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WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Ecological Hazard and Environmental Risk Assessment Chapter for the Alkyl Trimethylenediamines Reregistration Eligibility Decision (RED) Document (Case No.: 3014)

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<u>Chemical Names</u>	<u>PC Codes</u>	<u>CAS Nos.</u>
N-(coco alkyl)trimethylenediamine	067301	61791-63-7
1-(Alkyl* amino)-3-aminopropane monoacetate	067302	61791-64-8
1-(Alkyl* amino)-3-aminopropane hydroxyacetate	067309	68155-43-1
1-(Alkyl* amino)-3-aminopropane	067310	68155-37-3
1-(Alkyl* amino)-3-aminopropane diacetate	067313	61791-64-8

Attached is the Ecological Hazard and Environmental Risk Assessment chapter for the alkyl trimethylenediamines RED Document.

**ECOLOGICAL HAZARD AND ENVIRONMENTAL
RISK ASSESSMENT CHAPTER
Alkyl Trimethylenediamines**

PC Codes 067301, 067302, 067309, 067310, 067313

CASE No.: 3014

04/30/07

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Ecological Hazard and Environment Risk Assessment for Alkyl Trimethylenediamines

Executive Summary:

Alkyl trimethylenediamines (Alkyl TMD) is currently registered as a bactericide, microbicide, and molluscicide for industrial process and water systems. Its uses include: secondary oil recovery injection water, industrial processing water (not including freshwater cooling tower systems), oilfield and petrochemical water injection systems, cooling water recirculating systems, packer and workover fluids, natural gas wells, gathering systems and pipelines, and oil well completions, stimulation fluids, petroleum transportation systems, storage systems and surface equipment. These label uses have minimal potential for environmental exposure following use and thus an ecological risk assessment is not required for alkyl TMD.

The alkyl trimethylenediamine 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.

Data Gaps:

There are no outstanding data requirements for alkyl TMD. However, the registrant needs to clarify the labeling for product 69100-1, which states:

“Mexel 432 is to be used for the control of mollusks, including zebra mussels and clams, only in closed delivery systems of non-potable industrial waters. Sites of application do not include fresh water cooling tower systems.”

It is not clear if this use is a closed system or involves once-through industrial water systems. For this assessment we have concluded the product is used only in closed industrial water systems. Once-through industrial water systems require an environmental risk assessment.

Label Hazard Statements/Use Recommendations:

Alkyl TMD labels must state:

“This pesticide is toxic to fish, aquatic invertebrates, clams/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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities

are 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."

1. Ecological Toxicity Data

The toxicity endpoints presented below are based on the results of ecotoxicity studies submitted to EPA to meet the Agency's data requirements for the uses of alkyl trimethylenediamines (alkyl TMD).

A. Toxicity to Terrestrial Animals

(1) Birds, Acute

In order to establish the toxicity of alkyl TMD to avian species, the Agency requires an acute oral toxicity study using the technical grade active ingredient (TGAI). The preferred test species is either the mallard duck (a waterfowl) or the bobwhite quail (an upland game bird). The results of six acute oral toxicity studies, submitted for alkyl TMD, are provided in the following table (Table 1).

Table 1. Acute Oral Toxicity of Alkyl TMD to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Bobwhite quail (<i>Colinus virginianus</i>)	Alkyl TMD 100%	LD ₅₀ = 0.24 NOAEL = 0.1	Very highly toxic	No (supplemental) - 14-day test duration - >16 weeks of age - lack of controls	470013023
Bobwhite quail (<i>Colinus virginianus</i>)	Alkyl TMD % purity unknown	LD ₅₀ = 492.5 (M) and 366.8 (F)	Moderately toxic	No (supplemental) - 14-day test duration - 17 weeks of age	97534
Bobwhite quail (<i>Colinus virginianus</i>)	Alkyl TMD 32%	LD ₅₀ = 0.24	Very highly toxic	Yes (core) - 14-day test duration - >16 weeks of age	40062404
Bobwhite quail (<i>Colinus virginianus</i>)	Alkyl TMD 23.5%	LD ₅₀ = 681	Slightly toxic	No (supplemental) -21-day test duration - Adult	134550
Bobwhite quail (<i>Colinus virginianus</i>)	Alkyl TMD 22%	LD ₅₀ = 500	Moderately toxic	No (supplemental) -21-day test duration -Young adult - Formulation of test material not given	106859
Mallard duck (<i>Anas platyrhynchos</i>)	Alkyl TMD 22%	LD ₅₀ = 3,200	Relatively nontoxic	No (supplemental) -14-day test duration -Young adult - Formulation of test material not given	110384

These acceptable acute oral toxicity studies on the mallard duck and bobwhite quail indicate that alkyl TMD 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.

(2) Birds, Subacute

A subacute dietary study using the TGAI may be required on a case-by-case basis depending on the results of lower-tier ecological studies and pertinent environmental fate characteristics in order to establish the toxicity of a chemical to avian species. This testing was required for alkyl TMD. The preferred test species is either the mallard duck or bobwhite quail. The results of eight subacute dietary toxicity studies, submitted for alkyl TMD, are provided in the following table (Table 2).

Table 2. Subacute Oral Toxicity of Alkyl TMD to Birds

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

(3) Mammals, Acute and Chronic Toxicity

Wild mammal testing is not required by the Agency. In most cases, rat toxicity values obtained from studies conducted to support data requirements for human health risk assessments substitute for wild mammal testing. Refer to the human toxicology chapter of this RED for mammalian toxicity data.

B. Toxicity to Aquatic Animals

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

(1) Freshwater Fish, Acute

In order to establish the acute toxicity of alkyl TMD to freshwater fish, the Agency requires freshwater fish toxicity studies using the TGAI. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). The results of 7 freshwater fish acute studies submitted for alkyl TMD, 3 coldwater and 4 warmwater, are presented in Table 3.

Table 3. Acute Toxicity of Alkyl TMD 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 (<i>Lepomis macrochirus</i>)	Alkyl TMD 32%	LC ₅₀ = 0.30 (a.i.)	Highly toxic	No (supplemental) - 96-hr test duration - static test system	41786601
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Alkyl TMD 32%	LC ₅₀ = 0.12 (a.i.)	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786606
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Alkyl TMD 0.03%	LC ₅₀ = 1,390 NOAEC = 1,000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123862
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Alkyl TMD 0.03%	LC ₅₀ = 1,300 NOAEC = 1,000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123862

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Alkyl TMD % purity unknown	LC ₅₀ = 1.58 NOAEC = 1.0	Moderately toxic	No (supplemental) - 96-hr test duration - static test system	97518
Redear sunfish (<i>Lepomis microlophus</i>)	Alkyl TMD % purity unknown	LC ₅₀ = 3.63 NOAEC = 1.4	Moderately toxic	No (supplemental) - 96-hr test duration - static test system	97519
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Alkyl TMD 32%	LC ₅₀ = 0.87 NOAEC = 0.39	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786606
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Alkyl TMD 32%	LC ₅₀ = 0.96 NOAEC = 0.72	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786601
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Alkyl TMD 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 TMD 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 alkyl TMD labels must state: “This pesticide is toxic to fish.”

(2) Freshwater Invertebrates, Acute

The Agency requires a freshwater aquatic invertebrate study using the TGAI to establish the acute toxicity to freshwater invertebrates. The preferred test species is *Daphnia magna*. The results of three studies submitted for alkyl TMD are provided in the following table (Table 4).

Table 4. Acute Toxicity of Alkyl TMD to Freshwater Invertebrates

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

The results of these studies indicate that alkyl TMD 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 alkyl TMD labels must state: “This pesticide is toxic to aquatic invertebrates.”

(3) Estuarine and Marine Organisms, Acute

Acute toxicity testing with estuarine and marine organisms using the TGAI is required when the end-use product is intended for direct application to the marine/estuarine environment or effluent containing the active ingredient is expected to reach this environment. The preferred fish test species is the sheepshead minnow. The preferred invertebrate test species are mysid shrimp and eastern oysters. This testing is required for alkyl TMD based on the chemical’s potential to reach estuarine and marine environments. The results of eight toxicity studies submitted for alkyl TMD are presented in Table 5.

Table 5. Acute Toxicity of Alkyl TMD 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 (<i>Mercenaria mercenaria</i>)	Alkyl TMD 32%	EC ₅₀ = 0.019 (a.i.)	Very highly toxic	Yes (core) - 48-hr test duration - static test system	41786603
Atlantic silverside (<i>Menidia menidia</i>)	Alkyl TMD 32%	LC ₅₀ = 0.155 (a.i.)	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786604
Mysid shrimp (<i>Mysidopsis bahia</i>)	Alkyl TMD 32%	LC ₅₀ = 0.061 (a.i.)	Very highly toxic	Yes (core) - 96-hr test duration - static test system	41786605
Pink shrimp (<i>Penaeus duorarum</i>)	Alkyl TMD 0.03%	LC ₅₀ = 1000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123866
Fiddler crab (<i>Uca pugilator</i>)	Alkyl TMD 0.03%	LC ₅₀ = 1000	Relatively nontoxic	Yes (core) - 96-hr test duration - static test system	123866
Blue crab (<i>Callinectes sapidus</i>)	Alkyl TMD % purity unknown	LC ₅₀ = 387 NOAEC = 274	Relatively nontoxic	No (supplemental) - 96-hr test duration - static test system	97520
Atlantic silverside (<i>Menidia menidia</i>)	Alkyl TMD 32%	LC ₅₀ = 0.577 NOAEC = 0.22	Highly toxic	Yes (core) - 96-hr test duration - static-renewal test system	41786604
Mysid shrimp (<i>Mysidopsis bahia</i>)	Alkyl TMD 32%	LC ₅₀ = 0.19 NOAEC = 0.13	Highly toxic	Yes (core) - 96-hr test duration - static test system	41786605
Quahog clam (<i>Mercenaria mercenaria</i>)	Alkyl TMD 32%	LC ₅₀ = 0.059 NOAEC = 0.045	Very highly toxic	Yes (core) - 48-hr test duration - static test system	41786603

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID or ACC No.)
White shrimp (<i>Penaeus setiferus</i>)	Alkyl TMD 32%	LC ₅₀ = 2.39 NOAEC = 1	Moderately toxic	Yes (core) - 96-hr test duration - static test system	40062411
Eastern oyster (<i>Crassostrea virginica</i>)	Alkyl TMD 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 TMD 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 alkyl TMD labels must state: “This pesticide is toxic to clams/oysters and shrimp.”

(4) Aquatic Organisms, Chronic

Chronic toxicity testing (fish early life stage and aquatic invertebrate life cycle) is required for pesticides when certain conditions of use and environmental fate apply. The preferred freshwater fish test species is the fathead minnow. The preferred freshwater invertebrate is *Daphnia magna*. This testing is not required for alkyl TMD.

C. Toxicity to Plants

Non-target plant phytotoxicity testing is required for pesticides when certain conditions of use and environmental fate apply. Testing is conducted with one species of aquatic vascular plant (*Lemna gibba*) and four species of algae: (1) freshwater green alga, *Selenastrum capricornutum*, (2) marine diatom, *Skeletonema costatum*, (3) freshwater diatom, *Navicula pelliculosa*, and (4) bluegreen cyanobacteria, *Anabaena flos-aquae*. The rooted aquatic macrophyte rice (*Oryza sativa*) is also tested in seedling emergence and vegetative vigor tests. Non-target plant phytotoxicity testing is not required for alkyl TMD.

II. Risk Assessment and Characterization

Alkyl TMD uses are classified as “indoor” uses. An ecological risk assessment is not typically conducted for “indoor” uses.

Environmental Fate Assessment Summary

Alkyl trimethylenediamines are used primarily as microbicides, bactericides, or molluscides. The alkyl trimethylenediamines group is comprised of the following five compounds: N-(coco alkyl)trimethylenediamine (PC code 067301), 1-(alkyl* amino)-3-aminopropane monoacetate (PC code 067302), 1-(alkyl* amino)-3-aminopropane hydroxyacetate (PC code 067309), 1-(alkyl* amino)-3-aminopropane (PC code 067310) and 1-(alkyl* amino)-3-aminopropane diacetate (PC code 067313). The “alkyl*” indicates fatty acids of coconut oil, which contain one long alkyl chain, primarily C₁₂.

The alkyl trimethylenediamine 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.

B. Environmental Exposure and Ecological Risk Assessment

An ecological risk assessment for the uses of alkyl TMD was not necessary due to the nature of the uses.

C. Endangered Species Considerations

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

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency’s screening-level risk assessment is performed, if any of the Agency’s Listed Species

LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use.

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment.

This preliminary analysis indicates that alkyl TMD is used in low environmental exposure settings which include: secondary oil recovery injection water, industrial processing water (not including freshwater cooling tower systems), oilfield and petrochemical water injection systems, cooling water recirculating systems, packer and workover fluids, natural gas wells, gathering systems and pipelines, and oil well completions, stimulation fluids, petroleum transportation systems, storage systems and surface equipment. This preliminary analysis does not indicate whether there is a potential for such alkyl TMD uses to overlap with listed species and whether a more refined assessment is warranted, to include direct, indirect and habitat effects. The more refined assessment should involve clear delineation of the action area associated with proposed use of alkyl TMD and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment.

An endangered species effect determination will not be made at this time.

III. Confirmatory Data Required:

No confirmatory data are needed at this time.

There are no outstanding data requirements for alkyl TMD. However, the registrant needs to clarify the labeling for product 69100-1, which states:

“Mexel 432 is to be used for the control of mollusks, including zebra mussels and clams, only in closed delivery systems of non-potable industrial waters. Sites of application do not include fresh water cooling tower systems.”

It is not clear if this use is a closed system or involves once-through industrial water systems. For this assessment we have concluded the product is used only in closed industrial water systems. Once-through industrial water systems require an environmental risk assessment.

IV. Label Hazard Statements for Terrestrial and Aquatic Organisms:

Alkyl TMD labels must state:

“This pesticide is toxic to fish, aquatic invertebrates, clams/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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are 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."

V. REFERENCES

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