United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-07-004
September 2007

Reregistration Eligibility Decision (RED) for Alkyl trimethylenediamines (Case 3014)

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 antimicrobial, alkyl trimethylenediamines (ATMD). The Reregistration Eligibility Decision (RED) was approved on September 26, 2007.

Based on the Agency's review of alkyl trimethylenediamines (ATMD), the 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 alkyl trimethylenediamines (ATMD) will be available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0537 at http://www.regulations.gov.

Please note that the attached RED document pertains only to alkyl trimethylenediamines and presents the Agency's conclusions on the residential, occupational and ecological risks posed by exposure to ATMD alone. This document also identifies product-specific data for which the Agency intends to issue Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. At this time, generic confirmatory data are required. For product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that alkyl trimethylenediamines (ATMD) is eligible for reregistration. Sections IV and V of this RED document describe product-specific and generic data requirements.

If you have questions pertaining to this document, please contact the Chemical Review Manager, ShaRon Carlisle, at (703) 308-6427. For questions regarding product reregistration and or the product DCI that accompanies this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank Sanders, Director
Antimicrobials Division (7510P)

REREGISTRATION ELIGIBILITY

DECISION

for

Alkyl trimethylenediamines (ATMD),
Case Number 3014

Approved by:

Betty Shackleford for
Frank T. Sanders, Director
Antimicrobials Division

9-26-07
Date

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Glossary of Terms and Abbreviations

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

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

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for alkyl trimethylenediamines (ATMD) and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and discussions with the registrant. As a result of this review, EPA has determined that ATMD containing products are eligible for reregistration, provided that labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency. 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 health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the EPA decision regarding the reregistration eligibility of the registered uses of the alkyl trimethylenediamines (ATMD). There are five active ingredients in the the alkyl trimethylenediamines case: Alkyl*-1,3-propylenediamine (PC Code 067301); N-Alkyl*-1,3-propylenediamine acetate *(as in fatty acids of coconut oil) (PC Code 067302); 1-(Coco alkylamino)-3-aminopropane hydroxyacetate Cocodiamine salt (PC Code 067309); Alkyl*-1,3-propylenediamine *(42%C12, 26%C18, 15%C14, 8%C16, 5%C10, 4%C8) (PC Code 067310); and 1-(alkyl* amino)-3-aminopropane diacetate (PC Code 067310).

The alkyl trimethylenediamines are used primarily as a microbicide, bactericide, or molluscide. Use sites for ATMD include the following industrial processes and water systems: oilfield/petrochemical injection water systems; industrial recirculating water cooling systems; non-potable industrial waters; other industrial processing water systems; petroleum transport systems, storage systems and subsurface equipment; natural gas well gathering systems and pipelines; and well completion, packer, stimulation and work over fluids. There are currently twelve registered products for oilfield uses and three registered products for industrial recirculating water cooling tower.

Any risks summarized in this document are those that result only from the use of the active ingredients in the ATMD case. FQPA requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for alkyl trimethylenediamines. 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/.

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 ATMD referenced in this RED. The risk assessments are not included in this document, but are available in the EPA's Pesticide Docket EPA-HQ-OPP-2007-0537 at http://www.regulations.gov.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of ATMD and its regulatory history. Section III, Summary of ATMD risk assessment, gives an overview of the human health and environmental assessments, based on the information available to the Agency. Section IV, Risk Management, Reregistration and Tolerance Reassessment, 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 alkyl trimethylenediamines, case 3014, consists of five active ingredients (PC codes: 067301, 067302, 067309, 067310, and 067313). One of these active ingredients was registered in June of 1955. ATMD is currently an active ingredient in 14 products. End use products are approved for use in industrial processes and water systems such as oilfield injection water systems. There are no tolerances for these chemicals.

B. Chemical Identification

The ATMD group is comprised of the five compounds shown in Table 1 and the physical chemistry is shown in Table 2 below. The alkyl indicates fatty acids of coconut oil, which contain one long alkyl chain, primarily C_{12}. Each chemical is identified by an individual CAS number, so as a result, product chemistry information is provided for each. The values presented have been obtained from the best available data and the Agency believes it is adequate to make an assessment. However, the information can be further refined with input from the registrants involved in this RED case.

Table 1 Active Ingredients in the Cluster Identified by Alkyl Trimethylenediamines (ATMD) (a-e)

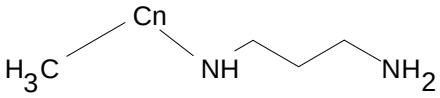
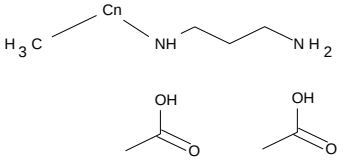
PC Chemical Code	CAS Number	Chemical Name	Structure	Common Name
067301	61791-63-7	Alkyl*-1,3-propylenediamine **(a)**	$R\text{-}NH(CH_2)_3NH_2$ R = derived from alkyl groups found in coconut oil	N-(coco alkyl) trimethylenediamine
067302	61791-64-8	N-Alkyl*-1,3-propylenediamine acetate *(as in fatty acids of coconut oil) **(b)**	$[RNH_2\text{-}[CH_2]_3\text{-}NH_3] + 2[CH_3COO]$ R = derived from fatty acids of coconut oil	1-(Alkyl*amino)-3-aminopropane monoacetate *(as in fatty acids of coconut oil)
067309	68155-43-1	1-(Coco alkylamino)-3-aminopropane hydroxyacetate Cocodiamine salt **(c)**	$[RNH_2\text{-}[CH_2]_3\text{-}NH_3] + [OHCH_2COO]$ R = derived from fatty acids of coconut oil	1-(Alkyl*amino)-3-aminopropane hydroxyacetate
067310	68155-37-3	Alkyl*-1,3-propylenediamine *(42%C12, 26%C18, 15%C14, 8%C16, 5%C10, 4%C8) **(d)**	 n = (42%C12, 26%C18, 15%C14, 8%C16, 5%C10, 4%C8)	1-(Alkyl*amino)-3-aminopropane * (42%C12, 26%C18, 15%C14, 8%C16, 5%C10, 4%C8)
067313	61791-64-8	1-(alkyl* amino)-3-aminopropane diacetate **(e)**	 n = (42%C12, 26%C18, 15%C14, 8%C16, 5%C10, 4%C8)	1-(Alkyl*amino) -3-aminopropane diacetate

Table 2. Physical/Chemical Properties for Alkyl trimethylenediamines (ATMD)

Parameter	PC Codes				
	067301(a)	067302 (b)	067309 (c)	067310 (d)	067313 (e)
Molecular Weight	139 g/mol	276 g/mol	338 g/mol – 478 g/mol. Average weight is 394 g/mol, and variable distribution in weight is based on varying alkyl chain	Not Available	Not Available
Specific Gravity	0.836 @ 25 °C	Not Available	Not Available	Not Available	Not Available
Physical State	Not Available	Solid @ 20 °C	Not available	Not Available	Not Available
Boiling Point	572 °F	180-250 °C	81 °C	Not Available	Not Available
Solubility	0.086 g/100 mL water which equals 0.00086 g/mL of water. Insoluble in water; miscible in organic solvents.	99.2 g/100 mL water, which equals 0.992 g/mL of water	50.5 g/100 mL water which equals 0.505 g/mL water	Not Available	Not Available
Density	Not Available	0.83-0.87	0.9588 g/mL	Not Available	Not Available
Vapor Pressure	<0.1 mm Hg @ 20 °C	<5mm Hg @ 20 °C	<4.27 x 10^{-7} mm Hg @ 25 °C	Not Available	Not Available
Melting Point	62 °F	Not required since the end-use formulation is liquid at room temperature	Not Available	Not Available	Not Available
K_{ow}	Not Available	Not required because the active ingredient and end-use formulations are soluble in water and therefore polar	Not Available	Not Available	Not Available
pK	Not Available	6.42 – 8.77 for a product with 47% a.i.	Not Available	Not Available	Not Available

C. Use Profile

The following section provides information on the currently registered uses of alkyl trimethylenediamines shown in Table 3 below. Included is an overview of the use sites and application methods. Please refer to Appendix A for a comprehensive table of uses of ATMD eligible for reregistration.

Table 3. Use Profile for Alkyl trimethylenediamines (ATMD)

Parameter	PC Codes				
	067301(a)	067302 (b)	067309 (c)	067310 (d)	067313 (e)
Type of Pesticide	Antimicrobial	Antimicrobial	Antimicrobial	Antimicrobial	Antimicrobial
Target Organisms	Bacteriocide, Molluscide	Microbicide, Bacteriocide	Microbicide	Microbicide	Microbicide
Use Sites	***Industrial Processes and Water Systems*** Secondary Oil Recovery Injection Water Industrial Processing Water, not including fresh water cooling tower systems	***Industrial Processes and Water Systems*** Oilfield and petrochemical water injection systems Cooling water recirculating systems	***Industrial Processes and Water Systems*** Oilfield Injection water systems	***Industrial Processes and Water Systems*** Oilfield injection water systems Packer and workover fluids	***Industrial Processes and Water Systems*** Oilfield injection water systems Industrial recirculating water cooling towers Well completion and workover fluids.
Formulation Types	Soluble solution	Soluble concentrate, ready to use solution	Soluble concentrate	Soluble concentrate	Soluble concentrate
Application Rates/Methods	Slug Method: 12 ounces of product per 1000 gallons of water. (95ppm.)	***Oilfield and petrochemical water injection systems:*** Slug Treatment:1-2 pints	Continuous injection: 1 part product to 5,000-10,000 parts	***Waterfloods and salt water disposal systems:*** Continuous injection: 0.4-2.0 gallons of product per	***Oilfield injection water systems:*** Slug Treatment: One pint to 2 quarts of

Table 3. Use Profile for Alkyl trimethylenediamines (ATMD)

Parameter	PC Codes				
	067301(a)	067302 (b)	067309 (c)	067310 (d)	067313 (e)
	Continuous: 12 ounces of product per 1000 gallons of water. (95ppm.), then 0.5-2.5 oz. per 100 gals 1 to 4 pints of product for each 120,000 gallons of water.	of product per 1000 gallons of water. Continuous Treatment: ¼-1/2 pint of product per 1000 gallons of water. ***Cooling water recirculating systems:*** Slug Treatment: 40 gallons of product per 1000 gallons of water. Continuous Treatment: 1-8 gallons of product per 1000 gallons of water.	water when noticeably fouled. 1 part product to 10,000-20,000 parts water to maintain control. Batch treatment: 1 part product to 5,000-10,000 parts water over a period of six (6) hours, several times a week.	1000 barrels of water Batch treatment: 2-8 gallons of product per 1000 barrels of water. ***Packer and workover fluids:*** 5-10 gallons of product per 1000 barrels	product per 1000 gallons of water. Continuous Treatment: ¼ pint of product per 1000 gallons of water. Slug Treatment: 21 gallons of product per 1000 barrels of water. Continuous Treatment: 4.2-8.4 gallons of product per 1000 barrels of water. ***Industrial recirculating water cooling towers:*** One pint to 2 quarts of product per 1000 gallons of water. *Well completion, work over and packer fluids:* 4.2-8.4 gallons of product per 1000 barrels of water.

III. SUMMARY OF ALKYL TRIMETHYLENEDIAMINES (ATMD) RISK ASSESMENTS

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 alkyl trimethylenediamines. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2007-0537. Hard copies of these documents may be found in the OPP public docket under this same docket number. The OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

The human health risk assessment for ATMD incorporates potential exposure and risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children. For information on the ATMD human health risk assessment, see ATMD Risk Assessment, dated May 8, 2007, available at www.regulations.gov (EPA-HQ-OPP-2007-0537).

1. Toxicity of Alkyl trimethylenediamines

A brief overview of the toxicity of ATMD is presented below. The Agency has reviewed all toxicity studies submitted for ATMD and has determined that the toxicological database is sufficient for reregistration. For more details on the toxicity and carcinogenicity of the ATMD, see the Alkyl trimethylenediamines Toxicology Disciplinary Chapter, dated April 5, 2007, which is available under docket number EPA-HQ-OPP-2007-0537 at www.regulations.gov.

The Agency has not established toxicity endpoints for ATMD. ATMD is being reevaluated qualitatively as a low exposure chemical. The classification as low exposure is based on the limited use patterns and low potential for occupational exposure. There are no non-occupational uses of ATMD.

Available acute toxicity data show that ATMD is toxic (Toxicity category II) in acute oral studies in rats, less toxic (Toxicity category III) in an acute dermal toxicity study in rabbits, highly corrosive (Toxicity category I) in a primary eye irritation study in rabbits and extremely irritating (Toxicity category I) in primary dermal irritation studies in rabbits. No acute inhalation or dermal sensitization is available. The acute toxicity of technical grade ATMD is summarized below in Table 4.

Table 4. Acute Toxicity Studies with 1-Alkyl*amino-3-aminopropane [* as derived from coconut oil fatty acids] Case Number 067310				
Guideline Number	**Study Type**	**MRID Number/Citation**	**Results**	**Toxicity Category/ Acceptable (Yes or No)**
870.1100	Acute Oral Toxicity (Rat)	240231210	LD_{50} = 147.5 mg/kg	II/Yes [Readability issues]
870.1100	Acute Oral Toxicity (Rat)	0658-040-03	LD_{50} =app. 500 mg/kg	II/Yes
870.1200	Acute Dermal (Rabbit)	240231210	LD_{50} > 2000 mg/kg	III/Yes
870.1300	Acute Inhalation	n/a	n/a	n/a
870.2400	Primary Eye Irritation (Rabbit)	0658-040-03	Corrosive	I/Yes [1% formulation]
870.2500	Primary Skin Irritation (Rabbit)	FDRL 81-080*	Extremely Irritating	I/Yes [Readability issues]
870.2500	Primary Skin Irritation (Rabbit)	0658-040-03	Corrosive	I/Yes
870.2600	Dermal sensitization	n/a	n/a	n/a

* Food and Drug Research Laboratories ID Number

As discussed in Chapter II, the uses include oilfield/petrochemical injection water systems; industrial recirculating water cooling systems; non-potable industrial waters and other industrial processing water systems. All applications of ATMD are commercial; there are no residential applications for this chemical. As discussed in the Occupational Handler Exposure section below, all applications of ATMD are made through closed delivery and loading systems that result in negligible or minimal exposure to the applicator, depending on the application equipment. No post-application exposure is anticipated. Additional information can be found in the Occupational Handler Exposure, Section 7a of this document.

The toxicology database for ATMD is fairly limited, subchronic and chronic toxicity data for these chemicals are not available. However, EPA believes that the available data is representative of all the active ingredients in this case. In addition, the Agency conducted a Structural Activity Relationship (SAR) analysis to determine if there was data available on any structurally similar chemicals. The Agency determined that Propanediamine, N-Octyl Diacetate (CAS 030619-57-9) is structurally similar and can be used to evaluate the relative toxicity of ATMD in this RED.

For the structurally similar Propanediamine, N-Octyl Diacetate, the Agency reviewed a 13 week dermal study in rabbits that indicated potential reproductive concerns such as decreased testicular weight and disturbance in spermatogenesis. These effects are shown in both low and high treatment groups in the study. The study concluded that these effects are treatment related. However, these effects are not seen in a typical, dose-responsive manner. Specifically, the study indicates a greater effect in the study group that received a lower dose. In addition, other signs of systemic effects including decreased body weight, inflation of internal organs, increased brain weight were noted in the study. The study indicates that these effects may be related to an infection in the test animals and are not treatment related.

Because the currently registered use patterns are not expected to result in appreciable exposure to workers, the Agency does not intend to require additional data at this time based on the SAR analysis. However, if additional uses are registered for ATMD, the Agency would require additional data to support the registrations. These studies would be intended to address potential systemic and reproductive concerns and include, but are not limited to: a subchronic (90-day) toxicity study; a developmental toxicity study; and a mutagenicity study.

Carcinogenicity Classification

ATMD has not been assessed for carcinogenic potential. However, based on the limited exposure of the registered use patterns, it is not believed that there is potential for long-term exposure to ATMD.

Mutagenicity Potential

Two mutagenicity studies were submitted for ATMD. The Ames Salmonella test where ATMD was negative for reverse mutations in the absence or presence of microsomal S9 in five Salmonella strains up to cytotoxic concentrations. In a mouse bone marrow chromosomal aberration test, ATMD was negative for inducing micronuclei in the polychromatic erythrocytes of mice treated orally at doses up to clinical and cytotoxic levels (125 mg/kg).

Although both studies are considered acceptable and meet the current guidelines, the database for mutagenicity of N-Coco-1, 3-diaminepropane is considered incomplete. As mentioned earlier, the Agency conducted a Structural Activity Relationship (SAR) analysis to determine if there was data available on any structurally similar chemicals. The Agency determined that the data for Propanediamine, N-Octyl Diacetate (CAS 030619-57-9) is structurally similar and can be used to evaluate the relative toxicity of ATMD in this RED.

Based on the results of the data from the SAR analysis, the Agency will require another mutagenicity study if additional use patterns for ATMD are registered in the future. If required, this study would be used to confirm that the effects noted were not treatment related

2. FQPA Safety Factor Considerations

The FQPA Safety Factor (as required by FQPA) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. However, because ATMD is a non-food use chemical, this risk assessment is not required.

3. Dietary Exposure and Risk Assessment

Based on the labeled use patterns for ATMD (oil field and recirculating cooling water

towers), the active ingredient is not expected to contact food. Although alkyl TMD is used in cooling water tower systems, which can discharge the water into potential drinking water sources, the label restricts the use to recirculating systems. It is anticipated that the biocides used in recirculating systems are degraded and the concentrations are diluted by the time any discharge actually occurs. Therefore, the Agency has determined that it is not necessary to conduct dietary or drinking water assessments for ATMD use in recirculating cooling water towers.

4. Residential Exposure and Risk

There are no registered residential uses for the alkyl trimethylenediamines. Therefore, residential exposures are not expected and an assessment is not required.

5. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. No exposure from food, drinking water and residential sources is expected. Therefore, this risk assessment is not required.

6. Occupational Exposure

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk assessed for exposure at the time of application is termed "handler" exposure. Post-application occupational exposures occur when worker re-enter sites treated with a pesticide. Application parameters used in the risk assessment are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site and by the application rate required to achieve an efficacious dose.

a. Occupational Handler Exposure

Since ATMD active ingredients have extremely low vapor pressures, respiratory protection is not required. The Agency believes that the use of labeled personal protective clothing (PPE) and closed loading and delivery systems results in negligible or minimal exposure, depending on the application equipment. Therefore, the Agency has determined that it is not necessary to perform quantitative exposure and risk assessments for these active ingredients. However, the current labels must be revised, if necessary, to ensure the use of PPE including gloves and specific closed delivery and loading systems such as dry coupling (i.e., drips no more than 2 ml) and/or metering pumps, as appropriate.

Closed loading systems are engineering controls that are *"…designed to prevent human exposure and should not require human intervention to eliminate exposure"* (CDPR 2003)[1]. Closed transfer systems that require the worker to open pour the concentrate into a transfer system are not considered under this definition of closed loading systems because the initial exposure for the open pour will require a quantitative assessment. Although closed loading and delivery systems are designed to prevent or eliminate exposure, zero exposure is difficult to obtain. Although analytical techniques can measure residues at extremely low levels, for practical purposes, these residues are considered to be negligible or minimal.

Negligible exposure can be considered to result from the use of systems that are designed to drip less than 2 mL per coupling as in dry coupling or metering pumps that are closed on both ends. The second category, minimal exposure, has been established because some closed systems are not entirely enclosed or have not been engineered to reduce drips to 2 ml, but for practical purposes effectively reduce exposure such that risks are not of concern. Minimal exposure can be considered to result from closed systems that are designed to prevent or eliminate inhalation and dermal exposure but are not engineered to a specification (e.g., volume expected to be discharged).

In the case of ATMD products, the Agency expects that occupational exposures will be negligible or minimal, assuming that the appropriate PPE (i.e., long pants, long-sleeved shirts, and chemical resistant gloves) and label-specified closed delivery *and loading systems* such as dry coupling and/or metering pumps, as appropriate, are consistently utilized. Therefore, a quantitative exposure and risk assessment is not warranted and the risks can be considered not a concern.

b. Occupational Post-application

Occupational post-application exposure is not expected based on the currently registered use patterns for the alkyl trimethylenediamines. Therefore postapplication exposures where not accessed.

7. Human Incident Data

The Agency reviewed the following sources of information for human poisoning incidents related to ATMD use: (1) OPP Incident Data System (IDS) - The Office of Pesticide Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) California Department of Pesticide Regulation (1982-2004) – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982. (3) National Pesticide Information Center (NPIC) - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which

[1] Fong, H.R. 2003. *An Overview of Closed System Use in California 2001-2002.* Report HS-1849. California Environmental Protection Agency, Department of Pesticide Regulation, Worker Health and Safety Branch. June2003.

telephone calls were received during calendar years 1984-1991. (4) National Poison Control Centers (PCC) (1993–1996). In the numerous data bases that have been reviewed and searched, there are no reported incidents associated with alkyl trimethylenediamines.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for ATMD use sites and any associated uncertainties. For a detailed discussion of all aspects of the environmental risk assessment, see the document "Environmental Hazard and Risk Assessment," dated March 6, 2006 at http://www.regulations.gov.

1. Environmental Fate and Ecotoxicity Assessment/Characterization

The alkyl trimethylenediamines compound, 1-(alkyl* amino)-3-aminopropane diacetate (applied as Duomeen-C Diacetate, 51.9% a.i. in isopropanol), has been shown to be hydrolytically stable under abiotic and buffered conditions over the pH 5-9 range and under abiotic and unbuffered conditions (deionized water, pH *ca*. 6.2) over a 30-day incubation period.

2. Ecological Exposures and Risk

For the registered uses of ATMD, the potential for exposure to ecological organisms is expected to be low. Although the Agency has not performed label hazard or ecological risk assessments, the Agency expects to need ecological toxicity studies for the active ingredient and/or any of its metabolic and/or hydrolytic transformation products identified to be of potential concern.

3. Ecological Risk

The ecotoxicological endpoints for ATMD are provided in tables 5-9 below.

Table 5. Acute Avian Toxicity Data for Alkyl trimethylenediamines

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Bobwhite quail (*Colinus virginianus*)	Alkyl trimethylenediamines 100%	LD_{50} = 0.24 NOAEL = 0.1	Very highly toxic	Yes (supplemental) - 14-day test duration - >16 weeks of age	470013023
Bobwhite quail (*Colinus virginianus*)	Alkyl trimethylenediamines % purity unknown	LD_{50} = 492.5 (M) and 366.8 (F)	Moderately toxic	Yes (supplemental) - 14-day test duration - 17 weeks of age	97534
Bobwhite quail (*Colinus virginianus*)	Alkyl trimethylenediamines 23.5%	LD_{50} = 681	Slightly toxic	Yes (supplemental) -21-day test duration - Adult	134550
Bobwhite quail (*Colinus virginianus*)	Alkyl trimethylenediamines 22%	LD_{50} = 500	Moderately toxic	Yes (supplemental) -21-day test duration -Young adult	106859
Mallard duck (*Anas platyrhynchos)*	Alkyl trimethylenediamines 22%	LD_{50} = 3,200	Relatively nontoxic	Yes (supplemental) -14-day test duration -Young adult	110384

These acceptable acute oral toxicity studies on the mallard duck and bobwhite quail indicate that ATMD is very highly toxic to relatively nontoxic to birds on an acute oral basis depending on the concentration of active ingredient. The guideline requirement OPPTS 850.2100/(71-1) is satisfied.

Table 6. Subacute Avian Toxicity Data for Alkyl trimethylenediamines

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (ppm)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Bobwhite quail (*Colinus virginianus)*	Alkyl trimethylenediamines 100%	LC_{50} (diet) = 6,400 NOAEC = 800	Relatively nontoxic	Yes (core) - 8-day test duration - 17 days of age	470013024
Bobwhite quail (*Colinus virginianus)*	Alkyl trimethylenediamines 0.03%	LC_{50} (diet) = 100,000 NOAEC = 100,000	Relatively nontoxic	Yes (core) - 8-day test duration	123864
Mallard duck (*Anas platyrhynchos)*	Alkyl trimethylenediamines 0.03%	LC_{50} (diet) = 100,000 NOAEC = 100,000	Relatively nontoxic	Yes (core) - 8-day test duration	123863
Mallard duck (*Anas platyrhynchos)*	Alkyl trimethylenediamines % purity unknown	LC_{50} (diet) = 5,000	Slightly toxic	Yes (supplemental) - 8-day test duration - 11 days of age	97516
Bobwhite quail (*Colinus virginianus)*	Alkyl trimethylenediamines % purity unknown	LC_{50} (diet) = 5,000 NOAEC = 500	Slightly toxic	Yes (supplemental) - 8-day test duration - 10 days of age	97535
Mallard duck (*Anas platyrhynchos)*	Alkyl trimethylenediamines 32%	LC_{50} (diet) = 6,400 NOAEC = 3,200	Relatively nontoxic	Yes (supplemental) - 8-day test duration - 10 days of age	470013025
Bobwhite quail (*Colinus virginianus)*	Alkyl trimethylenediamines 32%	LC_{50} (diet) = 6,400	Relatively nontoxic	Yes (core) - 8-day test duration - 16 days of age	40062405
Mallard duck (*Anas platyrhynchos)*	Alkyl trimethylenediamines 50%	LC_{50} (diet) = 5000	Slightly toxic	Yes (core) -8-day test duration -10 days of age	133266

The results from eight acceptable studies indicate that alkyl trimethylenediamines is slightly toxic to relatively non-toxic to avian species through subacute dietary exposure. These studies fulfill guideline requirements OPPTS 850.2100/ (71-2a – Bobwhite quail and 71-2b – Mallard duck).

The Agency requested that aquatic toxicity studies be conducted with alkyl trimethylenediamines since under typical use conditions; it may be introduced into the aquatic environment.

Table 7. Acute Toxicity of Alkyl trimethylenediamines to Freshwater Fish

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Bluegill sunfish (*Lepomis macrochirus)*	Alkyl trimethylene diamines 32%	LC_{50} = 0.30 (a.i.)	Highly toxic	Yes (supplemental) - 96-hr test duration - static test system	41786601
Rainbow trout (O*ncorhynchus mykiss*)	Alkyl trimethylene diamines 32%	LC_{50} = 0.12 (a.i.)	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786606
Bluegill sunfish (*Lepomis macrochirus)*	Alkyl trimethylene diamines 0.03%	LC_{50} = 1,390 NOAEC = 1,000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123862
Rainbow trout (O*ncorhynchus mykiss*)	Alkyl trimethylene diamines 0.03%	LC50 = 1,300 NOAEC = 1,000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123862
Rainbow trout (O*ncorhynchus mykiss*)	Alkyl trimethylene diamines % purity unknown	LC_{50} = 1.58 NOAEC = 1.0	Moderately toxic	Yes (supplemental) - 96-hr test duration - static test system	97518
Redear sunfish (*Lepomis microlophus*)	Alkyl trimethylene diamines % purity unknown	LC_{50} = 3.63 NOAEC = 1.4	Moderately toxic	Yes (supplemental) - 96-hr test duration - static test system	97519
Rainbow trout (O*ncorhynchus mykiss*)	Alkyl trimethylene diamines 32%	LC_{50} = 0.87 NOAEC = 0.39	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786606
Bluegill sunfish (*Lepomis macrochirus)*	Alkyl trimethylene diamines 32%	LC_{50} = 0.96 NOAEC = 0.72	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786601

Table 7. Acute Toxicity of Alkyl trimethylenediamines to Freshwater Fish

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Bluegill sunfish (*Lepomis macrochirus)*	Alkyl trimethylene diamines 50%	LC_{50} = 0.3 NOAEC = 0.1	Highly toxic	Yes (core) - 96-hr test duration - static test system	133265

Freshwater acute toxicity tests indicate that alkyl trimethylenediamines is relatively nontoxic to highly toxic to freshwater fish on an acute basis depending on the concentration of active ingredient. These studies fulfill the guideline requirement for freshwater fish species under OPPTS 850.1075 (72-1a&b). Because acute toxicity to fish is <1.0 mg/L the environmental hazard section of ATMD labels must state: "This pesticide is toxic to fish."

Table 8. Acute Toxicity of Alkyl trimethylenediamines to Freshwater Invertebrates

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Waterflea (*Daphnia magna)*	Alkyl trimethylenedia mines 32%	EC_{50} = 0.0512 (a.i.)	Very highly toxic	Yes (core) - 48-hr test duration - static test system	41786602
Waterflea (*Daphnia magna)*	Alkyl trimethylenedia mines 32%	EC_{50} = 0.160 NOAEC = 0.130	Highly toxic	Yes (core) - 48-hr test duration - static test system	41786602
Waterflea (*Daphnia magna)*	Alkyl trimethylenedia mines 32%	EC_{50} = 0.104 NOAEC = 0.050	Highly toxic	Yes (core) - 48-hr test duration - static test system	40062409
Waterflea (*Daphnia magna)*	Alkyl trimethylenedia mines % purity unknown	LC_{50} = 0.12 NOAEC = 0.1	Highly toxic	Yes (supplemental) - 48-hr test duration - static test system	97521

The results of these studies indicate that alkyl trimethylenediamines is very highly toxic to highly toxic to freshwater invertebrates. These studies fulfill guideline requirement OPPTS 850.1010 (72.2a). Because the acute aquatic invertebrate toxicity value is < 1.0 mg/L, the environmental hazard section of ATMD labels must state: "This pesticide is toxic to aquatic

invertebrates."

Table 9. Acute Toxicity of Alkyl trimethylenediamines to Estuarine and Marine Organisms

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Quahog clam (*Mercenaria mercenaria*)	Alkyl trimethylenediamines 32%	EC_{50} = 0.019 (a.i.)	Very highly toxic	Yes (core) - 48-hr test duration - static test system	41786603
Atlantic silverside (*Menidia menidia)*	Alkyl trimethylenediamines 32%	LC_{50} = 0.155 (a.i.)	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786604
Mysid shrimp (*Mysidopsis bahia)*	Alkyl trimethylenediamines 32%	LC_{50} = 0.061 (a.i.)	Very highly toxic	Yes (core) - 96-hr test duration - static test system	41786605
Pink shrimp (*Penaeus duorarum*)	Alkyl trimethylenediamines 0.03%	LC_{50} = 1000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123866
Fiddler crab (*Uca pugilator*)	Alkyl trimethylenediamines 0.03%	LC_{50} = 1000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123866
Blue crab (*Callinectes sapidus*)	Alkyl trimethylenediamines % purity unknown	LC_{50} = 387 NOAEC = 274	Relatively nontoxic	Yes (supplemental) - 96-hr test duration - static test system	97520
Atlantic silverside (*Menidia menidia)*	Alkyl trimethylenediamines 32%	LC_{50} = 0.577 NOAEC = 0.22	Highly toxic	Yes (core) - 96-hr test duration - static-renewal test system	41786604
Mysid shrimp (*Mysidopsis bahia)*	Alkyl trimethylenediamines 32%	LC_{50} = 0.19 NOAEC = 0.13	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786605
Quahog clam (*Mercenaria mercenaria*)	Alkyl trimethylenediamines 32%	LC_{50} = 0.059 NOAEC = 0.045	Very highly toxic	Yes (core) - 48-hr test duration - static test system	41786603

Table 9. Acute Toxicity of Alkyl trimethylenediamines to Estuarine and Marine Organisms

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
White shrimp (*Penaeus setiferus*)	Alkyl trimethylenediamines 32%	LC_{50} = 2.39 NOAEC = 1	Moderately toxic	Yes (core) - 96-hr test duration - static test system	40062411
Eastern oyster (*Crassostrea virginica*)	Alkyl trimethylenediamines 32%	EC_{50} = 720 NOAEC = 300	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	40062412

The results of the studies indicate that alkyl trimethylenediamines is highly toxic to estuarine/marine fish and very highly toxic to relatively nontoxic to estuarine/marine invertebrates on an acute basis. These studies fulfill the guideline requirements OPPTS 850.1075/(72-3a), OPPTS 850.1035/(72-3c) and OPPTS 850.1025/(72-3b). Because estuarine/marine aquatic fish, mollusk, and shrimp acute toxicity values are < 1.0 mg/L, the environmental hazard section of ATMD labels must state: **"**This pesticide is toxic to clams/oysters and shrimp."

Chronic toxicity testing and non-target plant phytotoxicity is required for pesticides when certain conditions of use and environmental fate apply. Neither of these test are required for alkyl trimethylenediamines.

4. Listed Species Consideration

a. The Endangered Species Act

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

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

This approach, will allow the Agency to determine whether ATMD use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that ATMD "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of ATMD is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (Services), as appropriate. The Agency has not conducted and Endangered Species Risk Assessment for ATMD.

IV. RISK MANAGEMENT, REREGISTRATION AND TOLERANCE REASSESMENT DECSION

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 ATMD 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 all products containing alkyl trimethylenediamines.

The Agency has completed its assessment of the dietary, residential, occupational and ecological risks associated with the use of pesticide products containing the active ingredient alkyl trimethylenediamines. Based on a review of the data from the SAR analysis and other available information for the active ingredient, alkyl trimethylenediamines, the Agency has sufficient information on the human health and ecological effects and exposure potential of ATMD to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that ATMD containing products are eligible for reregistration. Appendix A summarizes the uses of ATMD 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 ATMD and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of alkyl trimethylenediamines, the Agency has determined that ATMD products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of alkyl trimethylenediamines. If all changes outlined in this document are incorporated into the product labels, then all current risks for ATMD will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Risk assessments for ATMD were not issued for public comment per the Agency's public participation process because a risk assessment was not required based on the negligible potential for human health or ecological exposures. To ensure that an opportunity is presented to the public to comment on the risk assessments and risk management decisions for alkyl trimethylenediamines, the Agency will provide a 60-day public comment period on the ATMD RED document.

C. Regulatory Position

1. Food Quality Protection Act Findings

Based on the labeled use patterns for ATMD, the active ingredient is not expected to contact food. Therefore ATMD is considered a non-food use chemical. A risk assessment is not required.

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 the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, ATMD may be subject 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 alkyl trimethylenediamines. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for alkyl trimethylenediamines. 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/.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of ATMD as an active ingredient. The Agency feels there is reasonable certainty of no harm resulting from exposure to ATMD as an active ingredient to the general population and to infants or children in particular.

Because of the minimal potential for exposure to workers or the environment from ATMD use, the Agency has determined that a qualitative approach to assessing human health risks and ecological risks from exposure to these chemicals is appropriate. The chemicals in the ATMD case have extremely low vapor pressures, resulting in very low potential for inhalation exposure. In addition, the use of personal protective equipment (PPE) along with closed loading and delivery systems will result in negligible or minimal exposure to workers.

In Section 7a, the Agency presented information on the Structural Activity Analysis that was conducted for ATMD. This analysis indicated potential reproductive concerns such as decreased testicular weight and disturbance in spermatogenesis. However, the currently registered use patterns are not expected to result in significant exposure to workers; therefore, the Agency does not intend to require additional risk mitigation or data at this time. However, if additional uses are registered for ATMD, the Agency would require additional data to support the registrations. These studies would be intended to address potential systemic and reproductive concerns and include, but are not limited to: a two generation reproduction study; a subchronic (90-day) toxicity study; a developmental toxicity study; and a mutagenicity study.

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.

The future Endangered Species Assessment will allow the Agency to determine whether ATMD uses have "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that ATMD "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of ATMD is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (Services), as appropriate.

b. General Risk Mitigation

ATMD end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing ATMD 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.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that ATMD are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the label amendments are made to reflect these measures. The registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For ATMD technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

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

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

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

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

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

For end use products containing the active ingredient alkyl trimethylenediamines, 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 (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 (CSF) (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 15 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 Marshall Swindell at (703) 308-6341 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
Marshall Swindell (PM-33)
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk
Marshall Swindell (PM-33)
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of ATMD has been reviewed and determined to be substantially complete. Based on the currently registered use patterns, the Agency is not requiring additional data at this time. However, if additional uses are registered for ATMD, the Agency would require additional data to support the registrations. These studies would be intended to address potential systemic and reproductive concerns and include, but are not limited to: a two generation reproduction study; a subchronic (90-day) toxicity study; a developmental toxicity study; and a mutagenicity study.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling

should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 6, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 6.

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

a. Label Changes Summary Table

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

Table 6. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Product		
PPE	All labels must state long pants, long sleeved shirt,and chemical resistant gloves must be worn when handling the product and it must be applied using a closed delivery system such as a dry coupling and/or metering pump.	Precautionary Statements
Ecological Effects Language Required by the RED and PR Notice 93-10 and 95-1	"This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Environmental Hazard Statements
	For industrial water systems, all labels must limit use to closed systems. Use in once-through industrial water systems is prohibited.	

VI. APPENDICES

Alkyl trimethylenediames Appendix A

Use Site	Formulation/ Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Industrial processes and water systems.				
Oilfield Injections Water Systems	10707-5 (Ready-to use)	Continuous Injections Batch Treatment	Continuous Injections: Add product at 1 part per 10,000 parts water (4 gallons per 1,000 bbl water) when system is noticeably fouled. Product per 10,000 parts water (4 gallons per 1,000 bbl water) to maintain control. Batch Treatment: Add product at 1 part 10,000 parts water (4gallons per 1,000 bbl water) over a period of 6 hour several times per weeks	None Listed
Oilfield Injections Water Systems	10707-6 (Soluble concentrate)	None Listed	Continuous Injections: Add product at 1 part per 5,000 parts water (9 gallons per 1,000 bbl water) when system is noticeably fouled. Product per 10,000 parts water (4 gallons per 1,000 bbl water) to maintain control. Batch Treatment: Add product at 1 part 5,000 parts water (9gallons per 1,000 bbl water) over a period of 6 hour several times per weeks.	None Listed
Oilfield Injections Water	10707-33	Slug Treatment	Dosages may vary from 500	None Listed

Use Site	Formulation/ Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Systems (Continued)	(Ready-to use)		ppm in slug applications. To 30 – 50ppm in continuous treatment (1/4 pint per 1,000 gallons equals approximately 30ppm.) 30 – 60ppm for badly fouled systems	
	34688-55 (Formulation Intermediate)	Closed Delivery system	Formulation use only	Formulation use only
	68708-8 (Ready-to use)	Slug Treatment/ Continuous injections	Slug Method: 12 ounces of product per 1000 gallons of water. (95ppm.) Continuous: 12 ounces of product per 1000 gallons of water. (95ppm.), then 0.5-2.5 oz. per 100 gallons	Use with closed delivery systems only.
	68708-6 (Ready-to use)	Slug, Batch and Continuous Treatment	Continuous: 10 to 50ppm of product Batch or Slug: 50 to 200ppm of product for up to 16 hours once or twice a week as needed.	None Listed
Oil Well Completions, workover, stimulation fluids, petroleum transportation systems, storage systems and surface equipment	34688-67 (Ready-to use)	None stated	200 to 250ppm concentration	None Listed
Natural Gas Wells, Gathering Systems and Pipelines	10707-55 (Formulation Intermediate)	Slug Treatment or continuous application	Slug Treatment: 1,000 to 50,000 ppm of product. Continuous Treatment: 2,000 ppm of product	None Listed
Packer Fluids and Workover Fluids	68708-6 (Ready-to use)	Injection via chemical pump	1200 to 2400ppm product	None Listed

Use Site	Formulation/ Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Non potable Industrial Waters	69100-1 (Ready-to use)	Injection into closed delivery systems	1 to 4ppm (1 to 4 pints of product for each 120,000 gallons of water.	Closed Delivery Systems Only. Not for use in fresh water cooling tower systems.
Industrial Re-circulating Water Cooling Systems	10707-33 (Ready-to use)	Apply directly to system where it will be uniformly mixed	Apply 120 to 500ppm of product to system when re-growth is first noticed. Maintain 30 to 50ppm in system for system control	None Listed

APPENDIX B: ATMD

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of ATMD. These requirements apply to 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 **(12)** will identity 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		143397 43000801 43132901 43148501 43355601 43355602 43355604
830.1600 830.1620 830.1650	61-2 A	Starting Materials and Manufacturing Process		134346 143397 43000801 43132901 43148501 43355601 43355602 43355603 43355604
830.1670	61-2 B	Formation of Impurities		43132901 43148501 43355601 43355602 43355603 43355604
830.1700	62-1	Preliminary Analysis		143397 43029201 43148501 43355601 43355602 43355603 43355604

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.1750	62-2	Certification of Limits		143397 43029201 43087401 43148501
830.1800	62-3	Analytical Method		143397 43029201 43103701 43148501 43355601 43355602 43355603 43355604
830.6302	63-2	Color		43087401 43148501 43406801
830.6303	63-3	Physical State		43024504 43029202 43087401 43148501 43390601 43406801
830.6304	63-4	Odor		43084701 43148501 43406801
830.7220	63-6	Boiling Point		43024504 43029202 43090701 43132901 43148501 43390601

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.7300	63-7	Density		43029202 43090401 43148501 43390601
830.7840 830.7860	63-8	Solubility		43024504 43029202 43047301 43090501 43132901 43148501 43390601
830.7950	63-9	Vapor Pressure		43024504 43029202 43132901 43148501 43390601 43460301
830.7370	63-10	Dissociation Constant in Water		43047801 43132901 43148501 43301201
830.7000	63-12	pH		43024504 43029202 43090401 43132901 43148501 43390601

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.6313	63-13	Stability		43024504 43029202 43132901 43148501 43231501 43390601
830.6314	63-14	Oxidizing/Reducing Action		43024504 43132901 43148501
	63-15	Flammability		43132901 43148501
830.6316	63-16	Explodability		43024504 43029202 43132901
830.6317	63-17	Storage Stability		143397 43132901 43148501
	63-18	Viscosity		43024504 43132901 43148501
830.6320	63-20	Corrosion Characteristics		43132901 43148501
ECOLOGICAL EFFECTS				
850.2100	71-1 A	Avian Acute Oral Toxicity Test - Quail/duck		97534 106859 110384 134550 40062404

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/duck		97516 97535 123863 123864 133266 40062405 470013023 470013024 470013025
850.1075	72-1 A	Fish Acute Toxicity - Bluegill		97519 133265 123862 41786601
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout		97518 41786606
850.1010	72-2 A	Acute Aquatic Invertebrate Toxicity		97521 41786602
850.1025?	72-3 A	Estu/Mari tox. Fish		123866 41786604
850.1035?	72-3 B	Estu/Mari tox. Mollusk		40062412 41786603
850.1045?	72-3 C	Estu/Mari tox. Shrimp		97520 40062411 41786605
TOXICOLOGY				
870.1100	81-1	Acute Oral – Rat		145463
870.1200	81-2	Acute Dermal – Rabbit		145464
870.1300	81-3	Acute Inhalation – Rat		Data gap

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.2400	81-4	Acute Eye Irritation - Rabbit		145465
870.2500	81-5	Acute Skin Irritation - Rabbit		145466
870.2600	81-6	Dermal Sensitization		Data gap
870.3700	83-3 A	Prenatal Developmental Toxicity - Rat		Data Gap
870.3700	83-3 B	Prenatal Developmental Toxicity – Rabbit		Data Gap
870.5100	84-2 A	Bacterial Reverse Mutation Test - Ames		42594101
870.5375	84-2 B	In Vitro Mammalian Chromosome Aberration Test		42594102
*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.				
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of Parent and Degradates		40062413 41069001 93034010

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

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

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at www.regulations.gov

These documents include:

- Alkyl trimethylenediamines: Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Codes: 067301, 067302, 067309, 067310, and 067313. Antimicrobials Division, May 8, 2007, SanYvette Williams-Foy, D.V.M., Risk Assessor

- Alkyl trimethylenediamines: Occupational Risk Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document. PC Codes: 067301, 067302, 067309, 067310, and 067313, Antimicrobials Division, March 21, 2007, Cassi L. Walls, Ph.D., Chemist.

- Ecological Hazard and Environmental Risk Assessment Chapter for the Alkyl Trimethylenediamines Reregistration Eligibility Decision (RED) Document (Case No. 3014). Risk Assessment and Science Support Branch, Antimicrobials Division, January 30, 2007, Genevieve Angle, Biologist.

- Product Chemistry Chapter for the Alkyl trimethylenediamines Reregistration Eligibility Decision Document (RED). Antimicrobials Division, February 27, 2007, Talia Lindheimer, Chemist, Team II.

- Environmental Fate Science Chapter for the Alkyl trimethylenediamines Reregistration Eligibility Decision (RED) Document Case No. 3014, DP Barcode: 336032. Risk Assessment and Science Support Branch, Antimicrobials Division, January 30, 2007, Srinivas Gowda, Microbiologist/Chemist.

- Evaluation of Toxicology Database for the Registration Eligibility Decision Document Disciplinary Chapter for Alkyl Trimethylenediamines. Risk Assessment and Science Support Branch, Antimicrobials Division, April 5, 2007, S.L. Malish, Ph.D., Toxicologist.

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

GUIDE TO APPENDIX D

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

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

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

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

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

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

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

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

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

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

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

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

1. MRID Studies

MRID # Citation

MRID 106859. Fletcher, D. (1973) Report to Nalco Chemical Company: Acute Oral Toxicity Study with 32D16 in Bobwhite Quail: IBT No. 651-02892. Unpublished study received Apr 9, 1973 under 1706-126; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Nalco Chemical Co., Oak Brook, IL; CDL: 051060-D)

MRID 110384. Fletcher, D. (1973) Report to Nalco Chemical Company: Acute Oral Toxicity Study with 32D16 in Mallard Ducks: IBT No. 651-02893. Unpublished study received Apr 9, 1973 under 1706-126; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Nalco Chemical Co., Oak Brook, IL; CDL: 051060-C)

MRID 123862. Bentley, R. (1975) Acute Toxicity of Co-op Turbex to *Lepomis macrochirus* and *Salmo gairdneri*. (Unpublished study received Mar 5, 1975 under 1990-372; prepared by Bionomics, EG&G Environmental Consultants; submitted by Farmland Industries, Inc., Kansas City, MO; CDL: 110678-A)

MRID 123863. WARF Institute, Inc. (1975) Report: WARF Institute No. 4112599. (Unpublished study received Mar 5, 1975 under 1990-372; submitted by Farmland Industries, Inc., Kansas City, MO; CDL: 110680-A)

MRID 123864. WARF Institute, Inc. (1975) Report: WARF Institute No. 4112599. (Unpublished study received Mar 5, 1975 under 1990-372; submitted by Farmland Industries, Inc., Kansas City, MO; CDL: 110680-B)

MRID 123866. Heitmuller, T. (1975) Acute Toxicity of Surflo-B15 to Larvae of the Eastern Oyster (*Crassostrea virginica*), Pink Shrimp (*Penaeus duorarum*), and Fiddler Crab (*Uca pugilator*). (Unpublished study received Jun 1, 1975 under 17664-11; prepared by Bionomics—EG&G, Inc., submitted by Baroid Div., N.L. Industries, Inc., Houston, TX; CDL: 165021-A)

MRID 133265. Thompson, C.; McAllister, W. (1983) Acute Toxicity of EH&S 266 to Bluegill Sunfish: Static Bioassay Report 30595. (Unpublished study received Oct 25, 1983 under 10349-14; prepared by Analytical Biochemistry Laboratories, Inc., submitted by Visco, Div. of Nalco Chemical Co., Sugar Land, TX; CDL: 251787-A)

MRID 133266. Beavers, J.; Jaber, M.; Joiner, G.; *et al*. (1983) A Dietary LC50 in the Mallard with EH&S 267: Project No. 187-103. Final Report. (Unpublished study received Oct 25, 1983 under 10349-14; prepared by Wildlife International, Ltd., submitted by Visco, Div. of Nalco Chemical Co., Sugar Land, TX; CDL: 251788-A)

MRID 134346. Armak Co. (1978) Product Chemistry: Duomeen C. (Compilation; unpublished

study receive Nov. 23, 1979 under 6922-19; CDL241391-A).

MRID 134550. Fletcher, D. (1972) Report to Esso Research and Engineering Company: Acute Oral Toxicity Study with MRD 72-10 in Bobwhite Quail: IBT No. J1739. (Unpublished study received Jul 25, 1972 under 8928-4; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Exxon Chemical Americas, Houston, TX; CDL: 005650-D)

MRID 143397. Welchem, Inc. (19??) Product Chemistry Requirements for Welchem Microbiocide 56. Unpublished compilation. 18p

MRID 145463. Andresen, M. (1984) Acute Oral Toxicity Study of Microbiocide 56 in Rats: Final Report: IIRi Project No. L8100: Study No. 887. Un- published study prepared IIT Research Institute. 20 p.

MRID 145464. Andresen, M. (1984) Acute Dermal Toxicity Study on Microbiocide 56 in rabbits: Final Report: IITRI Project No. L8100: Study No. 888. Unpublished study prepared by IIT Research Institute. 11 p.

MRID 145465. Andresen, M. (1984) Primary Eye Irritation Study of Microbiocide 56 in rabbits: Final Report: IITRI Project No. L8100: Study No. 886. Unpublished study prepared by IIT Research Institute. 13 p.

MRID 145466. Andresen, M. (1984) Acute Dermal Irritancy/Corrosivity study of Microbiocide 56 in Rabbits: Final Report: IITRI Project No. l8100: Study No. 885. Unpublished study prepared by IIT Re- search Institute. 19 p.

MRID 240231210 (ID#). Reagen, E.L. (1981). Acute Oral LD50 Assay in Rats; Study 6874. Final Report Unpublished study received April 29, 1981; prepared by Food and Drug Research Laboratories, Inc. submitted by Armak Co, McCook, IL. 3 p.

MRID 240231210 (ID#). Siglin, J.C. (1981). Acute Dermal Toxicity in Rabbits; Study 6874. Final Report Unpublished study received May 7, 1981; prepared by Food and Drug Research Laboratories, Inc. submitted by Armak Co, McCook, IL. 1 p.

MRID 40062404. Bisinger, E. (1984) Avian Oral LD50 in Bobwhite Quail: Wildlife and Aquatic Organism Data Requirements: Armohib B-101: Report No. T-4000: [Supplemental Data Submitted in Response to EPA's Comments]. Unpublished study prepared by Akzo Chemie America and Product Safety Labs. 14p.

MRID 40062405. Bisinger, E. (1984) Avian Dietary LC50 in Bobwhite Quail: Wildlife and Aquatic Organism Data Requirements: Armohib B-101: Report No. T-3995: [Supplemental Data Submitted in Response to EPA's Comments]. Unpublished study prepared by Akzo Chemie America and Product Safety Labs. 13p.

MRID 40062411. Bisinger, E. (1984) Acute LC50 in Estuarine and Marine Organisms/96-hour

LC50 in White Shrimp: Wildlife and Aquatic Organism Data Requirements: Armohib B-101: Report No. H-8241: [Supplemental Data Submitted in Response to EPA's Comments]. Unpublished study prepared by Akzo Chemie America and MBA Laboratories. 14p.

MRID 40062412. Bisinger, E. (1984) Acute LC50 in Estuarine and Marine Organisms/96-hour LC50 in Oyster: Wildlife and Aquatic Organism Data Requirements: Armohib B-101: Report No. H-8241: [Supplemental Data Submitted in Response to EPA's Comments]. Unpublished study prepared by Akzo Chemie America and MBA Laboratories. 14p.

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MRID 41069001. Bisinger, E. (1989) Hydrolysis of Duomeen-C Diacetate: Environmental Fate Data Requirements for Armohib B-101. Unpublished study prepared by Akzo Chemicals Inc. 30 p.

MRID 41786601. Surprenant, D. (1988). Acute Toxicity of Microbiocide 56 to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions: Lab Project Number: 88-6-2734: 384.1187.6100.00. Unpublished study prepared by Springborn Life Sciences, Inc. 20p.

MRID 41786602. Surprenant, D. (1988). Acute Toxicity of Microbiocide 56 to Daphnids (*Daphnia magna*): Lab Project Number: 88-3-2669: 384.1187.6100.110. Unpublished study prepared by Springborn Life Sciences, Inc. 20p.

MRID 41786603. Surprenant, D. (1988). Acute Toxicity of Microbiocide 56 to Embryo-Larvae of the Quahog Clam (*Mercenaria mercenaria*) Under Static Renewal Conditions: Lab Project Number: 88-5-2712. Unpublished study prepared by Springborn Life Sciences, Inc. 20p.

MRID 41786604. Surprenant, D. (1988). Acute Toxicity of Microbiocide 56 to Silversides (*Menidia menidia*) Under Static Renewal Conditions: Lab Project Number: 88-4-2687: 384.1187.6100.501. Unpublished study prepared by Springborn Life Sciences, Inc. 19p.

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MRID 41786606. Surprenant, D. (1990). Acute Toxicity of Microbiocide 56 to Rainbow Trout (*Salmo gairdneri*) Under Static Conditions: Lab Project Number: 88-11-2861: 384.0788.6101.103. Unpublished study prepared by Springborn Life Sciences, Inc. 19p.

MRID 42594101. Bisinger, E. C. (1990).Evaluation of the Mutagenic Activity of Duomeen C in the Ames/Salmonella/Microsome Test; Study No. 031444. Final Report Unpublished study received April 3, 1990; prepared by RCC Notox B.V, s' Hertogen-bosch (The Netherlands), submitted by Baker Performance Chemicals. 6 p.

MRID 42594102. O' Loughlin, K. G. (1991). Measurement of Micronuclei in bone Marrow Erythrocytes of Swiss-Webster Mice Treated with Duomeen C; Study No 1924-CO1-90. Final Report Unpublished study received March 28, 1991; prepared by SRI International, Menlo Park, CA, submitted by baker Performance Chemicals. 7 p.

MRID 43000801. Doane, B,; Cox, W.; Linton, K. (1993) 1-(Alkylamino)-3-aminopropane hydroxyacetate: Chemical Identity Beginning Materials and Manufacturing Process: Lab Project Number: 15-056210: 5120-12: 90230000. Unpublished study prepared by Baker Performance Chemicals, Inc. 61p.

MRID 43024504. Ellison, F. (1993) Physical and Chemical Characteristics of Duomeen O; Physical State, Boiling Point, Specific Gravity, Solubility, Vapor Pressure, pH, Stability, Oxidizing or Reducing, Explodability, and Viscosity: Final Report: Lab Project Number: 00459-002. Unpublished study prepared by Case Consulting Labs, Inc. 19p.

MRID 43029201. Ellison, F. (1993) Duomeen C and Jet Amine DC: Preliminary Analysis and Precision and Accuracy of Analytical Method Used to Validate Certified Limits: Final Report: Lab Project Number: 00459-002. Unpublished study prepared by Case Consulting Labs, Inc. 29 p.

MRID 43029202. Ellison, F. (1993) Duomeen C: Physical and Chemical Characteristics of Duomeen C: Physical State, Boiling Point, Specific Gravity, Solubility, Vapor Pressure, pH, Stability, Oxidizing or Reducing, Explodability and Viscosity: Final Report: Lab Project Number: 00459-002. Unpublished study prepared by Case Consulting Labs, Inc. 19 p.

MRID 43087401. Matherly, R.; Baham, G. (1993) Determination of olor, Physical State, and Odor for Magnacide 434 (Alkyl Trimethylene): Final Report: Lab Project Number: GLP/0005. Unpublished study prepared by Baker Performance Chemicals, Inc. 53p.

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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 the V of the RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

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

Appendix G.

Batching of Alkyl trimethylenediamines Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency intends to complete batching at a later date.

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

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

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

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

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

Instructions

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

   b. 84-1 Clarification of Label Improvement Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

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.