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Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510C)

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September 2007

Reregistration Eligibility Decision for Trimethoxysilyl Quaternary Ammonium Chloride Compounds

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 (EPA) has completed its review of the available data on the trimethoxysilyl quaternary ammonium chloride compounds (trimethoxysilyl quats). The Reregistration Eligibility Decision (RED) was approved and signed on September 25, 2007.

Based on the Agency's review of the trimethoxysilyl quats, the Reregistration Eligibility Decision (RED) and supporting documentation are now being published. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for the trimethoxysilyl quats will be available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0831 at <http://www.regulations.gov>

Please note that the attached RED document pertains only to the trimethoxysilyl quats compounds and presents the Agency's conclusions on risks associated with the uses of these compounds. Based on the information contained in our files, these compounds have been identified as low risk chemicals. This document also identifies generic and product-specific data for which the Agency intends to issue Data Call-Ins (DCIs). As part of the RED, the Agency has determined that the trimethoxysilyl quats are eligible for reregistration.

If you have questions pertaining to this document, please contact Melba Morrow at (703) 308-2716. Note that DCIs with all pertinent instructions will be sent to the registrant 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. For questions regarding product reregistration please contact Velma Noble at (703) 308-6233.

Sincerely,



Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION

for

Trimethoxysilyl Quaternary Ammonium Chloride Compounds

List C

Case No. 3148

Approved By:

A handwritten signature in black ink, appearing to read "Frank T. Sanders", written in a cursive style.

Frank T. Sanders

Director, Antimicrobials Division

September 25, 2007

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
AD	Antimicrobials Division
ADTC	Antimicrobials Division Toxicology Endpoint Selection Committee
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
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
EPISUIT	Environmental Protection Agency, Estimation Program Interface Suite
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Fl. oz.	Fluid Ounces
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FWS	United States Fish and Wildlife Services
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
HPV	High Production Volume
IDS	Incident Data System
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that

LD ₅₀	can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fishery Service
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NPTN	National Pesticide Telecommunications Network
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PCC	National Poison Control Center
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose

RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SAR	Structure Activity Relationship Assessment
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
ug/g	Micrograms Per Gram
ug/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed its human health and environmental review for the reregistration case 3148; Trimethoxysilyl Quaternary Ammonium Chloride Compounds, and is issuing its risk management decision. There are currently 30 active products for this group of compounds. This includes chemical codes 107401, 107403, 107409 and 169160. Chemical code 107403 is a trihydroxysilyl quat compound that has been included in this action. The decision to include this compound is based on the finding that when exposed to water, the trimethoxysilyl quats undergo a chemical reaction which leads to the formation of trihydroxysilyl quats.

The following Reregistration Eligibility Decision (RED) addresses the use of the trimethoxysilyl and trihydroxysilyl quats as bacteriostatic and fungistatic treatments in human clothing and bedding, household areas, carpets and upholstery. These products are also used as material preservatives in the manufacturing of paints, coatings, and concrete. Collectively, these compounds will be referred to as trimethoxysilyl quats.

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. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient (a.i.), as well as a review of all submitted data by the U.S. Environmental Protection 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 risks arising from the currently registered uses of the pesticide; to determine the need for additional data on human 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 human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for the trimethoxysilyl quats.

As active ingredients trimethoxysilyl quats are used as materials preservatives for, paints (in can), coatings, textiles (such as those used in human bedding, footwear, clothing/apparel, upholstery, diapers and carpet), sails, ropes, fire hose, concrete additive, roofing materials, filter media and polyurethane foam and cellulose products and cleaning buffers. The chemical is also formulated to provide residual fungistatic activity in household and domestic dwellings on hard non-porous surfaces, bathroom premises (hard non-porous surfaces), and in garbage cans.

The Agency has concluded that the FQPA Safety Factor for the trimethoxysilyl quats should be reduced to 3X based on: (1) the potential for significant contact of infants and children through the proposed homeowner uses for this active ingredient and (2) no evidence of increased susceptibility in the prenatal developmental study in rats nor is there evidence of neurotoxicity to the offspring.

Risks summarized in this document are those that result from the use of the active ingredients octadecanaminum-N-N-dimethyl(3-trimethoxysilyl)propyl chloride; octadecanaminum-N-N dimethyl(3 trihydroxy silyl)propyl chloride; tetradecanaminum-N-N dimethyl (3trimethoxysilyl)propyl chloride; and didecyl N-methyl-(3trimethoxysilyl)propanaminum chloride. The chemicals have been grouped as trimethoxysilyl quaternary ammonium compounds for the purpose of reregistration.

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 the trimethoxysilyl quats and any other substances. The trimethoxysilyl quats do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that the trimethoxysilyl quats 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>.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of the trimethoxysilyl quats. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for the trimethoxysilyl quats referenced in this RED. The risk assessments and related addenda are not included in this document, but are available in the Public Docket at <http://www.regulations.gov> (EPA-HQ-OPP-2007-0831).

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 the trimethoxysilyl quats and the regulatory history. Section III, Summary of Trimethoxysilyl Quats Risk Assessment, gives an overview of the human health and environmental assessments, based on the information available to the Agency. Section IV, Risk Management, and Reregistration 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 trimethoxysilyl quats are registered as active ingredients as bacteriostatic, algaestatic and fungistatic compounds. The first products containing a trimethoxysilyl quat were registered in January 1960. There are currently a total of 30 registered products for PC Codes 107401, 169160, 107403 and 107409. The Agency has determined that the Reregistration Eligibility Decision (RED) will include all of the aforementioned products, which includes a trihydroxysilyl quat (107403). This decision is supported by the finding that when the methoxysilyl quat compounds are exposed to water, there is a reaction which leads to the formation of hydroxysilyl quat compounds.

Trimethoxysilyl quat and trihydroxysilyl quat containing products are currently used as a material preservative treatment for materials such as those used in human clothing and bedding, carpets and upholstery. The trimethoxysilyl quats are used as surface treatments in household areas and bathroom areas. These products are also used in the manufacturing of paints, coatings, and in concrete. There are no inert uses or tolerances for this reregistration case.

B. Chemical Identification:

Table 1 contains information on the chemicals included in this RED.

Table 1: Physical and Chemical Properties

Chemical name	1-Octadecanaminium-N,N-dimethyl-N-{3-(trimethoxysilyl)propyl}-chloride	1-tetradecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-chloride	1-Decanaminium,N-Didecyl-N-methyl-N-{3-(trimethoxysilyl)propyl}-chloride	1-ocatdecanaminium-N,N-dimethyl-N-(3-(trihydroxysilyl)propyl)-chloride
Empirical Formula	C ₂₆ H ₅₈ ClNO ₃ Si	C ₂₂ H ₅₀ ClNO ₃ Si	C ₂₇ H ₆₀ ClNO ₃ Si	C ₂₃ H ₅₂ ClNO ₃ Si
CAS #	27668-52-6	41591-87-1	6895920-6	199111-50-7
OPP Chemical Code	107401	107409	169160	107403
Molecular Weight	496.30	440.31	510.3	454
Physical State	liquid	liquid	liquid	liquid
Color	Pale yellow to off white	Clear yellowish	Light to dark amber	clear
Melting Point	267 C	245 C	272 C	306 C
Boiling Point	617 C	570 C	628 C	702 C
Specific Gravity	0.99	1.012	0.85	1.0
Vapor Pressure	5.8 x 10 ⁻¹⁴ mm Hg	1.7 X10 ⁻¹²	2.4 x 10 ⁻¹⁴	1.85 x10 ⁻²¹

Basic Manufacturers: Aegis Environmental Mgt, Inc., Sishield Technologies Inc., Sanitized Inc., Microbioguard, International Biochemical Industries, Inc.

C. Use Profile

The following section provides information on the currently registered uses of the trimethoxysilyl quat products. Included is an overview of the use sites and application methods for these compounds. Please refer to appendix A for a comprehensive table of uses of the trimethoxysilyl quats that are eligible for reregistration.

Type of Pesticide: Material preservatives, bacteriastatic, fungistatic, antimicrobial and algaestatic treatments

Use Sites: Trimethoxysilyl quats are used in industrial, commercial, institutional and residential premises.

Use Classification: Trimethoxysilyl quats are general use pesticides.

Formulation Types: Trimethoxysilyl quats are formulated as a soluble concentrate for both manufacturing and end use products and as a ready to use solution for end use products.

Application Rates/Methods: As a materials preservative and surface treatment, trimethoxysilyl quats are applied by open pour methods or by spraying, dipping or soaking, depending upon the material that is being treated. The application rates vary based on product and use site. A complete list can be found as part of Appendix A.

III. SUMMARY OF RISK ASSESSMENT for TRIMETHOXSILYL QUATS

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 trimethoxysilyl quats. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed on the Agency's website at [http://www.regulations.gov\(EPA-HQ-OPP-2007-0831\)](http://www.regulations.gov(EPA-HQ-OPP-2007-0831)). Hard copies of these documents may be found in the OPP public docket under docket number OPP-2007-0831. The OPP public docket is located in Room S-4400, One Potomac Yard (South Building) 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of Trimethoxysilyl Quats

A brief overview of the toxicity of the trimethoxysilyl quats is presented below. Further information on the toxicity of this compound can be found in Appendix C in a risk characterization document dated February 2, 2000.

The Agency has reviewed all toxicity studies submitted for the trimethoxysilyl quats and has determined that the toxicological database is sufficient for reregistration. The toxicological database for trimethoxysilyl quats is currently comprised of unpublished studies submitted to the Agency; however, limited data are available for these compounds. The data matrix for trimethoxysilyl quats includes acute toxicity studies, a subchronic dermal toxicity study, one subchronic oral study in rats, one developmental toxicity study in rats, and six mutagenicity studies (four of which have been classified as being acceptable).

Table 2. Toxicity of Trimethoxysilyl Quats

Test	Species	Results	MRID
Oral LD ₅₀	Rat	>5000 mg/kg (Toxicity Category IV)	40385201
Dermal LD ₅₀	Rabbit	>2000 mg/kg (Toxicity Category III)	40385201
Inhalation LC ₅₀	Rat	>2.0 mg/L (1-Hour) (Toxicity Category IV)	Not available*
Eye Irritation	Rat	Severe Ocular Toxicity (Toxicity Category I)	403385201
Dermal Irritation	Rabbit	Severe dermal toxicity (Toxicity Category I)	Not available*
Subchronic dermal toxicity	Rat	Dermal and Systemic NOAEL ≥ 1000 mg/kg/day	41339403
Subchronic oral toxicity	Rat	NOAEL ≥ 240 mg/kg/d (HDT)	46280411
Developmental Toxicity	Rat	Maternal NOAEL ≥ 1000 mg/kg/day Developmental NOAEL ≥ 1000 mg/kg/day	41438003
Ames Salmonella Assay	Salmonella	No increase in number of revertant colonies (unacceptable study)	40385211
In-vitro Reverse Mutation Assay	Salmonella, E-coli	No evidence of induced mutant colonies	46280412
In-vitro Forward Mutation Assay	Salmonella, E-coli	No evidence of mutagenicity	46280413
Chromosome Aberration	Chinese hamster cells	No association with the induction of structural chromosome aberrations	46280414
Mouse Micronucleus	Mouse	No evidence of compound induced cytotoxicity	41296803
Unscheduled DNA Synthesis	Hepatocytes	Unacceptable study	41296804

* These studies are summarized in the data base for the trimethoxysilyl quats, however, accession/MRID numbers were not included on the study reviews.

General Toxicity Observations

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral or dermal exposure to the trimethoxysilyl quats. This conclusion is based on low toxicity observed in acute, subchronic and developmental studies conducted with the trimethoxysilyl quat compounds. The risk from inhalation exposure has not been characterized and an additional study designed to assess inhalation toxicity over time may be needed. In addition, severe toxicity has been observed with regard to skin and eye irritation.

Carcinogenicity Classification

There are no concerns for carcinogenicity for the trimethoxysilyl quats based on the results of the mutagenicity studies and the lack of any systemic toxicity being observed in the toxicity data base; therefore, no carcinogenic analysis is required.

Mutagenicity Potential

The mutagenicity of the trimethoxysilyl quats is fully characterized. For all of the compounds covered under this RED, there are a total of four acceptable mutagenicity studies, all of which demonstrate that the trimethoxysilyl quats are negative for mutagenicity.

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, residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been reduced to 3X based on: (1) the potential for significant contact of infants and children through the proposed homeowner uses for this active ingredient and (2) no evidence of increased susceptibility in the prenatal developmental study in rats nor is there evidence of neurotoxicity to the offspring. It should be pointed out that at this time, there are no risks of concern which would require the use of a FQPA safety factor.

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. Since toxicological endpoints for the risk assessment were not identified based on the available data, RfDs and PADs have not been calculated for trimethoxysilyl quats. In addition there does not appear to be oral exposure to this chemical based on use patterns.

4. Dietary and Residential Risk Assessment

There are currently no dietary exposure scenarios for the trimethoxysilyl quats. Although there are residential uses for trimethoxysilyl compounds, there are no toxicological endpoints of concern based on the available toxicity data.

5. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act require “that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information”(FFDCA, Section 408(b)(2)(A)(ii)). Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure. Residential exposure to the trimethoxysilyl quats is likely; however there are no toxicological endpoints of concern. An aggregate risk assessment was therefore not conducted for this chemical.

6. Occupational Exposure

The occupational exposure assessment for the trimethoxysilyl quats addresses potential exposures and risks to humans who may be exposed in “occupational settings.” An occupational risk assessment is required for an active ingredient if certain toxicological criteria are triggered and there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For the trimethoxysilyl quats there is potential for exposure; however, there are no toxicological endpoints of concern according to a review of the available toxicity data.

7. Human Incident Data

EPA consulted the following sources of information for human poisoning incidents related to the trimethoxysilyl quats: (1) OPP Incident Data System (IDS), (2) California Department of Pesticide Regulation (1982-2004) and (3) National Pesticide Information Center (NPIC). There were no human incidents reported for the trimethoxysilyl quats in these data bases.

B. Environmental Risk Assessment

A summary of the Agency’s environmental risk assessment is presented below. The following risk characterization is based on the use sites for the trimethoxysilyl quats and any associated uncertainties. For further information concerning all aspects about the environmental risk assessment refer to the product chemistry, environmental fate and ecological toxicology in the trimethoxysilyl quats risk assessment available on the Agency’s website in the EPA Docket at <http://www.regulations.gov>.

1. Environmental Fate and Transport

The Agency has conducted an environmental fate assessment dated September 19, 2007 for the trimethoxysilyl quats. The hydrolysis data indicate that the trimethoxysilyl quats are soluble but not stable in water. Environmental fate studies for the trimethoxysilyl quats consist of only a hydrolysis study and it was concluded by the Agency that no further fate studies would be required because of the instability of the compounds and the formation of an insoluble silane degradate. The trimethoxysilyl quats are not expected to contaminate surface or ground water due to rapid degradation by hydrolysis.

2. Ecological Risk

The Agency expects exposure to the trimethoxysilyl quats to be minimal to avian, fresh water estuarine/marine aquatic organisms and plants based on the registered indoor use patterns.

a. Toxicity (Hazard) Assessment

The results from the avian acute toxicity and dietary studies and from the freshwater invertebrate acute toxicity studies for the trimethoxysilyl quats are summarized in Table 3. The trimethoxysilyl quats are characterized as practically non-toxic to birds and based on the data in the Agency's files, the chemical is considered highly toxic to freshwater invertebrates in acute studies. The trimethoxysilyl quats are classified as being moderately toxic to coldwater fish species.

Table 3: Ecological Acute Toxicity Studies

Test and Organism	Chemical PC Code	Results	Toxicity Category
Acute Toxicity LC ₅₀ Rainbow Trout	169160	96 hour LC ₅₀ = 1.73 mg/L	Moderately toxic
Single Dose Oral LD ₅₀ Mallard Duck	107401	LD ₅₀ > 1590 mg/kg	Practically non-toxic
Dietary LC ₅₀ Mallard Duck	107401	LC ₅₀ > 5620 mg/L	Practically Non-toxic
Eight -day Dietary LC ₅₀ Bobwhite Quail	169160	LC ₅₀ > 5620 mg/L	Practically Non-toxic
Acute Toxicity LC ₅₀ Freshwater Daphnids	169160	LC ₅₀ =0.18mg/L	Highly toxic

b. Risk to Threatened and Endangered Species

It is expected that the proposed uses for the trimethoxysilyl quats will involve minimal environmental exposure from registered use patterns. However, an endangered species effect determination has not been made at this time because a more refined assessment that would include direct, indirect and habitat effects, has not been conducted.

IV. RISK MANAGEMENT AND REREGISTRATION 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 generic (i.e., active ingredient-specific) data to support reregistration of products containing the trimethoxysilyl quats as an active ingredient. The Agency has completed its review of the generic data and has determined that the data are sufficient to support reregistration of products containing the trimethoxysilyl quats.

The Agency has completed its assessment of the dietary, occupational and ecological risks associated with the use of pesticide products containing trimethoxysilyl quats as the active ingredient. Based on a review of the data and other available information for the active ingredient, the Agency has concluded that there is sufficient information on the human health and ecological effects of the trimethoxysilyl quats to make decisions as part of the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing trimethoxysilyl quats are eligible for reregistration provided that current data gaps and confirmatory data needs are addressed. Appendix A summarizes the uses of the trimethoxysilyl quats 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 the trimethoxysilyl quats 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 the evaluation of the trimethoxysilyl quats, the Agency has determined there are no human health or ecological risks of concern.

B. Public Comments and Responses

Risk assessments for the trimethoxysilyl quats were not issued for public comment per the Agency's public participation process because no toxicological endpoints were identified, and as such, these assessments were qualitative in nature. To ensure that an opportunity is presented to the public to comment on the risk assessments and risk management decisions for the trimethoxysilyl quats, the Agency will implement a 60-day comment period on this RED.

C. Regulatory Position

1. Food Quality Protection Act Findings

An FQPA Safety Factor of 3X was recommended for the trimethoxysilyl quat compounds. Although there are no food uses for these compounds, it is likely that infants and children will be exposed to these compounds through the existing uses. The FQPA Safety Factor was reduced to 3X, based on the findings that there was no evidence of increased susceptibility in the prenatal developmental study in rats and there was no evidence of neurotoxicity to the

offspring. There is a lack of a second developmental toxicity study in a second species for this active ingredient and a lack of a two-generation reproduction study.

2. Endocrine Disruptor Effects

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

When appropriate screening and testing protocols that are currently being considered under the Agency’s EDSP have been developed, the trimethoxysilyl quats may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Cumulative Risks

Risks summarized in this document are those that result only from the use of the triemthoxysilyl quats. The Food Quality Protection Act (FQPA) requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residue 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 the EPA has followed a cumulative risk approach based on a common mechanism of toxicity, the EPA has not made a common mechanism of toxicity finding for the trimethoxysilyl quats. For further information regarding the 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 statement released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at: <http://www.epa.gov/pesticides/cumulative/>.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of the trimethoxysilyl quats as an active ingredient. The Agency believes there is reasonable certainty of no harm resulting from exposure to the trimethoxysilyl quats as an active ingredient to the general population and to infants and children in particular. This is based on the existing toxicity data which supports the finding that these products did not elicit a toxic response when administered to laboratory animals at the limit dose level. In addition, in conducting a human health hazard assessment, the Agency found that there were no endpoints of concern for the oral and dermal routes of exposure.

The Agency believes that the trimethoxysilyl quats have minimal potential to cause human health or environmental risks and has determined that a qualitative approach to assessing human health and ecological risks from exposure to the trimethoxysilyl quats is appropriate. Therefore, no risk mitigation measures are necessary at this time.

1. 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) significantly reduce 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 it is 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 determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (*Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations*, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment and are considered to fall under a “no effect” determination. Due to the low likelihood of exposure and the low toxicity of the trimethoxysilyl quats, the Agency expects no effects to listed species; however, an endangered species no effect determination has not been made at this time because an assessment has not been made which includes direct, indirect and habitat effects.

b. General Risk Mitigation

Trimethoxysilyl quat end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing trimethoxysilyl quats specific to federally listed, threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

2. Labeling

a. Label Amendment

Currently, no label amendments are necessary in order for trimethoxysilyl quat products to be eligible for reregistration.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that the trimethoxysilyl quats are eligible for reregistration provided that additional data are submitted to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or to request time extension and or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required.

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 Melba Morrow at (703) 308-2716 with questions regarding generic reregistration.

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

By express or courier service:
Document Processing Desk (DCI/AD)
Melba Morrow
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

The registrant needs to submit the following items for each product.

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

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);
2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. Five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;
4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
6. The product-specific data responding to the PDCI.

Please contact Velma Noble at (703) 308-6233 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Velma Noble
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

A. Manufacturing-Use Products

There are currently no registered manufacturing-use products for the trimethoxysilyl quats; therefore, the end-use manufacturer is responsible for the submission of any generic data requirements requested by the Agency.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of the trimethoxysilyl quats for the above eligible uses has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency and are included in the generic DCI for this RED.

Table 4: Data Requirements for the Reregistration Eligibility Decision for the Trimethoxysilyl Quats

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Fresh Water Fish Acute Toxicity Study with TGAI	850.1075	72-1
Fresh Water Invertebrate Acute Toxicity Study with TGAI	850.1010	72-2

B. End-Use Products

1. Additional Product-Specific Data and Efficacy 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, the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

The Agency intends to issue a separate Product-Specific Data Call-In (PDCI), outlining specific data requirements 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 disinfection claim; the appropriate efficacy data must be submitted to support the claim. The efficacy studies the Agency intends to call-in are listed in Table 5 below.

Table 5. 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)
Residual Self-Sanitizing	Materials Preservative	Need to submit protocol for review		

2. Labeling for End-Use Products

No specific labeling changes are necessary to implement measures outlined in Section IV, above. However, to ensure compliance with FIFRA, end-use product labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

Description	Amended Labeling Language	Placement on Label
Declaration of amount of Methanol in product.	Contains ____ % Methanol ¹ .	Below the Ingredients Statement
Required for products containing Methanol \geq 4%	Danger. Poison . Skull and Crossbones Symbol	Signal Word
Precautionary Statements (Language Required by RED based on acute toxicity)	Danger. Corrosive. Causes irreversible eye damage and skin burns. Methanol may cause blindness. May be fatal if inhaled. May be harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear a NIOSH approved respirator with any N, R, P, or HE filter. Appropriate measures must be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Wear goggles or faceshield, rubber gloves, and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.	Precautionary Statements
Physical and Chemical Hazards	Combustible. Do not use or store near heat or open flame. Deactivation can be achieved by the addition of anionic surfactant (soap, sulfonates, sulfates) in quantity equivalent to that of product.	Physical and Chemical Hazards Statements
Products classified as corrosive	Probable mucosal damage may contraindicate the use of gastric lavage.	Note to Physician
Residual Self Sanitizing Claim	Delete Residual Self Sanitizing Activity claim against <i>Trichophyton mentagrophytes</i> in socks. Protocol and data is needed to support this type of claim.	Directions for Use
Nonpublic Health Claims	Effective against odor causing bacteria, bacteria which causes staining and discoloration, fungi (mold/mildew), and algae as a static agent. Can be used as a final bacteriastatic finish to impart bacteriastatic/fungistatic (mold/mildew activity)	Directions for Use
Application Method	Delete Fogging Application	Directions for Use

Description	Amended Labeling Language	Placement on Label
Use Surface Deletion	Delete Polyurethane and cellulose foam for household, industrial, and institutional sponges. This active ingredient is not cleared for use on food contact surfaces.	Directions for Use
Mold Remediation/Prevention (Water/Smoke restoration/ Sewer backup/river flood cleanup/clean water source)	Should any of the materials to be treated have prior mold or moisture contamination, add the appropriate remediation directions for use on the label as per the website below: Refer to http://www.epa.gov/mold/mold_remediation Table 1 and 2 for Remediation Directions for Use	Directions for Use

VI. APPENDICES

Trimethoxysilyl Quats
Table of Use Patterns for Trimethoxysilyl Quats (Appendix A)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Residential and Public Access areas				
Household and Domestic Dwellings, hard non porous surfaces	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 64881-6 70087-1 75497-4 75497-5 75497-8 4822-484 79652-1	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
	Soluble Concentrate 64881-3 75497-2 75497-3 82077-2 82077-3	Spray (pump or commercial), dip or soak	Add 2.5-128 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry. Soak: Use enough of product to completely submerge item.	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	
Bathroom Premises, hard non porous surfaces	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 64881-6 70087-1 75497-4 75497-5 75497-8 4822-484 79652-1	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
	Soluble Concentrate 64881-3 75497-2 75497-3 82077-2 82077-3	Spray (pump or commercial), dip or soak	Add 2.5-128 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry. Soak: Use enough of product to	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	
Human Bedding	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
Human Bedding	Ready to Use 64881-6 70087-1 75497-4 75497-5 79652-1	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
Human Footwear	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 70087-1	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	75497-4 75497-5 79652-1	Dip or soak	completely covered. Let stand until dry or let stand 3 minutes and wipe dry. Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	
Human Clothing/Apparel	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
Human Clothing/Apparel	Ready to Use 70087-1 75497-4 Ready to Use 75497-5 79652-1	Spray (pump or commercial), dip or soak Dip or soak	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry. Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			temperature of up to 160 degrees (a clothes dryer).	
Upholstery	Soluble Concentrate 75174-2 75497-1		Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 64881-6 70087-1 75497-4 75497-5	Spray (pump or commercial), dip or soak	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry.	
	Soluble Concentrate 64881-3	Spray (pump or commercial), dip or soak	Add 2.5 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry. Soak: Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Diapers	Ready to Use 75497-4 75497-5	Spray (pump or commercial), dip or soak	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry.	
		Dip or soak	Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	
Carpets	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 64881-6 70087-1 75497-4 75497-5 79652-1	Spray (pump or commercial),	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry. One gallon treats 200 square feet.	
	Soluble Concentrate 64881-3 75497-2 75497-3 82077-2 82077-3	Spray (pump or commercial), dip or soak	Add 2.5 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Toweling	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 75497-4 75497-5	Spray (pump or commercial), dip or soak	Remove filter from unit. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry.	
Garbage Cans	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 75497-4 75497-5 75497-8	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
Materials Preservative				
Adhesives	Soluble Concentrate 75174-2 75497-1 75497-2 75497-3 82077-2 82077-3	Open pour	Add 5 pounds of product per 100 pounds of adhesive.	
Paints (In Can)	Soluble Concentrate 75174-2	Open pour	Add 5 pounds of product per 100 pounds of paint	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	75497-1 75497-2 75497-3 82077-2 82077-3			
Coatings	Soluble Concentrate 75174-2 75497-1 75497-2 75497-3 82077-2 82077-3	Open pour	Add 5 pounds of product per 100 pounds of coatings	
Textiles, sails, ropes, fire hose	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), Dip, soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 75497-4 75497-5	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry.	
	Ready to Use 75497-4 75497-5	Dip, soak	Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Concrete Additive	Soluble Concentrate 75497-4 75497-5	Open pour	40 ounces per cubic foot of concrete Add water before adding to concrete.	
	Soluble Concentrate 75174-2 75497-1		6 ounces per 500 cubic feet. Add water before adding to concrete.	
	Soluble Concentrate 75497-2 75497-3 82077-2 82077-3		6-16 ounces per cubic yard. Add water before adding to concrete.	
	Soluble Concentrate 64881-3	Spray (pump or commercial), dip or soak	Add 2.5 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
Roofing Materials (shingles, felt, synthetic overcoats)	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 70087-1 75497-4	Spray (pump or commercial)	Spray entire surface area 6-12" from surface until completely covered. Let	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	75497-5		stand until dry.	
	Soluble Concentrate 64881-3	Spray (pump or commercial), dip or soak	Add 2.5 ounces of product per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
Air Filters (vacuum, A/C units, automobiles, aquariums)	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 70087-1 75497-4 75497-5 79652-1	Spray (pump or commercial), dip or soak	Remove filter from unit. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	
Air Filters (vacuum, A/C	Soluble	Spray (pump or	Add 2.5 ounces of product	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
units, automobiles, aquariums)	Concentrate 64881-3	commercial), dip or soak	per gallon of water. Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry. Soak: Use enough of product to completely submerge item. Soak item for 3 minutes. Remove item and wring excess liquid. Dry treated articles before use at a temperature of up to 160 degrees (a clothes dryer).	
Polyurethane foam and cellulose products, cleaning buffers	Soluble Concentrate 75174-2 75497-1	Spray (pump or commercial), dip or soak	Add 8 ounces of product per gallon of water. Then apply as in ready to use.	
	Ready to Use 70087-1 75497-4 75497-5 79652-1	Spray (pump or commercial)	Spray entire surface area 4-6" from surface until completely covered. Let stand until dry or let stand 3 minutes and wipe dry.	

APPENDIX B: Trimethoxysilyl Quats (3148)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of trimethoxysilyl Quats. These requirements apply to trimethoxysilyl Quats in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.
2. **Guideline Description** (Column 3). Identifies the guideline type.
3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

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

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

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY				
830.1550	61-1	Product Identity and Composition		101490 105186 105988 128481 130316 164909 41438002 42456501 42456508
830.1600 830.1620 830.1650	61-2 A	Starting Materials and Manufacturing Process		101490 105186 105988 128481 130316 164909 42456502
830.1670	61-2 B	Formation of Impurities		101490 105186 105988 128481 130316 164909 42456502
830.1700	62-1	Preliminary Analysis		41959401 42456507 41959401
830.1750	62-2	Certification of Limits		105988 41959401

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.1800	62-3	Analytical Method		105988 101490 128481 41959401 42456504 42456506 130316
830.6302	63-2	Color		105988 101490 128481 70190 129655 130316
830.6303	63-3	Physical State		105988 70190 129655 130316
830.6304	63-4	Odor		105988 101490 128481
830.7220	63-6	Boiling Point		105988 101490 128481 70191 129565 130316
830.7300	63-7	Density		105988 101490 128481 70191 123565 130316

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.7840 830.7860	63-8	Solubility		43589401
830.7950	63-9	Vapor Pressure		105988 101490 42469601
830.7370	63-10	Dissociation in Water		41276601 42469601
830.7000	63-12	pH		105988 101490 128481 70191 130316
830.6313	63-13	Stability		41276601 70191 130316 42456509
830.6315	63-15	Flammability		105988 101490 128481
830.6317	63-17	Storage Stability		42456510
830.6318	63-18	Viscosity		105988 101490 128481
830.6320	63-20	Corrosion Characteristics		105988 101490 128481
830.6321	63-21	Dielectric Breakdown Voltage		
<u>ECOLOGICAL EFFECTS</u>				
850.2100	71-1 A	Avian Acute Oral Toxicity Test - Quail/duck		40385218

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.2200	71-2 A	Avian Acute Dietary - Quail		101491
850.2200	71-2 B	Avian Acute Dietary – Duck		40385217
850.1075	72-1 A	Fish Acute Toxicity - Bluegill		
850.1075	72-1 D	Fish Acute Toxicity - Rainbow Trout		105187
850.1010	72-2 A	Acute Aquatic Invertebrate Toxicity		105187
870.1100	81-1	Acute Oral Toxicity		40385201 41948702
870.1200	81-2	Acute Dermal Toxicity		40385201 41948701 43219901
870.1300	81-3	Acute Inhalation Toxicity		126471 41157803 93218038
870.2400	81-4	Acute Eye Irritation		40385201
870.2500	81-5	Acute Dermal Irritation		40385201 41157801 41157802 41977901 42456513
870.2600	81-6	Skin Sensitization		86703 42197401
870.3250	82-3	90-Day Dermal		41339403
<u>TOXICOLOGY</u>				
870.3700	83-3 A	Prenatal Developmental Toxicity - Rat		41438003

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.5100	84-2 A	Mutation		105185 128480 41353301
870.5380 870.5385 870.5395	84-2 B	Structural Chromosomal Aberration		42456517 41296802 40385213
870.6300	84-4	Other Genotoxic Effects		41296804
870.7485	85-1	General Metabolism		130319
870.7600	85-2	Dermal Penetration		40385216 57346
<p>*For guidelines 82-3 and 82-4, at least one is required to be fulfilled; not both (for both food and non-food uses). **Only required for food use.</p>				
<u>ENVIRONMENTAL FATE</u>				
835.2120	161-1	Hydrolysis		43578601
<u>OCCUPATIONAL AND RESIDENTIAL EXPOSURE</u>				
875.2400	133-3	Dermal Exposure		41412201
875.2500	133-4	Inhalation Exposure		41761201 41412201

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

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

<http://www.regulations.gov> (EPA-HQ-OPP-2007-0831).

These documents include:

3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride (AEM 5700 Antimicrobial): Risk Characterization for non-food use, dated February 2, 2000.

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

1. MRID Studies

- 28989 Isquith, A.J.; White, W.C.; Malek, J.R.; et al. (1976) Durability of Dow Corning[®]I 5700 Antimicrobial Agent on Textiles. Includes method CTM 0824 dated Jan 29, 1976. (Unpublished study received Nov 7, 1979 under 34292-1; submitted by Dow Corning Corp., Midland, Mich.; CDL:241924-A)
- 28990 Schechtman, L.M.; Beard, S.F.; Sinsky, P.M. (1979) Activity of T1482 in~in vitro~Mammalian Cell: Transformation Assay in the Absence of Exogenous Metabolic Activation. Final Rept. (Unpublished study received Sep 19, 1979 under 34292-1; prepared by Microbiological Associates, submitted by Dow Corning Corp., Midland, Mich.; CDL:241925-A)
- 29136 Dow Corning Corporation (1977?) Dow Corning[®]I5700 Antimicrobial Agent: Durability Study. (Unpublished study received Feb 27, 1980 under 34292-1; prepared in cooperation with Litton Bionetics Laboratory Products; CDL:241856-A)
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- 29138 Dow Corning Corporation (1952?) Acute Oral Toxicity. (Unpublished study received Feb 27, 1980 under 34292-1; CDL:241856-C)
- 29139 Groh, C.L. (1972) Acute Dermal Toxicity--Albino Rats. (Unpublished study received Feb 27, 1980 under 34292-1; submitted by Dow Corning Corp., Midland, Mich.; CDL:241856-D)
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- 31557 Mogul Corporation (1973) ?Study of Dow Corning^(R)I Q9-5700 Antimicrobial Agent|. (Unpublished study received Mar 25, 1980 under 8591-EX-2; CDL:242184-A)
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- 58118 Salamon, C.; Smith, S. (1977) Report to Dow Corning Corporation: Host-Mediated Assay for Detection of Mutations Induced by TX-1347: IBT No. 8533-10127. (Unpublished study received May 9, 1977 under 34292-1; submitted by Dow Corning Corp., Midland, Mich.; CDL:232331-A)
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- 67672 Oshita, G.; Richter, W.R. (1976) Report to Burlington Hosiery Company, Division of Burlington Industries: Three-week vaginal Irritation Study with Treated Panty Hose Fabric (Cotton and Nylon) in Beagle Dogs: IBT No. 8531-08440. (Unpublished study received Sep 18, 1978 under 34292-1; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Dow Corning Corp., Midland, Mich.; CDL:235110-A)
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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 trimethoxysilyl quats RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

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

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

The Agency intends to insert the batching for the trimethoxysilyl quats at a later date.

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

The Agency intends to insert the list of registrants for the trimethoxysilyl quats at a later date.

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

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

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

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

8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program—Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

- b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
- a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition. To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.