cooling water systems*: CMA pulp and paper gloved data were used. The inhalation unit exposure is 0.000265 mg/lb a.i. The value is based on 7 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. This unit exposure was used for the once through cooling water system because no representative data exists for the volume of water treated in power plant facilities.
    - *Small process water systems:* CMA cooling tower data. The inhalation unit exposure is 0.00432 mg/lb a.i. and is based on 4 replicates.
- For the ***high-pressure/high volume spray*** and ***medium pressure spray*** scenarios, the PHED inhalation unit exposure value for liquid/open pour/high pressure spray (PHED scenario 35) was used (0.12 mg/lb a.i.).

- For the ***fogging, ULV/mist sprayer and automated system*** scenarios, it was assumed that most of the exposure to the handler will be due to preparing the fogger, and that the handler leaves the room immediately after fogging commences. Therefore, the available CMA disinfectant liquid pour inhalation unit exposure value was used. The inhalation unit exposure value is 1.89 mg/lb a.i., respectively. This value is based on data collected from two gloved replicates involving pouring a disinfectant product from a jug into sterilization trays designed for dental instruments, adding water and instruments to the tray, removing the instruments, and discarding the old solution.

Agriculture Use - Mixer/Loader/Applicators:

- Mixing/Loading Liquids Concentrates for Groundboom Applications (PHED) (1a)
- Mixing/Loading Liquid Concentrates to Support LCO Handgun Applications (mixing/loading supports 20 LCOs) (PHED) (1b)
- Mixing/Loading Liquids Concentrates for Airblast Applications (PHED) (1c)
- Mixing/Loading Liquid Concentrates via Dip or Soak (PHED) (1d)
- Mixing/Loading Dry Flowables for Groundboom Applications (PHED) (2a)
- Mixing/Loading Dry Flowables for Airblast Applications (PHED) (2b)
- Mixing/Loading Dry Flowables to Support LCO Handgun Applications (mixing/loading supports 20 LCOs) (PHED) (2c)
- Mixing/Loading Dry Flowables via Dip or Soak (PHED) (2d)
- Applying Sprays via Groundboom Equipment (PHED) (3)
- Applying Sprays via Airblast Equipment (PHED) (4)
- Applying Sprays via Handgun Equipment (PHED) (5)
- Applying as a Soak or Dip (no data) (6)
- Mixing/Loading/Applying Liquid Concentrates with Low Pressure Handwand (ORETF data) (7)
- Mixing/Loading/Applying Dry Flowables with Low Pressure Handwand (using liquid concentrate ORETF data) (8)
- Mixing/Loading/Applying Liquid Concentrates with a Handgun Sprayer (LCO ORETF data) (9)
- Mixing/Loading/Applying Water Soluble Bags with Handgun Sprayer (LCO ORETF data) (10)
- Mixing/Loading/Applying Dry Flowables Concentrates with a Handgun Sprayer (LCO ORETF data) (11)
- Mixing/Loading/Applying Liquid Concentrates with a High Pressure Handwand (PHED) (12)
- Applying Ready to Use Formulations via Trigger-Pump Sprayer (ORETF) (13)
- Mixing/Loading/Applying Liquids with a Watering Can (using ORETF residential hose-end data) (14)
- Mixing/Loading/Applying Dip or Soak (no data) (15)

ADBAC 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 exposed to end-use products containing concentrations off ADBAC that result in classification of toxicity 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. For a diluted product, the classification of a toxicity category IV for skin irritation potential would result in the elimination of the required personal protective clothing and gloves; such as, chemical-resistant gloves and chemical-resistant apron, for applicators and others exposed to the end-use product. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

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) surrogate exposure data (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998). The specific inhalation unit exposures and quantity of ADBAC handled are provided in the Occupational and Residential Exposure Assessment for ADBAC dated July 27, 2006.

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

c. Occupational Handler Risk Summary

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

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The resulting inhalation exposures and MOEs for the representative occupational handler scenarios are presented in Table 8.1. The calculated MOEs were above the target MOE of 100 for all scenarios, except those listed below.

- Agricultural fogging (mixing and loading): ST/IT Inhalation MOE = **26**
- Pulp and paper, liquid pump: ST/IT Inhalation MOE = **33**
- Once-through cooling water, metering pump: Using the average flow rate for high flow streams (153 MGD) the ST Inhalation MOE = **50**
- Small process water systems, liquid pour: ST/IT Inhalation MOE = **6**.

Table 8.1: 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	0.012 lb ai/gal	2 gallons	0.00091	3,300
	High pressure/high volume spray	0.12	0.017 lb ai/gal	40 gallons	0.0014	2,200
	Low pressure hand wand	0.681	0.017 lb ai/gal	10 gallons	0.002	1,500
	Trigger pump sprayer	1.3	0.017 lb ai/gal	0.26 gallons	0.000098	31,000
	Wipe	67.3	0.017 lb ai/gal	0.26 gallons	0.0051	590
Fogging (mix/load only)	Liquid pour	1.89	2.46E-05 lb/ft^3	150,000 ft^3	0.12	**26**
Food Handling/Storage Establishments Premises And Equipment (Use Site Category II)						
Application to indoor hard surfaces (including dishes, utensils, equipment)	Low pressure hand wand	0.681	0.0176 lb ai/gal	2 gallons	0.0004	7,500
	Mop	2.38	0.0176 lb ai/gal	2 gallons	0.0014	2,100
	Wipe	67.3	0.0176 lb ai/gal	0.26 gallons	0.0051	580
	Trigger pump sprayer	1.3	0.025 lb ai/gal	0.26 gallons	0.00014	21,000
	Immersion, Flooding, Circulation	1.89	0.00325 lb ai/gal	2 gallons	0.0002	15,000
Commercial, Institutional and Industrial Premises and Equipment (Use Site Category III)						
Application to indoor hard surfaces	Low pressure hand wand	0.681	0.0283 lb ai/gal	2 gallons	0.00064	4,700
	Mop	2.38	0.0283 lb ai/gal	2 gallons	0.0022	1,300
	Wipe	67.3	0.0283 lb ai/gal	0.26 gallons	0.0083	360
	Trigger pump sprayer	1.3	0.0283 lb ai/gal	0.26 gallons	0.00016	19,000
	Immersion	1.89	0.025 lb ai/gal	2 gallons	0.0016	1,900
Air deodorization	Aerosol spray	1.3	0.20% a.i. by weight	3.0 lbs	0.00013	23,000
Application to carpets	Liquid pour	0.00346	0.141 lb ai/gal	32 gallons	0.00026	12,000
Medical Premises and Equipment (Use Site Category V)						
Application to hard surfaces	Mop	2.38	0.0176 lb ai/gal	45 gallons	0.031	**95**
Application to dental instruments	Immersion (Liquid pour)	1.89	0.0209 lb ai/gal	2 gallons	0.0013	2,300
Industrial Processes and Water Systems (Use Site Category VIII)						
Pulp and Paper	Metering pump	0.000265	41.7 lb ai/ton paper	500 tons	0.092	**33**
Papermaking Chemicals	Metering pump	0.000265	0.0019 lb ai/gal additive	1,000 gallons	8.5E-6	350,000
Once-through Cooling Water System - Power plant	Metering pump	0.000265	Initial Dose (ST): 8.86E-5 lb ai/gal water	5,900,000 gallons	0.0023	ST=1300

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)
			Maintenance Dose (IT): 4.69E-5 lb ai/gal	5,900,000 gallons	0.0012	IT=2,500
			Initial Dose (ST): 8.86E-5 lb ai/gal water	153,000,000 gallons	0.06	ST =**50**
			Maintenance Dose (IT): 4.69E-5 lb ai/gal	153,000,000 gallons	0.032	IT=**95**
Small process water systems: Recirculating cooling tower/evaporative condenser/pasteurizers	Liquid pour	0.45	6.67 lb ai/gal product	10 gallons	0.5	**6**
	Metering pump	0.00432	Initial Dose (ST): 3.34E-4 lb ai/gal water	20,000 gallons	0.00048	ST=6,200
			Maintenance Dose (IT): 1.25E-4 lb ai/gal water	20,000 gallons	0.00018	IT=17,000
Oil field operations - drilling mud and packing fluids	Liquid pour	0.00346	1.00 lb ai/gal product	5.6 gallons	ST = 0.00032	ST = 9,300
				2.8 gallons	IT = 0.00016	IT = 19,000
Metal/wood cooling tower surface spray	Airless spray	0.83	0.000168 lb ai/gal water	100 gallons	0.00023	13,000
				1,000 gallons	0.0023	1,300
Swimming Pools (Use Site Category X)						
Application to swimming pools	Liquid pour	0.00346	Winterizing Dose (ST): 0.000052 lb ai/gal	200,000 gallons	0.0006	ST =5,000
			Maintenance Dose (IT/LT): 0.0000098 lb ai/gal	200,000 gallons	0.00011	IT/LT =27,000

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 = 3 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.

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In all occupational handler scenarios, the inhalation MOEs are above the level of concern of 100 at baseline PPE (i.e., no respirator).

TABLE 8.2: ADBAC: Occupational Handler Inhalation Risks

Exposure Scenario	Crop or Target	Application Rate [a]	Area Treated Daily [b]	Inhalation MOEs[c]
				Baseline
Mixer/Loader				
Mixing/Loading (M/L) Liquids for Groundboom Applications (1a)	Carnations (drench)	256 lb ai/acre	1 acres	590
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	1 acres	2100
	Sodfarm Turf	0.9 lb ai/acre	1 acres	170,000
	Seedlings (planted in field)	0.43 lb ai/acre	1 acres	350,000
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, and Standing Water	0.0017 lb ai/gal of water to be treated	800,000 gallons of water	110
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, and Standing Water	0.0017 lb ai/gal of water to be treated	100,000 gallons of water	880
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, and Standing Water	0.0017 lb ai/gal of water to be treated	20,000 gallons of water	4,400
ML Liquid to Support LCO Handgun Applications (mixing/loading supports 20 LCOs) (1b)	Residential & Commercial Turf	7 lb ai/acre	1 acres	21,000
	Residential & Commercial Turf	0.9 lb ai/acre	1 acres	170,000
M/L Liquids for Airblast (1c)	Ornamental Trees	0.65 lb ai/acre	2 acres	120,000
M/L Liquid via Dip or Soak (1d)	Ornamental Herbaceous Plants,	0.0065 lb ai/gal	100 gallons	230,000
	Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal	100 gallons	350,000
M/L DF for Groundboom (2a)	Carnations (drench)	256 lb ai/acre	1 acres	910
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	1 acres	3,200
	Sodfarm Turf	0.9 lb ai/acre	1 acres	260,000
	Seedlings (planted in field)	0.43 lb ai/acre	1 acres	540,000
M/L DF for Airblast (2b)	Ornamental Trees	0.65 lb ai/acre	1 acres	360,000
M/L DF to Support LCO Handgun Applications (mixing/loading supports 20 LCOs) (2c)	Residential & Commercial Turf	7 lb ai/acre	1 acres	33,000
	Residential & Commercial Turf	0.9 lb ai/acre	1 acres	260,000
M/L DF via Dip or Soak (2d)	Ornamental Herbaceous Plants,	0.0065 lb ai/gal	100 gallons	360,000
	Seedlings, Seeds, Cuttings (preplant or at plant)	0.0043 lb ai/gal	100 gallons	540,000
Applicator				
Applying Sprays via Groundboom Equipment (3)	Carnations (drench)	256 lb ai/acre	1 acres	950
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	1 acres	3,400
	Sodfarm Turf	0.9 lb ai/acre	1 acres	270,000
	Seedlings (planted in field)	0.43 lb ai/acre	1 acres	570,000
	Mosquito Control in Decorative Ponds, Sewage	0.0017 lb ai/gal of water to be	800,000 gallons of	180

Exposure Scenario	Crop or Target	Application Rate [a]	Area Treated Daily [b]	Inhalation MOEs[c]
				Baseline
	Treatment Systems, Swimming Pools and Standing Water	treated	water to be treated	
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, Swimming Pools and Standing Water	0.0017 lb ai/gal of water to be treated	100,000 gallons of water to be treated	1,400
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, Swimming Pools and Standing Water	0.0017 lb ai/gal of water to be treated	20,000 gallons of water to be treated	7,200
Applying Sprays via Airblast Equipment (4)	Ornamental Trees	0.65 lb ai/acre	1 acres	62,000
Applying Sprays via Handgun (5)	Residential and Commercial Turf	7 lb ai/acre	0.05 acres	370,000
		0.9 lb ai/acre	0.05 acres	2,900,000
Mixer/Loader/Applicator				
Mixing/Loading/Applying Liquid Concentrates with a Handgun Sprayer (LCO ORETF data) (10)	Carnations (drench)	256 lb ai/acre	0.05 acres	2,000
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	0.05 acres	6,900
	Ornamental Trees and Ornamental Herbaceous Plants	0.65 lb ai/acre	0.05 acres	770,000
	Ornamental Shrubs, Seedlings (planted in field)	0.43 lb ai/acre	0.05 acres	1,200,000
Mixing/Loading/Applying Liquid Concentrates with a Handgun Sprayer (LCO ORETF data) (7)	Carnations (drench)	0.0235 lb ai/gallon	0.04 acres	71,000,000
	Ornamental Trees and Ornamental Herbaceous Plants	0.0065 lb ai/gallon	0.04 acres	260,000,000
	Ornamental Shrubs, Seedlings (planted in field)	0.0043 lb ai/acre	0.04 acres	390,000,000
Mixing/Loading/Applying Water Soluble Bags with Handgun Sprayer (LCO ORETF data) (10)	Carnations (drench)	256 lb ai/acre	0.05 acres	2,000
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	0.05 acres	6,900
	Ornamental Trees and Ornamental Herbaceous Plants	0.65 lb ai/acre	0.05 acres	770,000
	Ornamental Shrubs, Seedlings (planted in field)	0.43 lb ai/acre	0.05 acres	1,200,000
Mixing/Loading/Applying Dry Flowables Concentrates with a Handgun Sprayer (LCO ORETF data) (11)	Carnations (drench)	256 lb ai/acre	0.05 acres	640
	Ornamental Herbaceous Plants (drench)	72 lb ai/acre	0.05 acres	2,300
	Ornamental Trees and Ornamental Herbaceous Plants	0.65 lb ai/acre	0.05 acres	250,000
	Ornamental Shrubs, Seedlings (planted in field)	0.43 lb ai/acre	0.05 acres	380,000
Mixing/Loading/Applying Liquid Concentrates with a High Pressure Handwand (PHED) (12)	Ornamental Herbaceous Plants and Ornamental Trees	0.0065 lb ai/gallon	1,000 gallons	230
	Ornamental Shrubs	0.0043 lb ai/gallon	1,000 gallons	350

Exposure Scenario	Crop or Target	Application Rate [a]	Area Treated Daily [b]	Inhalation MOEs[c]
				Baseline
Applying Ready to Use Formulations via Trigger-Pump Sprayer (ORETF) (13)	Ornamental Shrubs, Seedlings, Seeds, Cuttins (preplant or at plant)	0.0043 lb ai/gallon	1 gallons	2,200,000
Mixing/Loading/Applying Liquids with a Watering Can (using ORETF residential hose-end data) (14)	Ornamental Palms	0.013 lb ai/gallon	5 gallons	160,000
	Seedlings, Seeds, Cuttins (preplant or at plant)	0.0043 lb ai/gallon	5 gallons	490,000
	Mosquito Control in Decorative Ponds, Sewage Treatment Systems, Swimming Pools, and Standing Water	0.0017 lb ai/gallon of water to be treated	20,000 gallons to be treated	310
	Mosquito Control in Fountains, Water Displays, Decorative Pools	0.0017 lb ai/gallon of water to be treated	1,000 gallons to be treated	6,200

a Application rates are the maximum application rates determined from EPA registered labels for ADBAC

b Amount handled per day values are HED estimates of gallons applied per day based on Exposure SAC SOP #9 Standard Values for Daily Acres Treated in Agriculture, industry sources, and HED estimates.

c Inhalation MOE = inhalation NOAEL (mg/kg/day) / baseline inhalation dose (mg/kg/day), where baseline inhalation exposure (mg/day) = application rate (lb ai/gal) x amount handled per day (gal/day) x baseline inhalation unit exposure (µg/lb ai) x conversion factor from µg to mg (0.001) and the baseline inhalation dose (mg/kg/day) = baseline inhalation exposure (mg/day) x inhalation absorption factor (100%) / female bodyweight (60 kg)

d. Occupational Post-Application Exposures

Post-Application exposure may occur from entering food processing plants, hatcheries, wood treatment facilities, ornamental greenhouse/nurseries, or from handling treated wood or turf. Except for the post-application scenarios assessed for fogging (food processing plants and hatcheries) in Section 8.2.2, occupational post-application dermal and inhalation exposures are assumed to be negligible.

i. Fogging (Food Processing Plant and Hatchery)

There is a potential for post-application inhalation exposure for workers re-entering a treated hatchery or food processing plants, because dermal post application is presumed to be negligible, it was 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. Although the data libraries contained in MCCEM are limited to residential settings, the model can be used to assess other indoor environments. 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; they do not account for actual absorption into the body.)

The fogging application to a food processing plant was assessed using a maximum application rate of 0.011 lb ai/gal, one quart of the diluted product per 1,000 cubic feet of the treated area. For fogging applications, a two hour restricted entry interval is required on current labels for this use. The inhalation MOE for fogging is 1 which is considerably below the target MOE of 100. The risks of concern immediately after fogging are attributed to low air changes

per hour assumed (i.e., 0.18 ACH as a default parameter in MCCEM to represent low air flow). The assessment for fogging in food processing plants could be refined if more accurate ventilation rate information could be obtained.

The fogging application to hatcheries and incubators was assessed using a maximum application rate of 0.24 lb ai/gal. For fogging applications, the Agency estimated risks from 0-8 hours and 2-10 hours following treatment. The 8-hr inhalation MOE from 0-8 hours (immediately after fogging) is below the target MOE of 100 at 0.5; however, the 8-hr MOE from 2 to 10 hours was above the target MOE of 100.

e. Wood Preservation

ADBAC is used in products that are intended to preserve wood through both non-pressure treatment methods and pressure treatment methods. Section 1 presents the exposure analysis for the handler and post-application scenarios for non-pressure treatment scenarios, and Section 2 presents the exposure analysis for the handler and post-application scenarios for pressure treatment scenarios. Dermal irritation exposures from post-application activities in the wood preservation treatment facility will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. Therefore, only inhalation exposures and risks are presented.

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

a. Scenarios Assessed by Worker Function

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) was used to assess various worker functions/positions for individuals that handle DDAC-containing wood preservatives for non-pressure treatment application methods and post-application risk scenarios for individuals that could into contact with the preserved wood. The worker functions/positions identified in the DDAC study are presented below. It was assumed that similar tasks are performed when handling ADBAC products and ADBAC treated-wood as, therefore, these same functions were assessed for ADBAC.

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 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.

The post-application scenarios identified in the aforementioned DDAC study are presented below based on the assumption that these scenarios are the same for ADBAC.

Post-application:

- ***Graders***, positioned right after the spray box, grade dry lumber by hand (i.e., detect faults).
- ***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.
- ***Construction workers*** install treated plywood, oriented strand board, medium density fiberboard, and others.

As very little chemical specific data were available regarding typical exposures to ADBAC as a wood preservative, surrogate data were used to estimate exposure risks. 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

The inhalation exposures and risks to the composite wood blender/spray operators are reported in Table 8.2. The inhalation MOE is below the target MOE of 100 for short-, intermediate-, and long-term inhalation exposures (MOE = **84**).

Table 8.2: 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	**84**

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 = 3 mg/kg/day for inhalation. Target MOE = 100.

Chemical Operators, Graders, Millwrights, Clean-up Crews, and Trim Saw Operators

The inhalation exposures (all durations) to chemical operators, graders, millwrights, trim saw operators, and clean-up crews are presented in Table 8.3. 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 8.3: 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	0.625	0.000292	10,000
Occupational Post-Application				
Grader (n=13)	0.0295	0.625	0.000307	9,800
Trim Saw (n=2)	0.061	0.625	0.00063	4,800
Millwright (n=3)	0.057	0.625	0.00059	5,100
Clean-Up (n=6)	0.60	0.625	0.0063	480

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 Table E-1 in Appendix E for the calculation of the dermal and inhalation exposures. Inhalation exposure (mg/day) was calculated using the following equation: Air concentration ($\mu g/m^3$) 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. Conversion Ratio = 50% ADBAC / 80% DDAC

d. Daily dose (mg/kg/day) = exposure (mg/day) x conversion ratio (0.625) x absorption factor (100% for inhalation)/body weight (60 kg).

e. MOE = NOAEL (mg/kg/day)/ Daily dose [Where inhalation NOAEL = 3 mg/kg/day]. Target MOE = 100.

Diptank Operators

Exposures to diptank operators were also assessed using surrogate data from the DDAC study (Bestari et al., 1999). The diptank scenario assessment was conducted differently than for the other job functions because the concentration of DDAC in the diptank solution was provided. The exposure data for diptank operators were converted into unit exposures in terms of mg a.i. for each 1% of concentration of the product. Table 8.4 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 8.4: 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				
Dipping, (n=7)	0.046	3	0.0023	1,300

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 the 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 = 3 mg/kg/day. Target MOE = 100.

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

ADBAC 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 was not provided on the product labels; therefore, an application rate of 3% ai solution was used in this assessment, based on the master label. Since ADBAC-specific exposure data are not available to assess pressure treatment exposure, surrogate chromated copper arsenate (CCA) data (ACC, 2002b) was utilized and using the approach described in a previous exposure assessment (USEPA, 2003b).

The estimated inhalation exposures and risks for ADBAC are presented in Table 8.6. The calculated inhalation MOEs are above the target MOE of 100 for all scenarios and not of concern.

Table 8.6: 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)	Daily Doses[b] (mg/kg/day)	Inhalation MOEs[c] (Target MOE = 100)
Occupational Handler				
Treatment Operator (TO)	0.00257	3	0.0013	2,300
Treatment Assistant (TA)	0.000802	3	0.00040	7,500
Occupational Post-application				
All (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman)	0.00160	3	0.00080	3,800

a. Unit exposure values taken from CCA study and are shown in Table 6.11.
b. Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) x [% ADBAC 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 = 3 mg/kg/day for all durations. Target MOE = 100.

9. Human Incident Data

The Agency reviewed available sources of human incident data for incidents related to the use of the quaternary ammonium chlorides. As stated earlier, the Agency clustered the quaternary ammonium chloride chemicals into four groups. However, the available incident information does not differentiate between the specific groups; therefore, all the incident data are discussed together.

The Agency consulted the following sources of human incidents related to the use of ADBAC:

(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)** - Since 1982, California's Department of Pesticide Regulation Pesticide Poisoning Surveillance Program consists of reports from physicians who document all illnesses they suspect are related to pesticide exposure.
(3) **National Pesticide Information Center(NPIC)** - NPIC is a toll-free information service supported by OPP. The network provides information on the top 200 active ingredients by answering telephone calls during calendar years 1984-1991.
(4) **Published Incident Reports** - Some incident reports associated with Quats that are related to human health hazard 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 of eye and eyelid

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for ADBAC use sites and any associated uncertainties. For detailed information on the environmental risk assessment on ADBAC, see the following documents, "Environmental Fate Assessment of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)" dated July 31, 2006, "Ecological Risk Assessment on Antimicrobial Uses for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)" dated August 2, 2006, and "Ecological Risk Assessment on Agricultural Uses for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)" dated February 3, 2006.

1. Environmental Fate and Transport

The environmental fate assessment for ADBAC is based on the available data submitted to fulfill the reregistration data requirements. However, the data set is incomplete for the wood preservation use. An aqueous availablility study evaluating the leachability of ADBAC from treated wood is required.

Based on the available data, ADBAC is hydrolytically stable under abiotic and buffered conditions over the pH 5-9 range. The calculated half-lives for ADBAC were 379 days at pH 9, 150-183 days at pH 5 and pH 7. ADBAC is also stable to photodegradation in pH 7 buffered aqueous solutions. However, in the presence of a photosensitizer (e.g., acetone), ADBAC has been shown to degrade with an estimated half-life of 7.1 days.

Based on a biodegradation study, ADBAC readily degrades into 60% carbon dioxide in 13 days. ADBAC is immobile in soil. The available soil mobility study shows that ADBAC has a strong tendency to bind to sediment/soil with Freundlich K_{ads} values range from 5,123 to 32,429 depending on the soil type where as the corresponding K_{oc} values range from 640,389 to 6,171,657 depending on the soil type. Due to its strong adsorption to soils, ADBAC is not expected to contaminate surface and ground waters.

Although the estimated K_{ow} is high, bioaccumulation of ADBAC in freshwater fish nor is bioconcentration in aquatic organisms expected to pose a concern because ADBAC has broken down into its' degrades before it reaches the aquatic ecosystems.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimate environmental concentrations based on environmental fate characteristics and pesticide use data.

a. Toxicity (Hazard) Assessment

ADBAC is categorized as highly toxic to fish (LC_{50} = 280 µg ai/L) and very highly toxic to aquatic invertebrates (LC_{50} = 5.9 µg ai/L) on an acute exposure basis. Chronic effects were seen in fish at a concentration of 32.2 µg ai/L and a no observable adverse effect concentration

(NOAEC) of 4.15 µg ai/L was established for aquatic invertebrates. The results of the dietary avian studies categorized ADBAC as moderately toxic to birds on an acute basis (LC_{50} = 136 mg/kg-bw, with no chronic data available. ADBAC is categorized as slightly toxic to mammals on an acute basis (LD50 = 430 mg/kg-bw) and a chronic NOAEC of 44 mg/kg/day was established.

b. Exposure and Risk

ADBAC INDOOR USES

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

ADBAC OUTDOOR USES

Risk Quotients (RQs) are calculated by dividing acute and chronic estimated environmental concentrations (EECs), based on environmental fate characteristics and pesticide use data, ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs). When the RQ exceeds the LOC for a particular category, the Agency presumes risks of concern for that category.

Ornamental Nursery Plants

Expected environmental concentrations (EECs) of ADBAC resulting from runoff following application to ornamentals in nurseries were calculated using available ecotoxicity data and the EPA aquatic exposure model PRZM/EXAMS. Risk quotients (RQs) for freshwater fish ranged from 1.99 to 5.26, RQs for freshwater invertebrates ranged from 94.41 to 249.66, exceeding the acute risk LOC by greater than 180-fold. The chronic risk LOC (1.0) is exceeded many-fold for freshwater fish ranging from RQs 10-28 and for freshwater invertebrates ranging from RQs 87-222. Using the EPA terrestrial animal exposure model (TERX), acute avian RQs ranged from 19 to 2101, exceeding the acute LOC up to 4000-fold. Chronic avian RQs could not be calculated due to the lack of toxicity data, but chronic risk is presumed. Mammalian acute RQs for the nursery use range from 1.2 to 182 and chronic RQs range from 11 to 1782.

Turf and Golf Courses

Expected EECs of ADBAC resulting from runoff following application to turf and golf courses were calculated using available ecotoxicity data and the EPA aquatic exposure model PRZM/EXAMS. Risk quotients for freshwater fish range from 0.06 to 0.91, exceeding the endangered species and acute risk LOCs. Acute risk RQs for freshwater invertebrates range

from 2.3 to 10.6, exceeding the acute risk LOC. Using the EPA terrestrial animal exposure model (TERX), acute avian RQs range from 0.11 to 12.35, exceeding the endangered species LOC for all size classes and forage items. Chronic RQs cannot be calculated, but chronic risk to avian species is presumed. Acute risk mammalian RQs from the turf/golf course use ranged from 0.01 to 7.9, with exceedance of the endangered species LOC for all mammal size classes foraging on short grass, tall grass, broadleaf plants and small insects. Chronic RQs for mammals range from 0.07 to 77.2, and exceed the LOC for all mammal size classes foraging on short grass, tall grass, broadleaf plants and small insects. (http://www.epa.gov/oppefed1/models/terrestrial/index.htm).

Ornamental Ponds, Pools, and Puddles

Other outdoor uses of ADBAC on ornamental ponds, pools and puddles are not expected to result in appreciable exposure to aquatic ecosystems due to their limited size and confined use of ADBAC within the structure through the use of impermeable materials. (http://www.epa.gov/oppefed1/models/water/index.htm).

Algae Control and Mosquitocide

Although the algae control and mosquitocide uses are intended for waterbodies that are disconnected from the larger watershed to reduce nontarget environmental exposure, these uses may result in potential exposure to amphibians in treated water for a portion of their lifecycle and to birds and mammals utilizing treated waterbodies for drinking water. The mosquito control use has an initial concentration of 200 ppm ADBAC and represents the greatest risk to terrestrial animals. The algal control initial target concentration is 5 ppm ADBAC. At 200 ppm, RQs for amphibians are 0.71 for acute risk and 6.2 for chronic risk. RQs for birds drinking treated water range from 0.09 to 0.32. Smaller birds face greater acute risk. Chronic risk to birds is presumed due to lack of data. Neither acute nor chronic mammalian acute RQs exceed the LOCs at the 200 ppm initial concentration.

Once-through Cooling Tower Use

Tier I once-through cooling tower modeling indicates that ADBAC use will result in acute and chronic risk to non-endangered and endangered/threatened freshwater fish and acute risk to other aquatic animals at all 3 dosages modeled: 2.0 ppm, 5.0 ppm, and 10.0ppm. High water flow, and intermittent dosing at 10.0 ppm had less acute and chronic impact on non-endangered freshwater fish than medium to low stream flow. However, LOC's for all aquatic animals were triggered at the 2.0 ppm dosage using continuous dosing regardless of high, medium, or low stream flow. Green algae were only adversely affected from use of continuous dosing in combination with low stream flow conditions. The continuous dosing, low flow nontarget plant LOC is triggered at all 3 dosages modeled. The aquatic plant risk assessment is incomplete due to a number of outstanding studies. Direct ADBAC exposure to terrestrial animals is not expected to occur from the once-through cooling tower use.

Antisapstain Wood Treatment Use

Terrestrial animal species are not expected to be directly impacted by this ADBAC use. Nontarget aquatic species (fish, invertebrates, green algae) are not expected to be at risk (acute or chronic) based on LOCs. Endangered/threatened fish and green algae species are not expected to be at risk from the ADBAC antisapstain use. Freshwater and marine aquatic invertebrates are expected to be at risk from ADBAC antisapstain use unless methods are used to prevent runoff from the treatment site (Ex. store treated wood indoors, cover treated wood and use berms or plastic barriers in outdoor storage areas). However, ADBAC is tightly adsorbed to clay and organic matter which greatly reduces potential for ADBAC to leach downward through soil to groundwater or move via surface runoff. The Tier I screening model is only intended as a screening-level model, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations.

c. Risk to Endangered (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 andronomus 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.

The endangered species Alternative Consultation Agreement (ACA) with NMFS, and FWS will take time to implement fully, depending on available resources. The Agency is currently preparing risk assessments with the services on 9 high priority agricultural pesticides. Endangered species assessments of antimicrobial and additional agricultural pesticides will commence in 2008 under the Registration Review program.

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 ADBAC with the exception of the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain wood preservation uses, fall into this category. Using Tier I screening modeling to assess potential exposure from the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain wood preservation uses of ADBAC 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 ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain uses of ADBAC. 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 ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain uses of ADBAC until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain use of ADBAC 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 ADBAC 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 ADBAC.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient ADBAC. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient, ADBAC, the Agency has sufficient information on the human health and ecological effects of ADBAC 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 ADBAC-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. Label changes are described in Section V. Appendix A summarizes the uses of ADBAC 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 ADBAC 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 ADBAC, the Agency has determined that ADBAC 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 ADBAC. If all changes outlined in this document are incorporated into the product labels, then all current risks for ADBAC 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 ADBAC. During the public comment period on the risk assessments, which closed on June 26, 2006, the Agency received comments from the ADBAC Consortium, Reckitt Benckiser, and The Clorox Company regarding the risk assessments assumptions. These comments in their entirety are available in the public docket, at http://www.regulations.gov (OPP-2006-0339).

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 ADBAC. The Agency has concluded that the risk from dietary exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. 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 ADBAC. The Agency has determined that food uses of ADBAC, 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 ADBAC. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of ADBAC.

As discussed in Section III, the chronic dietary aggregate risks from direct and indirect food contact as well as drinking water exposures for adults and children are below the Agency's level of concern provided that mitigation measures outlined in this document are adopted and labels are amended.

Since ADBAC toxicity endpoints for oral, dermal, and inhalation routes of exposure are based on different toxic effects, these three routes of exposure are not aggregated together for the short- and intermediate-term aggregate assessment. Instead, the short- and intermediate-term aggregate assessment is based solely on the co-occurrence of the same route of exposures. Only the short –term aggregate is presented because the endpoints for incidental oral and inhalation are identical for the short- and intermediate-term durations, and only a short term dermal exposure duration was identified. The aggregate risks are not of concern for adults and children for any of the three routes of exposure; the risk estimates were above the target MOE.

c. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of ADBAC, 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 ADBAC 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 ADBAC 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 ADBAC based on (1) the existence of a complete developmental and reproductive database (2) the lack of evidence for increased susceptibility in the data (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, ADBAC 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 ADBAC. 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 ADBAC. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Summary

Alkyl Dimethyl Benzyl Ammonium Chloride, (ADBAC) has tolerance exemptions in 40 CFR 180.940 (a) as a food contact sanitizer for use in public eating places, in dairies on processing equipment, and in food processing plants on equipment and utensils not to exceed the

limit of 200 ppm and (c) as a food contact sanitizer for use in food processing plants on equipment and utensils not to exceed the limit of 400 ppm.

Table 9: Tolerance Reassessment Summary for ADBAC

Tolerance Exemption Listed Under 40 CFR 180.940 (a)			
Use Site	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
Public eating places, dairies on processing equipment and utensils, and food processing plants on equipment and utensils	Total quat concentration does not exceed 200	Total quat concentration does not exceed 200	No change
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; total quat concentration does not exceed 400	Specific quat concentration does not exceed 200; total quat concentration does not exceed 400	No change

D. Regulatory Rationale

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

The following is a summary of the rationale for managing risks associated with the use of ADBAC. 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 chronic dietary risks from ADBAC residues on food, estimated using conservative measures, are below the Agency's level of concern. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

As an outdoor pesticide for use on nursery ornamentals, turf, and mosquito control in decorative fountain/ponds and puddles, ADBAC is expected to impact either surface or ground

water resources. There are no drinking water concerns since the risk estimates for children and adults were below the level of concern. Therefore, no mitigation measures are necessary at this time.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler risks were calculated for the short-term duration because it best represents most homeowner applications. The residential handler risks did exceeded the target MOEs for all scenarios. Therefore, no mitigation measures are needed at this time.

ii. Post-Application Risk Mitigation

As with the residential handler risk assessment, the post-application risks were also calculated for the short-term duration because it best represents most homeowner applications. All residential post application risks were above the Agency's level of concern except for inhalation exposures due to use in humidifiers, based on the 24 hr inhalation MOEs for adults and children, 10 and 4, respectively and incidental oral exposure for children due to residential treatment of lawns, MOE 76.

At this time, there are no available mitigation measures for the humidifier use. Because of remaining residential exposure concerns, the registrants for ADBAC 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 ADBAC 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.

In order to mitigate the risks of concern scenario, the Agency is requiring that the maximum application rate for use on residential lawns must be reduced to 5.4 lb ai/A. The MOE at this application rate achieves the target of 100.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

EPA determined that the greatest potential for handler exposure appears to be the short- and intermediate-term inhalation exposure scenarios. In order to reduce the occupational handler risk, the following mitigation measures must be adopted:

Fogging in Agricultural Premises and Equipment: All labels must indicate that a dust mist respirator will be used when pouring the product into the fogging equipment.

Pulp and Paper: In order to mitigate the risks of concern for occupational handlers in pulp and paper mills, the Agency is requiring that the maximum application rate must be reduced to 14 lbs ai/ton of paper for products coupled with the use of a metering pump system (a closed system).

The MOE at this application rate achieves the target of 100, and thus addresses the inhalation risk of concern.

Once-through Cooling Water (average flow rate for high flow streams): In order to mitigate the risks of concern for occupational handlers in once-through cooling tower, the Agency believes that the maximum number of applications per year for this use pattern must be reduced to four. This reduction, together with the fact that application of these products utilizes metered pump (a closed system) addresses the inhalation risk of concern. (The reduction in the # of applications should also be added to the eco risk mitigation piece for cooling towers.)

Small Process Water Systems: All labels must indicate that a dust mist respirator will be used when applying the product to the water system.

Blender/Spray Application for Wood Preservation: Due to the conservative nature of the risk assessment and the proximity of the MOE to the target of 100 (MOE = 84) the Agency believes that actual exposures do not exceed the Agency's level of concern.

Mopping in Medical Premises: Due to the conservative nature of the risk assessment and the proximity of the MOE to the target of 100 (MOE = 95) the Agency believes that actual exposures do not exceed the Agency's level of concern.

ii. Post-Application Risk Mitigation

Except for the post-application scenario assessed for fogging in hatcheries and food processing plants, the occupational post-application dermal and inhalation exposures are assumed to be negligible. Based on the inhalation risk estimates for fogging in hatcheries, a 2 hour re-entry interval must be prescribed to all labels with this use to mitigate the inhalation risk. In regard to food processing plants, the label must indicate a 2 hour reentry interval as well as a minimum requirement of 4 air changes per hour (ACH). The registrants for ADBAC have agreed to conduct air monitoring data and/or provide additional air exchange information that would allow the Agency to further refine the risks associated with this use.

2. Environmental Risk Management

There is minimal environmental exposure from the indoor uses of products containing ADBAC therefore no mitigation measures are needed for these use patterns at this time.

Conversely, there is significant environmental exposure from the outdoor uses from products containing ADBAC; such as ornamental nurseries, golf/turf, once-through cooling water towers, and antisapstain wood treatment, each of which resulted in RQs that exceeded the Agency's level of concern. . In order to reduce the environmental risk, the following mitigation measures must be adopted:

Ornamental Nurseries: Application is limited to Spot Treatment of diseased ornamental plants and flowers at a maximum rate of 800 ppm and total use of 5 lbs A.I/ acre. Treatment is restricted to indoor uses or uses in which controlled conditions prevent runoff and exposure to the environment. In the case of diseased trees, the spot treatment of trees must be at least 100 feet from any pond, lake, stream, or river to prevent possible runoff of the product into the waterway.

The label must state "**Do Not Apply by Aerial Spray."**

Golf/Turf: For commercial application to golf courses, treatment is be limited to the "Greens and Tees" at a rate of 0.8 lbs A.I./acre (200 ppm) not to exceed treatment of 10 acres (2000 gallons) with retreatment at 10 day intervals not to exceed 6 treatments per year.

For residential application to turf/lawns, application is limited to Spot Treatment of diseased areas of the lawn/turf only at a maximum rate of 5.4 lbs A.I/acre not to exceed 25 gallons per 1000 sq. ft. Treatment must be repeated up to 6 times a year at 10 day intervals.

Mosquitocide: The product labels supporting this use must state:

This product is not intended to be used for broadcast mosquitocide application but rather is limited to small residential ponds, decorative ponds, and similar areas. The product labels must be revised to reflect the following:

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. This product controls mosquitoes where they breed (fountains, water displays, decorative pools, decorative ponds, sewage treatment systems, spas, hot tubs, swimming pools and standing water in old tires, empty tin cans, barrels, puddles, and water drains around buildings). Do not exceed 10 applications at a minimum of 10-day intervals per year. NOTE: Only out-of-season, not-in-service, or inactive spas, hot tubs, swimming pools require treatment for mosquito control. Do not treat during the swimming season. Spray from fountains treated with this product will not harm poolside plantings. DO NOT use when fish or other wildlife (for example, amphibians) are present.

Once-Through Cooling Water Tower: All labels must state "Do Not Apply This Product more than 4 times 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 release.

Antisapstain Wood Treatment: All product labels supporting this use must add the following text:

Treated lumber must be stored under cover, or indoors, or at least 100 feet 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, wetland, 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.

3. 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 ADBAC. 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 ADBAC with the exception of the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain wood preservation uses, fall into this category. Using Tier I screening modeling to assess potential exposure from the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain wood preservation uses of ADBAC 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 ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain uses of ADBAC. 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 ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain uses of ADBAC until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the ornamental nurseries, golf/turf/lawns, once-through cooling tower, and antisapstain use of ADBAC will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

ADBAC end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing ADBAC 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 ADBAC 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 ADBAC 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 Jacqueline Campbell-McFarlane at (703) 308-6416 with questions regarding generic reregistration.

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

By express or courier service:
Document Processing Desk (DCI/AD)
Jacqueline Campbell-McFarlane
Office of Pesticide Programs (7510P)
Room S-4900, 1 Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

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

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

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

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

Within eight months from the receipt of the PDCI:

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

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

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

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

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

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

Please contact 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, 1 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 ADBAC 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
Dermal Outdoor Exposure	875.1100, 875.1600	231
Inhalation Outdoor Exposure	875.1300, 875.1600	232
Descriptions of Human Activity (All Uses)	875.2800	133-1
Dietary-Residues in Food from Treating Countertops with ADBAC (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Non-Guideline	Non-Guideline
Surface-Wipe Pressure-Treated Wood Study	Non-Guideline	Non-Guideline
Special Aquatic Leaching Study on Wood	Non-Guideline	Non-Guideline
90 Day Inhalation – Rat	870.3465	82-4
Non-Target plant phytotoxicity (Seedling Emergency using rice)	850.4225	123-1
Vegetative Vigor using rice	850.4250	123-1
Aquatic plant growth toxicity (*Lemna gibba)*	850.4400	123-2
Chronic Aquatic Invertebrate Life Cycle - *Daphnia magna*	850.1300	72-4
Acute estuarine/marine organism (Eastern Oyster embryo larvae)	850.1055	72-3b
Aquatic plant growth (4 Algal toxicity – 4 species: green algal Selenastrum capricornutum (*Pseudokirshnerierlla subcapitata*), blue-green cyanobacteria (*Anabeana flos-aquae*), freshwater diatom (*Navicula pelliculosa*), marine diatom *(Skeletonema costatum*)	850.5400	123-2

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Special Aquatic Field Monitoring (Once-Through Cooling Water Towers)	Non-Guideline	Non-Guideline
Avian reproduction study –bob white quail	850.2300	
Honeybee toxicity studies	850.3030	171-4

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)

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
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)
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)

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
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)
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)
Termiticide	Wood	Preventive Treatment – wood impregnation	N/A	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 Product		
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/commercial turf/lawns, greenhouses/nurseries, fountains/water displays/decorative ponds/standing water, sewage treatment systems, spas, air conditioner/refrigeration condensate water systems, air washer and industrial scrubbing systems, once- through and recirculating industrial/commercial cooling water systems, pulp/paper mill 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
PPE Requirements[1]	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
Pulp and Paper Applications *	Product labels listing uses for treatment of pulp/paper process components (eg., paper machine white water; catalase control in deinking loops; starch and sizing; coatings; fillers; pigments; adhesives; etc.), and which contain active ingredients not cleared by FDA for food contact, must state "For non-food use only". Those cleared for food contact, may state "For food and non-food contact".	Directions for Use
Ecological Effects 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
Physical and Chemical Hazards*	Do not use or store near heat or open flame. Do not mix with oxidizers, soap, or other anionic materials	Physical and Chemical Hazards
End-Use Products for Commercial, Industrial, Institutional 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
Fogging in Hatcheries	2 hour Reentry Interval for fogging applications	Directions for Use
Fogging in Food Processing Plants	2 hour Reentry Interval for fogging applications and a minimum of 4 air exchanges (ACH) per hour in the facility	
Swimming Pools*	Do not apply when swimmers are in the immediate vicinity (the Agency recommends a 15 minute reentry interval)	Directions for Use
Wood Preservation	Label must include dilution rate and retention chart specific to the type of wood used 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 ADBAC shall not be used in the construction of bee hives.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Agricultural fogging (loading)	Labels must indicate that a dust mist respirator must be worn when applying the product to the fogging equipment.	Directions for Use
Pulp and Paper	Maximum use rate is 14 lb ai/ton of paper. Product labels involving treatment of pulp and paper processes (eg., treatment of paper machine white water; catalase control in deinking loops; starch and sizing; coatings; fillers; pigments; adhesives; etc.), which result in finished products which may have direct or indirect food contact, must have FDA clearance for the entire formula via a food additive petition, and must state whether each use is cleared for "food contact" uses, and/or involves "non-food contact" uses. Products without FDA clearance must state: Do not use to treat paper or paperboard which will contact food.	Directions for Use
Small Process Water Systems	Labels must indicate that a dust mist respirator must be worn when applying the product to the water system.	Directions for Use
Hand Sanitizer	Delete the Use	Delete all claims and Directions for Use
Udders, Teats and Flanks	Delete the Uses	Delete all claims and Directions for Use
Treatment of Hatching Eggs	Delete the Use	Delete all claims and Directions for Use
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
Sanitizing Hatchery Rooms*	Label must include the following text: Remove all animals and feed from premise, vehicles and enclosures.	Directions for Use
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
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

Description	Amended Labeling Language	Placement on Label
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
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 " to the must be added or the following MOU language from PR Notice 94-4: 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
Hard nonporous surfaces in Institutional/Commercial Food Handling Facilities*	After disinfection, a potable water rinse is required. Do not use to disinfect appliances, refrigerator interiors, and microwave oven interiors. Do not use on dishes, glasses, and utensils.	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
Disinfection/Sanitizing Drains/Disposals*	Delete the claim because the Agency believes it is not feasible to disinfect throughout a drain w/ or w/o 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
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, wetland, 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 a minimum ratio 5 ppm clay to 1 ppm product. Deactivation must occur prior to discharge of the NPDES outfall.	Directions for Use
Ornamental Uses	Application is limited to Spot Treatment of diseased ornamental plants and flowers at a maximum rate of 800 ppm and total use of 5 lbs A.I/ acre. Treatment is restricted to indoor uses or uses in which controlled conditions to prevent runoff and exposure to the environment. In the case of diseased trees, the spot treatment of trees must be at least 100 feet from any pond, lake, stream, or river to prevent possible runoff of the product into the waterway. **Do Not Apply by Aerial Spray.**	Directions for Use
Golf/Commercial Turf/Lawn	For commercial application to golf courses, the treatment is limited to the "Greens and Tees" at a rate of 0.8 lbs A.I./acre (200 ppm) not to exceed treatment of 10 acres (2000 gallons) with retreatment at 10 day intervals not to exceed 6 treatments per year.	Directions for Use
Mosquitocide	The product labels must state: This product is not intended to be used for broadcast mosquitocide application but rather is limited to small residential ponds, decorative ponds, and similar areas. 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. This product controls mosquitoes where they breed (fountains, water displays, decorative pools, decorative ponds, sewage treatment systems, spas, hot tubs, swimming pools and standing water in old tires, empty tin cans, barrels, puddles, and water drains around buildings). Do not exceed 10 applications at a minimum of 10-day intervals per year. NOTE: Only out-of-season, not-in-service, or inactive spas, hot tubs, swimming pools require treatment for mosquito control. Do not treat during the swimming season. Spray from fountains treated with this product will not harm poolside plantings. DO NOT use when fish or other wildlife (for example, amphibians) are present.	Directions for Use

Description	Amended Labeling Language	Placement on Label
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 Table 1 and 2 for Remediation Directions for Use	Directions for Use
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.	Precautionary Statements:
Hard nonporous 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
Disinfection/Sanitizing Drains/Disposals*	Delete the claim because the Agency believes it is not feasible to disinfect throughout a drain w/ or w/o 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
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
Humidifiers	Delete the Use	
Residential Turf/Lawn	For residential lawns/turf, application is limited to Spot Treatment of diseased areas of the lawn/turf at a maximum use rate of 5.4 lbs A.I/acre (800 ppm) not to exceed 25 gallons per 1000 sq. ft. Treatment must be repeated up to 6 times a year at 10 day intervals.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Residential Mosquitocide	The product labels must state: This product is not intended to be used for broadcast mosquitocide application but rather is limited to small residential ponds, decorative ponds, and similar areas. The product labels must be revised to reflect the following: 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. This product controls mosquitoes where they breed (fountains, water displays, decorative pools, decorative ponds, sewage treatment systems, spas, hot tubs, swimming pools and standing water in old tires, empty tin cans, barrels, puddles, and water drains around buildings). Do not exceed 10 applications at a minimum of 10-day intervals per year. NOTE: Only out-of-season, not-in-service, or inactive spas, hot tubs, swimming pools require treatment for mosquito control. Do not treat during the swimming season. Spray from fountains treated with this product will not harm poolside plantings. DO NOT use when fish or other wildlife (for example, amphibians) are present.	Directions for Use
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 Table 1 and 2 for Remediation Directions for Use	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 ADBAC Label

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					
10324-21	Small Process Water Systems	Re-circulating Cooling Tower	Pour Metered	Wear dust mist respirator when applying product to system	795,000 ppm Initial = 39.8 ppm Maint.= 14.9 ppm
10324-102	Small Process Water Systems	Waste water treatment Evaporative condenser	Pour Metered	Wear dust mist respirator when applying product to system	795,000 ppm Initial = 39.8 ppm Maint.= 14.9 ppm
6836-58	Industrial Recirc Water Systems	Pulp/Paper	Metered	Max appl. rate must be reduced to 14 lbs ai/ton of paper	226 ppm
10324-21	Industrial Water Systems	Once-through Cooling	Metered	Do Not Apply This Product More Than 4 Times Per Year Label must carry NPDES statement	Initial = 10.6 ppm Maint.= 5.6 ppm Based on treatment of 153,000,000 gallons of water
6836-234	Small Process Water Systems	Brewery pasteurizers	Pour Metered	Wear dust mist respirator when applying product to system	795,000 ppm Initial = 39.8 ppm Maint.= 14.9 ppm
1839-179	Oil Field	injection and wastewater packer fluids drilling muds	continuous injection batch treatment		119,000 ppm
Swimming Pools					
1839-141		Swimming Pool/ Outside Spas/Whirlpools/Hot Tub Bath	Pour	Do not apply when swimmers are in the immediate vicinity (Allow 15 minute REI)	Initial/Winter. = 6.2 ppm Maint. = 1.2 ppm
Aquatic Areas					
53642-1		fountains, water displays, decorative pools, decorative ponds, sewage treatment systems, spas, standing water	spray	Refer to Table 13. Labeling Changes Summary Table p. 71 and 73	203 ppm for Mosquito Control
499-368	Greenhouse/Nurseries	decorative pools, fountains, water displays	pour		Initial= 6.2 ppm Maint. = 1.2 ppm
499-482	Greenhouse/Nurseries	watering lines, watering tubes, emitters, drip lines, watering nozzles and hoses	pour, immerse		6.2 ppm
Wood Preservatives					
6836-308		lumber	Pressure Treatment Double vacuum	Refer to Table 13. Labeling Changes Summary Table p. 68	3% AI solution
1839-184		lumber	Dip/Brush/Spray surface treatment	Refer to Table 13. Labeling Changes Summary Table p. 68	3% AI solution

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-184		lumber	dip, spray	Refer to Table 13. Labeling Changes Summary Table p.70	3% AI solution for sapstsain control
Agricultural Premise and Equipment					
10324-118	Animal facilities, hog/swine/poultry farms	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, feeders, fountains, drinkers, blocks, chutes, incubators, hatchers, waterers, feeders, fountains, hauling equipment, loading equipment, kennels, runs, cages, coops, crates, pens, trays	Fogging	Wear a dust mist respirator when pouring product into fogging equipment	0000675 lb ai/ 1000 ft^3
1839-81	hatcheries	hatchery rooms	Fogging	Wear a dust mist respirator when pouring product into fogging equipment 2 hr reentry interval	.0000675 lb ai/ 1000 ft^3
10324-81	hatcheries	incubators, setters, hatchers	Fogging	Wear a dust mist respirator when pouring product into fogging equipment	
67517-15	hatcheries	egg shell sanitizing	spray, immersion,		200 ppm
1839-155	Animal facilities, farms, mushroom farms, animal life science laboratories, animal quarters, other animal care facilities, hatcheries, stables, catteries, stalls, animal transportation vehicles Dairy/equine/hog/ swine/ poultry/turkey farms, barns, pens, egg receiving area, egg holding area, setter s, trays, chick holding room, poultry buildings, dressing plants, offal rooms, blocks, creep areas	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, feeders, fountains, drinkers, blocks, chutes, incubators, hatchers, waterers, feeders, fountains, hauling equipment, loading equipment, kennels, runs, cages, coops, crates, pens, trays, shoes, gloves	mop, immersion, cloth, sponge, spray		2036 ppm
10324-80	citrus grove or farm	trucks, vehicles, equipment, trailers, field harvesting equipment, cargo area, wheels, tires, under carriage, hood, roof, fenders	trigger spray, immersion, mopping		2036 ppm Treat Citrus canker

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1072-16	stables, dairies	Dairy and Hoof trimming equipment	cloth, mop, sponge, spray, immersion		2036 ppm
507-3	greenhouses, nurseries	ornamental crops	drench or spray	Do Not Apply by Aerial Spray. Refer to Table 13. Labeling Changes Summary Table p. 71	Spot Treatment max. rate of 800 ppm Total Use = 5 lbs AI/ acre
507-3	greenhouses, nurseries	gloves	immersion		2036 ppm
53642-1	greenhouses, nurseries	work areas, benches, pots, flats, flower buckets, cutting tools, greenhouse glass, bird baths, walkways, houseplants	Spray, mopping, Swab, immersion		2036 ppm
53642-1	greenhouses, nurseries	lawns, golf courses, commercial turf	Spray	**Commercial** =Limit Treatment to "Greens and Tees" Retreatment at 10 day intervals not to exceed 6 treatments per year **Residential** = Only Spot Treatment of diseased areas. Treatment repeated up to 6x a year at 10 day intervals.	**Commercial** = 200 ppm not to exceed treatment of 10 acres **Residential** = 800 ppm not to exceed 25 gallons per 1000 sq. ft.
499-368	greenhouses, nurseries	cutting tools	Immersion/ Spray/Wipe		2036 ppm
499-368	greenhouses, nurseries	evaporative coolers, cooler pads	Spray or swab		2036 ppm
Medical premises and equipment					
10324-111	day-care centers, hospitals, medical/dental offices, nursing homes, other health care institutions, mortuaries, autopsy rooms, EMS facilities, medical research facilities, patient care rooms, recovery anesthesia rooms, operating rooms	Metal, stainless steel, glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, enameled surfaces, painted woodwork, Formica, plastic upholstery, floors, walls, toilets, urinals, lavatories, bathtubs, sinks, sink tops, shower stalls, shower doors/curtains, mirrors, ultrasonic bath, whirlpools, countertops, cabinets, tables, chairs, desks, bed springs, bed frames, traction devices, MRI, CAT, examining tables, scales, paddles, wheelchairs, lifts, door knobs, linen carts, hampers, telephones, fixtures, toys, high chairs, cribs, changing tables	mop, pour, immersion		2080 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1203-41	hospitals, nursing homes, clinics	tables,walls, ceramic tiles, metal surfaces, plastic, asphalt, finished/painted wood and glass	spray, mop, sponge		2080 ppm
1839-81	Hospitals	carpet	Portable extraction units, truck mounted extraction machines, rotary floor machines, metered, spray		16,800 ppm
1839-110	hospital	Laundry	Pour @ final rinse in wash cycle		0.10 lb AI/ 100 lbs dry laundry
1839-81	autopsy rooms, funeral homes,	human remains	sponge, wash cloth, soft brush		2080 ppm
62401-6	nursing homes	walls, telephones, chairs, tables, sinks, counters, appliance exteriors, garbage cans, stovetops	Presaturated wipe		2080 ppm
7211-10	Medical Premises & Equipment	critical instruments	immersion	Instruments must be sterilized after disinfection	2490 ppm
Commercial, institutional, and industrial premises and equipment					
10324-118	hair/nail salons, barber beauty shops, tanning salons, tattoo parlors, veterinary clinics, locker facilities, shopping malls, motels, hotels, bookstores, dressing rooms, photo copy centers, bicycle shops, toy factories, computer manufacturing sites, burial vaults, mausoleums, jails, penitentiaries, transportation terminals, Cruise ships, airplanes, schools, universities, churches, libraries, cosmetic manufacturing facilities, medical device manufacturing facilities, pharmaceutical manufacturing facilities, bowling alleys, crime scenes, pet shops, grooming and breeding establishments, zoos, tack shops, atheletic facilities, Sport Arenas,	floors, walls, toilets, urinals, bathrooms, bathtubs, sinks, countertops, shower doors/curtains, toilet seats, shower stalls, ultrasonic bath, whirlpools, barber/salon instruments/tools, tables, chairs, shelves, telephones, cabinets, desks, tanning beds, bed springs, door knobs, linen carts, hampers, garbage pails, telephones, recycling equipment, exercise equipment, personal safety equipment, automobile/truck interiors, garbage cans/pails, metal, stainless steel, glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, chrome plated intakes, enameled surfaces, painted woodwork, Formica, vinyl and plastic upholstery, terrariums, cages, and cage furniture	mop, wipe (cloth, swab), pour, immersion		2080 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-81	manufacturing sites/facilities	Floors, walls, counters, stainless steel, glazed porcelain, granite, vinyl, glass, chrome	fogging	Wear a dust mist respirator when pouring product into fogging equipment	0000246 lb ai/ 1000 ft^3
6836-193	hair/nail salons, barber beauty shops, tanning salons, tattoo parlors, veterinary clinics, locker facilities, shopping malls, motels, hotels, bookstores, dressing rooms, photo copy centers, bicycle shopes, toy factories, computer manufacturing sites, burial vaults, mausoleums, jails, penitentiaries, transportation terminals, Cruise ships, airplanes, schools, universities, churches, libraries, cosmetic manufacturing facilities, medical device manufacturing facilities, pharmaceutical manufacturing facilities, bowling alleys, crime scenes, pet shops, grooming and breeding establishments, zoos, tack shops, atheletic facilities, Sport Arenas,	hair/nail salons, barber beauty shops, tanning salons, tattoo parlors, veterinary clinics, locker facilities, shopping malls, motels, hotels, bookstores, dressing rooms, photo copy centers, bicycle shopes, toy factories, computer manufacturing sites, burial vaults, mausoleums, jails, penitentiaries, transportation terminals, Cruise ships, airplanes, schools, universities, churches, libraries, cosmetic manufacturing facilities, medical device manufacturing facilities, pharmaceutical manufacturing facilities, bowling alleys, crime scenes, pet shops, grooming and breeding establishments, zoos, tack shops, atheletic facilities, Sport Arenas,	spray (RTU spray		2980 ppm
1839-81	hotels, motels, dressing romms, bowling alleys, salons, libraries, office buildings, schools, universities	Carpet	portable extraction units, truck mounted extraction machines, rotary floor machines, metered, spray		16,800 ppm
62401-6	schools, food service establishments	telephones, walls, chairs, tables, sinks, counters, appliance exteriors, garbage cans, stovetops	Presaturated wipe		2080 ppm
1839-110	commercial	laundry	Pour @ final rinse in wash cycle		0.10 lb AI/ 100 lbs dry laundry
1839-81	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, RTU spray		2036 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-85	hair/nail salons, barber beauty shops, tanning salons, tattoo parlors, veterinary clinics, locker facilities, shopping malls, motels, hotels, bookstores, dressing rooms, photo copy centers, bicycle shopes, toy factories, computer manufacturing sites, burial vaults, mausoleums, jails, penitentiaries, transportation terminals, Cruise ships, airplanes, schools, universities, churches, libraries, cosmetic manufacturing facilities, medical device manufacturing facilities, pharmaceutical manufacturing facilities, bowling alleys, crime scenes, pet shops, grooming and breeding establishments, zoos, tack shops, atheletic facilities, Sport Arenas,	air deodorizer/air freshener	RTU spray		0.2% ai by weight
32977-1	schools and music studios	wind instruments	Immersion		596 ppm
507-3	industrial premises	gloves	Immersion		2036 ppm
Residential and public access premises					
10324-111	RVs, motor homes	RV Holding Tank	Pouring		0.834 lb ai/gal
6836-193	Households, campgrounds, playgrounds, picnic facilities, recreational facilities, other public facilities	Floors, walls, windows, toilets, bathtubs, whirlpools, shower stalls, shower door/curtain, sinks, mirrors, restroom fixtures, cabinets, tables, chairs, desks, bed frames, doorknobs, garbage cans/pails, picnic tables, outdoor furniture, telephones, countertops, external surfaces of appliances, tables, sinks, shelves, plastic chopping blocks, metal, stainless steel, glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, chrome plated intakes, enameled surfaces, painted woodwork, Formica, vinyl, plastic upholstery, terrariums, cages, and cage furniture	RTU spray/mop		2980 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-68	homes	Carpet	portable extraction units, truck mounted extraction machines, rotary floor machines, metered, spray		16,680 ppm
1839-85	homes	air deodorizer/air freshener	RTU spray		0.2% a.i. by weight
32977-1	Homes	Musical instrument mouthpieces and reeds	immersion		596 ppm
1839-110	Homes	Laundry	Pour @ final rinse in wash cycle		0.10 lb AI/ 100 lbs dry laundry
1839-155	homes	water softeners and reverse osmosis units	Liquid Pour		200 ppm
Food handling/storage establishments premises and equipment					
10324-111	restaurants, bars, supermarket, convenience stores, pizza parlors, meat and poultry processing plants, rendering plants, fish, milk, wine, citrus processing facilities, institutional kitchens, food storage areas, tobacco processing facilities, ood service establishments, food processing plants/facilities, beverage processing plants, Cafeterias, Dairies, Egg Processing plants, Federally inspected meat and poultry plants, Food Handling areas, Food preparation areas, Food storage areas, 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 metal, stainless steel, glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, chrome plated intakes, enameled surfaces, painted woodwork, Formica, vinyl and plastic upholstery	mop, wipe (cloth, swab), pour, immersion mop, (cloth, swab), pour, immersion		**Disinfect** 2080 ppm **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
507-3	dairies and food processing plants	gloves	Immersion		2036 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
1839-86	federally inspected meat and poultry plants, food processing facilities, dairies, tobacco processing facilities, beverage processing facilities	Shoe	immersion/ foam generating machine/ aerator		2036 ppm
6836-193 (Disinfect)	restaurants, bars, supermarket, convenience stores, pizza parlors, meat and poultry processing plants, rendering plants, fish, milk, wine, citrus processing facilities, institutional kitchens, food storage areas, tobacco processing facilities, ood service establishments, food processing plants/facilities, beverage processing plants, Cafeterias, Dairies, Egg Processing plants, Federally inspected meat and poultry plants, Food Handling areas, Food preparation areas, Food storage areas, 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 metal, stainless steel, glazed porcelain, glazed ceramic tile, plastic, granite, marble, chrome, vinyl, glass, chrome plated intakes, enameled surfaces, painted woodwork, Formica, vinyl and plastic upholstery	RTU Spray		2036 ppm
1839-155	Restaurants, Food Service Establishments, Bars, Cafeteria, Convenience Stores, Dairies, Food Handling Areas, Food Preparation Areas, Food Storage Areas Institutional Kitchens, Fast Food Operations	dairy equipment, dairy farm bulk milk tanks, milking equipment, tanks, piping, pasteurizers, cow udders, dairy product dispensing equipment, drinking glasses, eating utensils, cooking utensils, silverware, glassware, dishes, ice machines, beverage dispensing equipment, counters, tables, cutting boards, Slurrpy machines, ice cream dispensing equipment, food dispensing equipment, utensils and other food contact articles	spray, flood, immersion, brushing, RTU spray		**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
1839-155	Food processing plants, food service establishments	water softeners and reverse osmosis units			200 ppm

EPA Reg Number used for Max. Appl. Rate	Use Site	Treatment Site/Surfaces	Method of Application	Mitigation	Maximum Application Rate
10324-118	dairies, beverage and food processing plants	room surfaces	fogging	Wear a dust mist respirator when pouring product into fogging equipment 2 hr reentry interval Minimum of 4 air exchanges per hour	.0000027 lb ai/ 1000 ft^3
1203-41	food processing plants, food service areas, institutional kitchens, industrial/hospital cafeterias, school lunchrooms, canning plants, dairies, and packing plants	tables, walls, ceramic tiles, metal surfaces, plastic, asphalt, finished/painted wood and glass	Spray, mop, sponge		2080 ppm
Cleaning/ Deodorizing					
1839-81	Water/Smoke restoration (institutional, industrial, hospital, nursing home)	carpets, carpet cushion, sub floors, drywall, trim, farm lumber, tackless strip and paneling	Mop, cloth, brush, sponge, sprayer	Refer to Table 13 (Label Changes Summary Table) for appropriate label restrictions	16,800 ppm
10324-118	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 (Label Changes Summary Table) for appropriate label restrictions	16,800 ppm
10324-118	residential, commercial, institutional, industrial,	garbage cans, garbage trucks, industrial waste receptacles, garbage handling equipment	sprayer, sponge, cloth,		2036 ppm

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 #0350 (ADBAC) covered by this RED. It contains generic data requirements that apply to ADBAC 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 ADBAC

PRODUCT CHEMISTRY

New Guideline Number	Old Guideline Number		Use Pattern	Citation
830.1550	61-1	Product Identity and Composition	All	4446702
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	4446702
830.1670	61-2B	Formation of Impurities	All	44467401
830.1700	62-1	Preliminary Analysis	All	4446702
830.1750	62-2	Certification of limits	All	4446702
830.1800	62-3	Analytical Method	All	4446702
830.6302	63-2	Color	All	44467403
830.6303	63-3	Physical State	All	44467403
830.6304	63-4	Odor	All	44467403
830.7050	None	UV/Visable Absorption	All	44467403
830.7200	63-5	Melting Point	All	44467403
830.7220	63-6	Boiling Point	All	44467403

New Guideline Number	Old Guideline Number		Use Pattern	Citation
830.7300	63-7	Density	All	44467403
830.7840 830.7860	63-8	Solubility	All	44467403
830.7950	63-9	Vapor Pressure	All	44467403
830.7370	63-10	Dissociation Constant	All	N/A
830.7550	63-11	Octanol/Water Partition Coefficient	All	44467403
830.7000	63-12	pH	All	44467403
830.6313	63-13	Stability	All	44467403
830.6314	63-14	Oxidizing/Reducing Action	All	N/A
830.6315	63-15	Flammability	All	44467403
830.6316	63-16	Explodability	All	N/A
830.6317	63-17	Storage Stability	All	44467403
830.7100	63-18	Viscosity	All	44467403
830.6319	63-19	Miscibility	All	N/A
830.6320	63-20	Corrosion characteristics	All	44467403

ECOLOGICAL EFFECTS

New Guideline Number	Old Guideline Number		Use Pattern	Citation
850.2100	71-1	Avian Acute Oral Toxicity	All	42885901
850.2100	71-1	Avian Acute Oral Toxicity	All	42885901
850.2200	71-2B	Avian Dietary Toxicity – Duck	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	
850.2300		Avian Reproduction (Mallard or Bobwhite)	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	
850.2400	71-3	Wild Mammal Toxicity	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Refer to Toxicology Data
850.1075	72-1A	Fish Toxicity Bluegill	All	41947201
850.1075	72-1C	Fish Toxicity Rainbow Trout	All	41947202
850.1010	72-2A	Aquatic Invertebrate Toxicity	All	41947203
None	72-3A	Estuarine/Marine Toxicity - Fish	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	42479502
850.1055	72-3B	Estuarine/Marine Toxicity - (Eastern Oyster embryo larvae)	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
None	72-3C	Estuarine/Marine Toxicity - Shrimp	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	42479501
None	72-4A	Fish- Early Life Stage	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	42302102

New Guideline Number	Old Guideline Number		Use Pattern	Citation
850.1300	72-4	Aquatic Invertebrate Life Cycle- Daphnia magna	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
850.440	123-2	Aquatic Plant Growth – Lemna gibba	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
850.5400	123-2	Aquatic Plant Growth (4 species) Green alga (Pseudokerschneria subcapitatum), blue-green alga (Anabaena flos-aquae), freshwater diatom (Navicula sps.), and marine diatom (Skeletonema costatum)	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
850.4225	123-1	Non-target Terrestrial Plant Phytotoxicity (seedling emergence test using rice)	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
850.4250	123-1	Non-target Terrestrial Plant Phytotoxicity (Vegetative vigor using rice)	Wood Preservation, Sapstain, Ornamental Nurseries, Turf, Once Through Cooling Water	Data Gap
850.3020	141-1	Honey Bee Acute Contact	Wood Preservative	Data Gap
850.1950		Aquatic Field Monitoring (Once-Through Cooling Water Towers)	Once Through Cooling Water	Data Gap

TOXICOLOGY

New Guideline Number	Old Guideline Number		Use Pattern	Citation
870.1100	81-1	Acute Oral Toxicity-Rat	All	45109204

New Guideline Number	Old Guideline Number		Use Pattern	Citation
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	45109202
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	44885201
870.2400	81-4	Primary Eye Irritation-Rabbit	All	40919701, 44825001
870.2500	81-5	Primary Skin Irritation	All	45109201
870.2600	81-6	Dermal/Photo- Sensitization	All	45109203, 40958501, and 44825002
870.3100	82-1A	Oral Subchronic - Rat	All	40746601
870.3200	82-2	21-Day Dermal – Guinea Pig	?	41105801
870.3250	82-3	90-Day Dermal – Rat	All	41499601
870.3465	82-4	90-Day Inhalation – Rat	All	Data Gap
870.3700 (a)	83-3A	Developmental Toxicity - Rat	All	42351501
870.3700 (b)	83-3B	Developmental Toxicity - Rabbit	Swimming pool & Wood Preservative	42392801
870.3800	83-4	2-Generation Reproduction - Rat	Indirect Food	41385001
870.4100	83-1B	Chronic Feeding Toxicity –Non Rodent	Indirect Food	43221101
870.4200(b)		Oncogenicity –Mouse	Swimming pool & Wood preservative	41765201
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	Swimming pool & Wood preservative	41947501

New Guideline Number	Old Guideline Number		Use Pattern	Citation
870.5300	84-2A	Gene Mutation (Ames Test)	All	41012701
870.5385	84-2B	Structural Chromosomal Aberration	All	40311101
870.5550	84-4	Unscheduled DNA Synthesis	All	42290801, 42290802
870.7485	85-1	General Metabolism	Indirect Food	40990701

OCCUPATIONAL and RESIDENTIAL EXPOSURE

New Guideline Number	Old Guideline Number		Use Pattern	Citation
875.2800	133-1	Description of Human Activity	All	Data Gap
875.1100 875.1200 875.1600	231 233 236	Outdoor/Indoor Dermal Exposure	All	417426-01, 425875-01
875.1300 875.1400 875.1600	232 234 236	Outdoor/Indoor Inhalation Exposure	All	455021101, 455243-04
Special Study		Surface Wood Wipe Study	Wood Preservative	Data Gap

ENVIRONMENTAL FATE

New Guideline Number	Old Guideline Number		Use Pattern	Citation
835.2120	161-1	Hydrolysis	All	408356-02
835.2240	161-2	Photodegradation - Water	Wood Preservative	40835603
835.4400	162-3	Anaerobic Aquatic Metabolism	Once Through Cooling Water Wood Preservative	41105501, 42415101
835.4300	162-4	Aerobic Aquatic Metabolism	Once Through Cooling Water Wood Preservative	40835604
835.1240	163-1	Leaching/Adsorption/Deadsorption	Wood Preservative	40835605, 42414801
None	165-4	Bioaccumulation in Fish	Wood Preservative	41026801
Special Study		Biodegradability	Not Required	46865601

RESIDUE CHEMISTRY

New Guideline Number	Old Guideline Number		Use Pattern	Citation
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg	Indirect Food	FDA, 2003. "Sanitizing Solutions: Chemistry for food Additives petitions." Http://www.cfasan.fda.gov/-dms/opa-cg3a Last accessed June 9, 2003
Special Study		Dietary Residues in Food from Treating Countertops with ADBAC (FDA Wipe Study Methodology)	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 (South Building), 2777 South Crystal Drive, Arlington, VA 22202. 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. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

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

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

These documents include:

1. Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Risk Assessment, 8/1/06

2. Toxicology Disciplinary Chapter for the Re-Registration Eligibility Decision (RED) Risk Assessment Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC), 8/10/06

3. Dietary Risk Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) for Reregistration Eligibility Decision (RED) Process, 7/27/06

4. Ecological Hazard and Environmental Risk Assessment of ADBAC for the Reregistration Eligibility Document (RED) – Antimicrobial Uses, 8/2/06

5. PDM4 Modeling of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) 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 Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) for the Reregistration Eligibility Decision (RED) Document, 7/27/06

9. Incident Reports Associated with Quaternary Ammonium Compounds (Quats), 2/15/06

10. Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment – Antimicrobial Uses, 7/27/06

11. Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC): Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document – Agricultural Uses, 7/31/06

12. Appendix A Standard Methods for Calculating Occupational Exposures to ADBAC, 7/31/06

13. Product Chemistry Science Chapter for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC), 1/11/06

14. Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)- 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.

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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 ADBAC 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@epa.gov.

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

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

	Chemical Properties (PR Notice 98-1)	

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' website.

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

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

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

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

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: 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; and
   · Product Manager assignment.

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

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

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.