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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 1, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: Three Exemptions from the Requirement of a Tolerance for Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride and Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds

FROM: Pauline Wagner, Chief Pauline Wagner 8/1/06
Inert Ingredient Assessment Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of three inert ingredient exemptions from the requirement of a tolerance. Current exemptions are to be maintained.

Chemical: See Table 1 below.

Table 1. Tolerance Exemption Expression

40 CFR 180	Inert Ingredients	Limits	Uses (Pesticidal)	CAS Reg. No. and Names
910[a]	Dialkyl (C_8-C_{18}) dimethyl ammonium chloride	Not more than 0.2% in silica, hydrated silica.	Flocculating agent in the manufacture of silica, hydrated silica for use as a solid diluent, carrier	See Appendix A
920[b]	Mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds, where the alkyl group(s) (C_8- C_{18}) are derived from coconut, cottonseed, soya, tallow, or hogfat fatty acids.	None	Surfactants, related adjuvants of surfactants	See Appendix A

930[c]	Dialkyl (C_8- C_{18}) dimethylammonium chloride	Not more than 0.2% in silica hydrated silica.	Flocculating agent in the manufacture of silica hydrated silica for use as a solid diluent, carrier	See Appendix A

[a]Residues listed in 40 CFR 180.910 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities (RAC)s after harvest.

[b]Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.

[c]Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

Use Summary: Dialkyl (C8-C18) dimethyl ammonium chloride and mono and dialkyl (C8-C18) methylated ammonium chloride compounds are used as surfactants in cleaning agents and personal care products as well as having use as active ingredients in antimicrobial pesticide products

List Classification Determination: Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when used as inert ingredients in pesticide formulations applied to growing crops, RACs after harvest, and animals, the List Classification for dialkyl (C_8-C_{18}) dimethyl ammonium chloride and mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds will be List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the three exemptions from the requirement of a tolerance for the inert ingredients dialkyl (C_8-C_{18}) dimethyl ammonium chloride and mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds as well as the List Classification Determination described above. I consider the three exemptions established in 40 CFR 180.910, 920, and 930 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois Rossi

Lois A. Rossi, Director
Registration Division

August 1, 2006

Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

APPENDIX A

Chemical Names and CAS Reg. Nos. for Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride and Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds

Chemical Name	CAS Reg. No.
Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride	
1-Hexadecanaminium, N-hexadecyl-N,N-dimethyl-, chloride	1812-53-9
1-Tetradecanaminium, N,N-dimethyl-N-tetradecyl-, chloride	10108-91-5
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	7173-51-5
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride	107-64-2
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	5538-94-3
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	32426-11-2
Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds	
Quaternary ammonium compounds, bis(C8-18 and C18-unsatd. alkyl) dimethyl, chlorides	68918-78-5
Quaternary ammonium compounds, dicoco alkyldimethyl, chlorides	61789-77-3
Quaternary ammonium compounds, coco alkyltrimethyl, chlorides	61789-18-2
Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	8030-78-2
Quaternary ammonium compounds, trimethylsoya alkyl, chlorides	61790-41-8
Quaternary ammonium compounds, dimethyldisoya alkyl, chlorides	61788-92-9
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	7173-51-5
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	5538-94-3
1-Tetradecanaminium, N,N,N-trimethyl-, chloride	4574-04-3
1-Octadecanaminium, N,N,N-trimethyl-, chloride	112-03-8
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride	107-64-2
Quaternary ammonium compounds, di-C8-18-alkyldimethyl, chlorides	73398-64-8
1-Hexadecanaminium, N,N,N-trimethyl-, chloride	112-02-7
1-Dodecanaminium, N,N,N-trimethyl-, chloride	112-00-5
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	32426-11-2

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August 1, 2006

MEMORANDUM

SUBJECT: Reassessment of Three Exemptions from the Requirement of a Tolerance for Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride and Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds

FROM: Kerry Leifer
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

BACKGROUND

Attached is the science assessment for dialkyl (C_8-C_{18}) dimethyl ammonium chloride and mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds, quaternary ammonium compounds which, for the ease of reading, are collectively referred to by the abbreviation "DDAC" throughout this document. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of DDAC. The purpose of this document is to reassess the three exemptions from the requirement of a tolerance for residues of DDAC when used as an inert ingredient in pesticide formulations as required under the Food Quality Protection Act (FQPA).

EXECUTIVE SUMMARY

This document evaluates three tolerance exemptions from the requirement of a tolerance, including the use of dialkyl (C_8-C_{18}) dimethyl ammonium chloride as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920 and the use of mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds when used as a flocculating agent at not more 0.2% in the manufacture of silica/hydrated silica for use as a solid diluent or carrier as a pesticide inert ingredient applied to growing crops or raw agricultural commodities after harvest under 40 CFR 180.910 and applied to animals under 40 CFR 180.930. An inert ingredient is defined by the U.S. Environmental Protection Agency (EPA) as any ingredient in a pesticide product that is not intended to affect a target pest.

The DDAC compounds are cationic surfactants that are used as detergents in cleaning products and shampoos; emulsifying agents in creams and lotions; and wetting agents. Additionally, DDAC is the active ingredient in a number of registered antimicrobial pesticide products.

This reassessment is based upon a risk assessment performed on DDAC in support of a Reregistration Eligibility Document (RED) for the Group I Quat Cluster (EPA 2006a). The Group I Quat Cluster is a group of structurally similar quaternary ammonium compounds ("quats") that have a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C_8 or longer) and two methyl substituents and an anionic counter ion of chloride or bromide.

The quaternary ammonium compounds considered under the risk assessment for the Group I Quat Cluster also comprise the predominant segment of the quaternary ammonium compound inert ingredient tolerance exemption expressions given in Table 1. The quaternary ammonium compounds considered under the Group I Quat Cluster RED risk assessment have been determined to have identical or similar physical, chemical and toxicological properties to the quaternary ammonium compounds included under the tolerance exemptions given in Table 1, therefore the risk assessment findings for the Group I Quat Cluster also apply to the inert ingredient tolerance exemptions given in Table 1.

DDAC is corrosive to both skin and eyes. Acute oral toxicity LD_{50} values range from 262 mg/kg for a 65% solution to 238 mg/kg for an 80% solution (Toxicity Category II[1]). Dermal LD_{50} values for the same concentrations are 2930 mg/kg and 4350 mg/kg, respectively (Toxicity Category III). Subchronic exposures to DAC at 50 mg/kg/day in dogs results in decreases in body weight gain, food consumption and food efficiency. The no-observed adverse effect level (NOAEL) was 15 mg/kg/day and the lowest observed adverse effect level was 50 mg/kg/day. Subchronic exposure to rats results in increased mortality, decreased mean body weights, body weight gain, and food consumption and an increased incidence of gross pathological observations and clinical chemistry changes at doses of 175 g/kg/day in males and 225.5 mg/kg/day in females, which are the respective LOAELs. The NOAEL was 60.7 mg/kg/day in males and 74.3 mg/kg/day in females. Both *in vitro* and *in vivo* genotoxicity data show that DDAC is not genotoxic. DDAC did not cause reproductive or developmental toxicity in acceptable studies. Carcinogenicity studies indicate that DDAC does not cause an increase in tumor incidence in rats.

The toxicology database for DDAC is essentially complete and of acceptable quality to assess the potential hazard to humans The toxicological endpoint selection in the Group I Quat Cluster risk assessment included acute and chronic dietary, short- and intermediate term incidental oral, short-term dermal and short-, intermediate- and/or long-term inhalation exposure scenarios. The acute and chronic reference dose (RfD) is 0.1 mg/kg/day. The chronic reference dose (cRfD) is derived from a no-observable

[1] As given in 40CFR 156.10

adverse effect level (NOAEL) of 10 mg/kg/day based on a chronic dog toxicity study in which increased incidence of clinical signs in males and females and decreased total cholesterol levels in females were observed at 20 mg/kg/day, the lowest observed no effect level (LOAEL). The Agency has decided that the FQPA safety factor be removed (i.e, FQPA Safety Factor = 1) for DDAC, based upon the existence of a complete developmental and reproductive toxicity database and lack of evidence for increased susceptibility in these data (EPA 2006b). The cRfD modified by a FQPA safety factor is a population adjusted dose (PAD)[2] . The chronic PAD (cPAD) is used to estimate chronic dietary risk.

Dietary (food and drinking water) exposures to DDAC when used as specified in the tolerance exemption expressions given in Table 1 would be far less than the cPAD, therefore there are no dietary risk concerns associated with the use of DDAC as specified in the tolerance exemption expressions given in Table 1 Residential exposures (dermal and inhalation) to DDAC as a pesticide product inert ingredient would be less than exposures resulting from the use of DDAC as an active ingredient and therefore not of concern.

Taking into consideration all available information on DDAC, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to DDAC (as identified in Table 1) when used as an inert ingredient in pesticide products when considering dietary exposure and all non-occupational sources of pesticide exposure for which there is reliable information. Overall, exposure due to the inert ingredient use of DDAC is expected to result in human exposure below any dose level that would produce an adverse effect. Therefore, it is recommended that the three exemptions from the requirement of a tolerance established for residues of DDAC can be considered reassessed as safe under section 408(q) of FFDCA.

Available data evaluated in the risk assessment for the Group I Quat Cluster demonstrate that DDAC is moderately to highly toxic to freshwater fish, very highly toxic to freshwater aquatic invertebrates, very highly toxic to a marine/estuarine invertebrate, and toxic to freshwater alga at microgram concentrations. DDAC is practically non-toxic to avian species in dietary studies but moderately toxic on an acute oral basis.

I. Introduction

This report provides a qualitative assessment for dialkyl (C_8-C_{18}) dimethyl ammonium chloride and mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds, pesticide inert ingredients which have three exemptions from the requirement of a tolerance when used as surfactants in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and applied to animals under 40 CFR180.930. For the ease of reading, these inert ingredients are collectively referred to by the abbreviation "DDAC" throughout this document.

[2] Chronic Reference Dose (cRfD)/FQPA Safety Factor =Chronic Population Adjusted Dose (cPAD)

II. Use Information

A. Pesticide Uses

The tolerance exemption expressions for the DDACs are provided in Table 1 below.

Table 1. CFR Citation CAS Registry Numbers and CAS 9th Collective Index Name for DDACs

40 CFR 180	Inert Ingredients	Limits	Uses (Pesticidal)	CAS Reg. No. and Names
910[a]	Dialkyl (C_8-C_{18}) dimethyl ammonium chloride	Not more than 0.2% in silica, hydrated silica.	Flocculating agent in the manufacture of silica, hydrated silica for use as a solid diluent, carrier	See Appendix A
920[b]	Mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds, where the alkyl group(s) (C_8- C_{18}) are derived from coconut, cottonseed, soya, tallow, or hogfat fatty acids.	None	Surfactants, related adjuvants of surfactants	See Appendix A
930[c]	Dialkyl (C_8- C_{18}) dimethylammonium chloride	Not more than 0.2% in silica hydrated silica.	Flocculating agent in the manufacture of silica hydrated silica for use as a solid diluent, carrier	See Appendix A

[a] Residues listed in 40 CFR 180.910 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.
[b] Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only
[c] Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

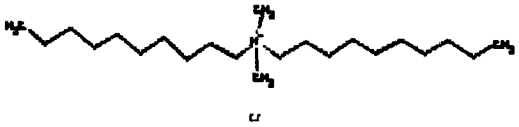
B. Other Uses

Quaternary ammonium compounds of the DDAC type are used as cationic surfactants and have as detergents in cleaning products and shampoos; emulsifying agents in creams and lotions; and wetting agents.

III. Physical and Chemical Properties

Some of the physical and chemical characteristics of didecyl dimethyl ammonium chloride, the predominant DDAC, along with a structure and nomenclature, are found in Table 2.

Table 2. Physical and Chemical Properties of Sodium Dodecyl Sulfate

Structure		ChemIDplus, 2004
CAS Reg. No.	7173-51-5	CAS, 2006
9CI Name	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	CAS, 2006
Physical State	Solid	EPA, 2006a
Molecular Weight	362.08 (M)	EPA, 2006a
Water Solubility	dispersable (M)	EPA, 2006a
Melting Point	NA	
Henry's Law Constant	NA	
Vapor Pressure	2.33×10^{-11} mmHg @ 25°C (E)	EPA, 2006a

Octanol/Water Partition Coefficient (Log P)	4.660 (E)	ChemIDplus, 2004

(E)=Estimated Value
(M)=Measured Value
NA=not available

IV. Hazard Assessment

A. Hazard Profile

The source of hazard information for this reassessment is a risk assessment performed on DDAC in support of a Reregistration Eligibility Document (RED) for the Group I Quat Cluster (EPA 2006a). The Group I Quat Cluster is a group of structurally similar quaternary ammonium compounds ("quats") that have a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C_8 or longer) and two methyl substituents and an anionic counter ion of chloride or bromide.

The quaternary ammonium compounds considered under the risk assessment for the Group I Quat Cluster also comprise the predominant segment of the quaternary ammonium compound inert ingredient tolerance exemption expressions given in Table 1. The quaternary ammonium compounds considered under the Group I Quat Cluster RED risk assessment have been determined to have identical or similar physical, chemical and toxicological properties to the quaternary ammonium compounds included under the tolerance exemptions given in Table 1, therefore the risk assessment findings for the Group I Quat Cluster also apply to the inert ingredient tolerance exemptions given in Table 1.

DDAC is corrosive to both skin and eyes. Acute oral toxicity LD_{50} values range from 262 mg/kg for a 65% solution to 238 mg/kg for an 80% solution (Toxicity Category II). Dermal LD_{50} values for the same concentrations are 2930 mg/kg and 4350 mg/kg, respectively (Toxicity Category III). Subchronic exposures to DAC at 50 mg/kg/day in dogs results in decreases in body weight gain, food consumption and food efficiency. The NOAEL was 15 mg/kg/day and the LOAEL was 50 mg/kg/day. Subchronic exposure to rats results in increased mortality, decreased mean body weights, body weight gain, and food consumption and an increased incidence of gross pathological observations and clinical chemistry changes at doses of of 175 g/kg/day in males and 225.5 mg/kg/day in females, which are the respective LOAELs. The NOAEL was 60.7 mg/kg/day in males and 74.3 mg/kg/day in females. Both *in vitro* and *in vivo* genotoxicity data show that DDAC is not genotoxic. DDAC did not cause reproductive or developmental toxicity in acceptable studies. Carcinogenicity studies indicate that DDAC does not cause an increase in tumor incidence in rats.

The toxicology database for DDAC is essentially complete and of acceptable quality to assess the potential hazard to humans The toxicological endpoint selection in the Group I Quat Cluster risk assessment included acute and chronic dietary, short- and

intermediate term incidental oral, short-term dermal and short-, intermediate- and/or long-term inhalation exposure scenarios. The acute and chronic reference dose (RfD) is 0.1 mg/kg/day. The chronic reference dose (cRfD) is derived from a no-observable adverse effect level (NOAEL) of 10 mg/kg/day based on a chronic dog toxicity study in which increased incidence of clinical signs in males and females and decreased total cholesterol levels in females were observed at 20 mg/kg/day, the lowest observed no effect level (LOAEL). The Agency has decided that the FQPA safety factor be removed (i.e, FQPA Safety Factor = 1) for DDAC, based upon the existence of a complete developmental and reproductive toxicity database and lack of evidence for increased susceptibility in these data (EPA 2006b). The cRfD modified by a FQPA safety factor is a population adjusted dose (PAD). The chronic PAD (cPAD) is used to estimate chronic dietary risk.

B. Toxicological Data

The following is a summary of the pertinent toxicological data relevant to the inert ingredient use of DDAC as taken from the a risk assessment performed on DDAC in support of a Reregistration Eligibility Document (RED) for the Group I Quat Cluster (EPA 2006a).

Didecyl dimethyl ammonium chloride is corrosive to both skin and eyes. Acute oral toxicity LD_{50} values range from 262 mg/kg for a 65% solution to 238 mg/kg for an 80% solution (Toxicity Category II). Dermal LD_{50} values for the same concentrations are 2930 mg/kg and 4350 mg/kg, respectively (Toxicity Category III).

There are two oral subchronic studies, one in the dog and one in the rat. In the dog study, dogs were fed diets containing DDAC at 0, 5, 15, or 50 mg/kg/day for ninety days. The high dose animals exhibited a marked decrease in body weight gain, food consumption and food efficiency. No other effects were noted. The NOAEL was 15mg/kg/day and the LOAEL was 50 mg/kg/day. In the rat study, rats were fed diets containing 0, 100, 300, 600, 1000 or 3000 ppm (0, 6.2, 18.5, 36.8, 60.7, or 175 mg/kg/day for males; 0, 7.5, 22.3, 44.4, 74.3, or 225.5 mg/kg/day for females) for ninety days. The high dose animals showed increased mortality; decreased mean body weights, body weight gain, and food consumption; and an increased incident of gross pathological observations and clinical chemistry changes. The NOAEL for the study was 1000ppm for males and females based upon the LOAEL of 3000 ppm where the effects were observed.

Two oral developmental studies were available, one in the rat and one in the rabbit. In the rat study, the rats were dosed by gavage with 0, 1, 20, or 30 mg/kg DDAC in water on gestation days 6-15 inclusive. The dams were sacrificed on gestation day 21. Maternal toxicity was observed at the high and mid-doses. Developmental toxicity described as increased incidences of skeletal variations were seen at the high dose. The maternal LOAEL was 10 mg/kg/day based on the reductions in body weight gain and clinical signs; the developmental LOAEL was 20mg/kg/day based on increased incidences of skeletal variations. The maternal NOAEL was 1 mg/kg/day and the

developmental NOAEL was 10 mg/kg/day. In the rabbit developmental study the female rabbits were dosed by gavage with 0, 1, 3, or 10 mg/kg of DDAC (80.8%) on gestational days 6 to 18, inclusive. Maternal toxicity was observed at the mid and high doses. At the high dose there were also increased mortalities. Developmental toxicity was observed at the high dose as decreased fetal weight and an increased incidence of dead fetuses. The LOAELs for maternal and developmental effects were 3, and 10 mg/kg/day, respectively. The NOAELs for maternal and developmental toxicity were 1, and 3 mg/kg/day, respectively.

DDAC was tested for carcinogenicity in two rodent life-time studies. The results for both studies indicated that at the dose levels tested, DDAC was not carcinogenic.

Mutagenicity data was uniformly negative in the *Salmonella typhimurium* assay, gene mutation, chromosome aberration in Chinese hamster ovary cells, and unscheduled DNA synthesis (UDS) in primary rat hepatocytes. In the UDS study, higher concentrations were severely cytotoxic.

In a rat pharmacokinetics/metabolism, DDAC was mostly excreted in the feces within 3 days, principally as the parent and metabolites. The elimination and metabolic profile appeared not to depend upon dose or exposure duration. The major metabolites were identified as oxidation products with oxidation confined to the decyl side chains.

C. Special Considerations for Infants and Children

The database for DDAC is sufficient for assessing the potential developmental and reproductive effects of these chemicals. In developmental and reproductive toxicity studies there were no adverse reproductive or developmental effects observed in the absence of maternal toxicity. Therefore, there is no concern at this time for increased sensitivity to infants and children from DDAC. The Agency has decided that the FQPA safety factor be removed (i.e, FQPA Safety Factor = 1) for DDAC, based upon the existence of a complete developmental and reproductive toxicity database and lack of evidence for increased susceptibility in these data (EPA 2006b).

D. Environmental Fate Characterization and Drinking Water Considerations

The environmental fate of DDAC is characterized in the risk assessment performed on DDAC in support of a Reregistration Eligibility Document (RED) for the Group I Quat Cluster (EPA 2006a). DDAC has been shown to be hydrolytically stable and stable to photodegradation in buffered aqueous solutions and stable to microbial degradation. DDAC is immobile in soil and binds strongly to soils and sediments. Because of its strong adsorption to soils DDAC is not expected to contaminate surface and ground water, therefore measurable concentrations of DDAC in drinking water are not anticipated.

VI. Exposure Assessment

Dietary (food and drinking water) and residential exposures to mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds when used as a flocculating agent at not more 0.2% in the manufacture of silica/hydrated silica for use as a solid diluent or carrier as a pesticide inert ingredient applied to growing crops or raw agricultural commodities after harvest under 40 CFR 180.910 and applied to animals under 40 CFR 180.930 would not be expected to occur based on the negligible amounts of free mono and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds that would be present in the resultant pesticide product. For the use of dialkyl (C_8-C_{18}) dimethyl ammonium chloride as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920, dietary (food) exposures may occur, however, based on the amount of dialkyl (C_8-C_{18}) dimethyl ammonium chloride used as a surfactant and the fact that soil applications of pesticide products containing dialkyl (C_8-C_{18}) dimethyl ammonium chloride would not result in any systemic uptake of dialkyl (C_8-C_{18}) dimethyl ammonium chloride (as it would be bound to soil and not available for further plant uptake), dietary exposures to residues of dialkyl (C_8-C_{18}) dimethyl ammonium chloride resulting from such use would be at levels far below the cPAD for DDAC and therefore not of concern. Measurable concentrations of DDAC in drinking water are not anticipated, therefore there are no risk concerns from drinking water exposures to DDAC.

Residential exposures (dermal and inhalation) to DDAC as a pesticide product inert ingredient would be less than exposures resulting from the use of DDAC as an active ingredient and therefore not of concern.

VII. Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFCDA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For DDAC, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the exposure via these pathways is orders of magnitude less than the established cPAD for DDAC.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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."

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 as to these DDACs and any other substances, and the DDACs do not

appear to produce toxic metabolites produced by other substances. For the purposes of these tolerance actions, therefore, EPA has not assumed that the DDACs have 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/.

IX. Human Health Risk Characterization

Taking into consideration all available information on DDAC as identified in Table 1, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to DDAC when used as an inert ingredient in pesticide products when considering dietary exposure and all non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the three exemptions from the requirement of a tolerance established for residues of DDAC (identified in Table 1) can be considered reassessed as safe under section 408(q) of FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

Available data evaluated in the risk assessment for the Group I Quat Cluster demonstrate that DDAC is moderately to highly toxic to freshwater fish, very highly toxic to freshwater aquatic invertebrates, very highly toxic to a marine/estuarine invertebrate, and toxic to freshwater alga at microgram concentrations. DDAC is practically non-toxic to avian species in dietary studies but moderately toxic on an acute oral basis (EPA, 2006a).

REFERENCES:

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ChemIDPlus. 2004. ChemIDPlus. National Library of Medicine. National Institute of Health. Last Updated: September 9, 2004.

EPA (U.S. Environmental Protection Agency). 2006a. Draft Didecyl Dimethyl Ammonium Chloride ((DDAC) Preliminary Risk Assessment. Office of Pesticide Programs, Antimicrobial Division. April 18, 2006.

EPA (U.S. Environmental Protection Agency) 2006b. Didecyl Dimethyl Benzyl Ammonium Chloride(DDAC-Report of the Antimicrobial Division Toxicity Endpoint Committee (ADTC) and the Hazard Indentification Assessment Review Committee (HIARC) January 9, 2006.

APPENDIX A

Chemical Names and CAS Reg. Nos. for Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride and Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds

Chemical Name	CAS Reg. No.
Dialkyl (C_8-C_{18}) Dimethyl Ammonium Chloride	
1-Hexadecanaminium, N-hexadecyl-N,N-dimethyl-, chloride	1812-53-9
1-Tetradecanaminium, N,N-dimethyl-N-tetradecyl-, chloride	10108-91-5
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	7173-51-5
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride	107-64-2
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	5538-94-3
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	32426-11-2
Mono and Dialkyl (C_8-C_{18}) Methylated Ammonium Chloride Compounds	
Quaternary ammonium compounds, bis(C8-18 and C18-unsatd. alkyl) dimethyl, chlorides	68918-78-5
Quaternary ammonium compounds, dicoco alkyldimethyl, chlorides	61789-77-3
Quaternary ammonium compounds, coco alkyltrimethyl, chlorides	61789-18-2
Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	8030-78-2
Quaternary ammonium compounds, trimethylsoya alkyl, chlorides	61790-41-8
Quaternary ammonium compounds, dimethyldisoya alkyl, chlorides	61788-92-9
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	7173-51-5
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	5538-94-3
1-Tetradecanaminium, N,N,N-trimethyl-, chloride	4574-04-3
1-Octadecanaminium, N,N,N-trimethyl-, chloride	112-03-8
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride	107-64-2
Quaternary ammonium compounds, di-C8-18-alkyldimethyl, chlorides	73398-64-8
1-Hexadecanaminium, N,N,N-trimethyl-, chloride	112-02-7
1-Dodecanaminium, N,N,N-trimethyl-, chloride	112-00-5
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	32426-11-2