201-14647

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VICE PRESIDENT
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American Chemistry Council
Good Chemistry Makes It Possible

August 7, 2003

By Mail
Marianne L. Horinko, Acting Administrator
US EPA
PO Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program – Test Plan Submission from HERTG
Registration Number

Dear Administrator Horinko:

The American Chemistry Council Petroleum Additives Panel (Panel) Health, Environmental, and Regulatory Task Group (HERTG) submits for review and public comments its test plan as well as related robust summaries for the Isooctadecanoic Acid Reaction products with TEPA (CAS # 68784-17-8) under the Environmental Protection Agency's High Production Volume (HPV) Chemical Challenge Program. The HERTG understands that there will be a 120-day review period for the test plan report and that all comments generated by or provided to EPA will be forwarded to the HERTG for consideration.

Thank you in advance for your attention to this matter. If you have any questions regarding the test plan report or the robust summaries, please contact Sarah Loftus McLallen at 703-741-5614 (telephone), 703-741-6091 (telefax) or Sarah_McLallen@americanchemistry.com (e-mail).

Sincerely yours,

cc: HERTG members

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HIGH PRODUCTION VOLUME (HPV)

CHALLENGE PROGRAM

TEST PLAN

For

Isooctadecanoic Acid Reaction Products with TEPA

Prepared by
The American Chemistry Council
Petroleum Additives Panel
Health, Environmental, and Regulatory Task Group

August 5, 2003

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LIST OF MEMBER COMPANIES IN THE
HEALTH, ENVIRONMENTAL AND REGULATORY TASK GROUP

The Health, Environmental, and Regulatory Task Group (HERTG) of the American Chemistry Council Petroleum Additives Panel includes the following member companies:

B.P. plc

Chevron Oronite Company, LLC

Crompton Corporation

Ethyl Corporation

ExxonMobil Chemical Company

Ferro Corporation

Infineum

The Lubrizol Corporation

Rhein Chemie Corporation

Rhodia, Inc.

1.0 INTRODUCTION

In March 1999, the American Chemistry Council (formerly the Chemical Manufacturers Association) Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG), and its participating member companies committed to review certain chemicals listed under the Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program. This test plan follows up on that commitment, and sets forth how the HERTG intends to address testing information for Isooctadecanoic acid reaction products with TEPA (CAS No. 68784-17-8).

In preparing this test plan the following steps were undertaken:

Step 1: A review of the literature and confidential company data was conducted on the physicochemcial properties, mammalian toxicity endpoints, and environmental fate and effects for Isooctadecanoic acid reaction products with TEPA using its CAS number, CAS name, and synonyms. Searches included the following sources: MEDLINE, BIOSIS, CANCERLIT, CAPLUS, CHEMLIST, EMBASE, HSDB, RTECS, EMIC, and TOXLINE databases; the TSCATS database for relevant unpublished studies on these chemicals; and standard handbooks and databases (e.g., Sax, CRC Handbook on Chemicals, IUCLID, Merck Index, and other references) for physicochemical properties.

Step 2: The compiled data was evaluated for adequacy in accordance with the EPA guidance documentation.

2.0 GENERAL SUBSTANCE INFORMATION

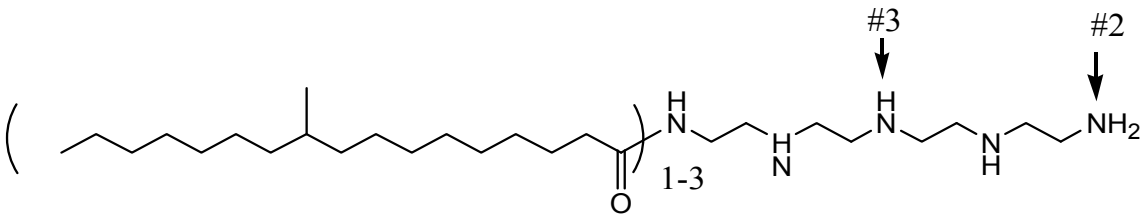
The substance that is the subject of this test plan is used as a petroleum additive in petroleum base stocks. The chemical name, CAS Registry Number, molecular weight and chemical structure for this substance are presented below.

Chemical Name: Isooctadecanoic acid reaction products with TEPA

Chemical Abstract Service Registry Number: 68784-17-8

Molecular Weight: 456.78 – 989.71 gm/mol (assuming three isooctadecanoic acid groups)

Chemical Structure:



68784-17-8

3.0 EXPOSURE INFORMATION

Manufacture

This substance is a reaction product of isooctadecanoic acid with tetraethylenepentaamine (TEPA). It is prepared by adding the liquid isooctadecanoic acid to a highly refined lubricant base oil diluent followed by addition of TEPA. The mixture is then heated to remove the water. At the end of water liberation, the product is cooled and filtered. These reactions occur in a solvent composed of highly refined lubricant base oil. Thus the "active ingredients" are not isolated during the life cycle of this substance. This is done for two reasons: 1) the kinetics of the chemical reactions used in the manufacturing process are optimized when highly refined lubricating base oils are used as the reaction solvent, and 2) lubricant additives diluted in highly refined lubricating base oils are required to control viscosities during blending with other additives or with additional highly refined lubricating base oil to make finished lubricants. To meet the required viscosity for this substance, the concentration of highly refined lubricating base oil is typically 5 wt%.

Use

This substance is used to formulate finished lubricating oils used in water-cooled 2-cycle engines. It is used as an ashless dispersant to control deposits on the piston and prevent ring sticking. Water cooled engines have tendencies for pre-ignition, thus the use of ashless lubricants. This substance is generally sold to finished oil blenders in additive packages, where the concentration ranges from 22 to 87 wt.%. These additive packages are then blended into finished oils where the typical concentration of this substance ranges from 9 to 34 wt.% in the finished oil. The finished oil is them mixed into gasoline at gasoline to oil ratios of 50 to100:1.

Distribution

This substance is manufactured and blended into additive packages at plants owned by members of the HERTG. Finished lubricants are blended at facilities owned by our customers. Additive packages are shipped to customers in isocontainers, railroad tank cars, tank trucks or in 55-gallon steel drums. The bulk additive packages are stored in bulk storage tanks at the customer blending sites. Finished oils are blended by pumping the lubricating oil blend stocks and the additive package from their storage tanks

through computer controlled valves that meter the precise delivery of the components into a blending tank. After blending, the finished lubricant products are packaged into 55-gallon drums, 5-gallon pails, and one-gallon, one-quart and smaller containers for sale to industrial users and consumers.

Based on these uses, the potentially exposed populations include (1) workers involved in the manufacture of this substance, blending it into additive packages, and blending the additive packages into finished lubricants; (2) quality assurance workers who sample and analyze this substance to ensure that it meets specifications; (3) workers involved in the transfer and transport of this substance and additive packages or finished lubricants that contain it; and (4) mechanics and consumers who may come into contact with both fresh and used lubricants while working on engines. The most likely route of exposure for these substances is skin and eye contact. Manufacturing, quality assurance, and transportation workers will likely have access to engineering controls and wear protective clothing to eliminate exposure. The most likely source of environmental exposure is accidental spills at manufacturing sites and during transport.

Table 1
Summary Table of Available Data and Proposed Testing on Isooctadecanoic Acid Reaction Products with TEPA

CAS No.: 68784-17-8	Study Results	Testing Proposed
Physical/Chemical Characteristics		
Melting Point	Not Applicable	No
Boiling Point	No Data Located	Yes
Vapor Pressure	No Data Located	Yes
Water Solubility	No Data Located	Yes
Partition Coefficient	No Data Located	Yes
Environmental Fate		
Biodegradation	<10% at 28 days	No
Hydrolysis	No Data Located	Yes
Photodegradation	No Data Located	Yes
Fugacity	No Data Located	Yes
Ecotoxicity		
Acute Toxicity to Fish	96 hr LC50: >1000 mg/L WAF 96 NOEC: 1000 mg/L WAF	No
Acute Toxicity to Invertebrates	24 hr LC50: 160 mg/L WAF 24 hr EC50: 150 mg/L WAF 48 hr LC50: 150 mg/L WAF 48 hr EC50: 150 mg/L WAF 48 hr NOEC: 100 mg/L WAF	No
Acute Toxicity to Algae	96 hr EC50: 1.0-1.4 mg/L WAF 72 and 96 hr NOEC: 1.0 mg/L WAF	No
Mammalian Toxicity		
Acute Toxicity	Oral LD50 > 5 g/kg (rat) Dermal LD50 > 2 g/kg (rabbit)	No
Repeated Dose Toxicity	No Data Located	Yes
Developmental Toxicity	No Data Located	Yes
Reproductive Toxicity	No Data Located	Yes
Genotoxicity		
Gene Mutation	Not Mutagenic	No
Chromosomal Aberration	No Data Located	Yes

4.0 PHYSICOCHEMICAL PROPERTIES

4.1 Data Assessment and Test Plan for Physicochemical Properties Relevant to Environmental Fate

Isooctadecanoic acid reaction products with TEPA are liquid at ambient temperatures (thus melting point is not-applicable). The boiling point, vapor pressure, and octanol/water partition coefficient of isooctadecanoic acid reaction products with TEPA will be evaluated using the EPIWIN modeling program as discussed in the EPA document titled "The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program." The model proposed for this purpose is the EPIWIN, version 3.02[1], which was developed by the Syracuse Research Corporation. The water solubility of Isooctadecanoic acid reaction products with TEPA will be determined experimentally.

5.0 ENVIRONMENTAL FATE DATA

The environmental fate of a substance and its degradation by products are dependent on their physicochemical properties. The physicochemical properties of a substance influence the way in which a substance will degrade by any of the important environmental pathways: biodegradation, hydrolysis, and photodegradation. The physicochemical properties of the parent substance and its degradation by products will also influence the way in which this substance will partition among environmental compartments (i.e., air, soil, sediment, suspended sediment, water, and biota).

5.2 Biodegradability

5.2.2 Summary of Available Data

Biodegradation, the measurement of the potential of a compound to be degraded by microorganisms, has been evaluated in one test conducted in accordance with OECD Test Guideline 301B (*CO_2 Evolution [Modified Sturm] Test*). The results indicate that isooctadecanoic acid reaction products with TEPA are not readily biodegradable after 28 days.

5.2.3 Data Assessment and Test Plan for Biodegradability

The *CO_2 Evolution (Modified Sturm) Test* conducted on isooctadecanoic acid reaction products with TEPA is adequate and reliable. Additional biodegradation testing is not proposed.

5.3 Hydrolysis

5.3.2 Summary of Available Data

No published or unpublished hydrolysis studies of isooctadecanoic acid reaction products with TEPA.

5.3.3 Data Assessment and Test Plan for Hydrolysis

The potential for isooctadecanoic acid reaction products with TEPA

[1] Environmental Science Center- Syracuse Research Corporation- EPI for windows.

to hydrolyze will be characterized in a technical discussion.

5.4 Photodegradation

5.4.2 Summary of Available Data

Photodegradation, the degradation of a chemical compound as a result of absorption of solar radiation, has not been evaluated. No published or unpublished photodegradation studies for isooctadecanoic acid reaction products with TEPA were located.

5.4.3 Data Assessment and Test Plan for Photodegradation

The Atmospheric Oxidation Potential (AOP) of this substance will be characterized using the modeling program AOPWIN.

5.5 Fugacity Modeling

5.5.2 Summary of Available Data

The relative distribution of isooctadecanoic acid reaction products with TEPA among environmental compartments has not been evaluated. No published or unpublished fugacity-based multimedia fate modeling data was located.

5.5.3 Test Plan for Fugacity

The relative distribution of isooctadecanoic acid reaction products with TEPA among environmental compartments will be evaluated using Level I Fugacity modeling.

Input data to run the EQC Level I model will require an additional computer model to estimate physical/chemical properties from a structure. The model used for this purpose will be EPIWIN, version 3.02[2], which was developed by the Syracuse Research Corporation. EPIWIN includes algorithms for estimating all physical and chemical properties needed for the EQC model.

6.0 ECOTOXICOLOGY DATA

6.1 Aquatic Toxicity of Isooctadecanoic Acid Reaction Products with TEPA

6.1.2 Summary of Available Data

The acute aquatic toxicity of isooctadecanoic acid reaction products with TEPA has been evaluated using water-accommodated fractions in freshwater fish, invertebrates, and algae in tests conducted in accordance with the following OECD Test Guidelines:

- OECD Test Guideline 203 (*Fish, Acute Toxicity Test):* The 96 hour LL_{50} in Rainbow trout is > 1000 mg/L WAF. The 96-hour NOEC is 1000 mg/L WAF.

[2] Environmental Science Center- Syracuse Research Corporation- EPI for windows.

- OECD Test Guideline 202 *(Daphnia sp., Acute Immobilization Test and Reproduction Test):* The 24 and 48 hour LC_{50}s in *Daphnia* magna are 160 and 150 mg/L WAF respectively. The 48-hour NOEC is 100 mg/L WAF.

- OECD Guideline 201 (*Alga, Growth Inhibition Test):* The 96-hour EC_{50} in unicellular green algae is 1.0-1.4 mg/L WAF. The 72 and 96 hour NOEC is 1.0 mg/L WAF.

6.1.2 Data Assessment and Test Plan for Acute Aquatic Ecotoxicity
The available acute aquatic toxicity data in fish, invertebrates and algae are adequate and reliable. Additional testing will not be performed.

7.0 MAMMALIAN TOXICOLOGY DATA

7.1 Acute Mammalian Toxicity

7.1.2 Summary of Available Data
The acute toxicity of isooctadecanoic acid reaction products with TEPA has been evaluated in tests conducted in accordance with the following OECD Test Guidelines:

- OECD Test Guideline 401(*Acute Oral Toxicity):* The LD_{50} in rats is greater than 5 g/kg indicating a low concern for toxicity.

- OECD Test Guideline 402 (*Acute Dermal Toxicity):* The LD_{50} in rabbits is greater than 2 g/kg indicating a low concern for toxicity.

7.1.3 Data Assessment and Test Plan for Acute Mammalian Toxicity
Adequate and reliable acute oral and dermal toxicity tests were performed for isooctadecanoic acid reaction products with TEPA. Additional acute mammalian toxicity testing will not be conducted.

7.2. Mutagenicity

7.2.2 Summary of Mutagenicity Data
The mutagenic potential of isooctadecanoic acid reaction products with TEPA has been determined in tests conducted in accordance with the following OECD Test Guidelines:

- OECD Test Guideline 471(Bacterial Reverse Mutation Test): A negative point mutation assay in the bacteria *Salmonella typhimurium* is available for isooctadecanoic acid reaction products with TEPA.
- OECD Test Guideline 476 (*In vitro* Mammalian Cell Gene Mutation Test): The clastogenic potential of isooctadecanoic acid reaction products with TEPA has not

been determined. A literature search revealed no published or unpublished chromosomal aberration studies for isooctadecanoic acid reaction products with TEPA.

7.2.3 Data Assessment and Test Plan for Mutagenicity Toxicity

An adequate and reliable point mutation assay in bacteria is available for isooctadecanoic acid reaction products with TEPA. Chromosomal aberration testing will be conducted with human lymphocytes according to OECD Test Guidelines 473 (*In Vitro* Mammalian Chromosome Aberration Test).

7.3 Repeated-dose, Reproductive and Developmental Toxicity

7.3.2 Summary of Repeated-Dose Toxicity Data

After a thorough literature search, the HERTG was not able to locate adequate published or unpublished studies for repeated-dose, reproductive or developmental toxicity tests for isooctadecanoic acid reaction products with TEPA.

7.3.3 Data Assessment and Test Plan for Repeated-dose Toxicity

Testing is proposed in the form of OECD Test Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test).

8.0 SUMMARY

Table 1 summarizes the available data and proposed testing on isooctadecanoic acid reaction products with TEPA.

Substance Group: **Isooctadecanoic acid reaction product with TEPA**

Summary prepared by: **Petroleum Additives Panel**
Health & Environmental Research Task Group

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1. Environmental Fate and Pathways

1.0 Biodegradation

Robust Summary 9-Biodeg-1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material purity - 95% active 5% HRLBO
Method	
Method/Guideline Followed	OECD 301B, Ready Biodegradability, Modified Sturm Test
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (study performed)	1997
Contact time (units)	28 days
Test apparatus	*Glass 4-liter Erlenmeyer flasks*
Inoculum	Activated sewage sludge from a domestic wastewater treatment plant prepared with soil filtrate per test guideline. Three cultures/group were prepared. The final combined volume of test medium, test substance and inoculum in each test container was 3 liters. Solutions were continuously aerated with CO_2 free air. The test substance was incrementally added at concentrations of 4, 8 and 8 mg C/L on days 0, 7 and 11. On day 14 equal volumes of each culture were combined and the composite inoculum screened and homogenized. A standard plate count was performed on the inoculum. Plates were incubated at 20±3°C for approximately 48 hours.
Cultures/replicates:	*Three replicate test cultures, three replicate blank control cultures and three reference control cultures.*
Temperature of incubation:	20±3°C
Dosing procedure:	Neat test chemical was gravimetrically added to glass cover slips, which were then added to culture medium in test vessels.
Study initiation:	Test flasks provided with CO_2 free air and mixed with a magnetic stirrer. The CO_2 produced from the degradation of organic carbon sources within each test chamber was trapped as K_2CO_3 in 0.5 N KOH and measured using a carbon analyzer.
Sampling:	Days 4, 8, 12, 15, 19, 22, 26, 28 and 29 (after acidification on day 28)
Concentration of test substance:	10 mg C/L weighed directly onto tared glass slides and placed into each test substance flask.
Controls:	Blank and positive controls used per guideline. Positive control was canola oil added to a control vessel at a loading of 10 mg C/L.

Analytical method:	The CO_2 produced from the degradation of organic carbon sources within each test chamber was trapped as K_2CO_3 in 0.5 N KOH and measured using a carbon analyzer.
Study termination:	On day 28 the pH of the content of each test flask was determined. The flasks were then acidified with 3 ml of concentrated hydrochloric acid to drive off inorganic carbonate. The chambers were aerated overnight and then the trapping solutions closest to the test chambers were analyzed for inorganic carbon.
Method of calculating biodegradation values:	Percent biodegradation calculated as percent ratio of cumulative net carbon dioxide to theoretical carbon dioxide as determined from elemental analysis of test material.
Results	The test substance was not considered readily biodegradable under the criteria that requires 60% biodegradation within 28 days, achieved within 10 days of reaching 10% biodegradation. The CO_2 production from the reference chemical exceeded the 60% of theoretical necessary to consider the test valid.
Degradation %	Test substance: 5.0 $\pm$ 1.6 % in 29days (Average final pH 6.92) Positive control substance: 88.3 $\pm$ 2.9 % in 29days
Conclusions	The test substance was not readily biodegradable.
Data Quality	Reliable without restriction. (Klimisch Code)
References	Confidential business information
Other	Updated: 5/30/2003

2. Ecotoxicity

AQUATIC ORGANISMS

2.1 Acute Toxicity to Fish

Robust Summary 9-Fish -1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material purity - 95% active 5% HRLBO
Method	
Method/Guideline followed	Test protocol followed US EPA Toxic Substances Control Act Test Guideline #797.1400 (1985), OECD Guideline for Testing of Chemicals #203, Fish Acute Toxicity Test (1984).
Test Type	Acute Toxicity to Fish (Static renewal test)
GLP (Y/N)	Y
Year (Study Performed)	1993
Species/Strain	Rainbow trout (Oncorhynchus mykiss)
Fish Number	30/concentration (10/replicate)
Fish Size	Average length 26-39 mm; Average weight 0.37 g
Analytical Monitoring	Total organic carbon (TOC) measurements of initial (0-h) test solutions and after one day on test (24-h) before renewal of fresh test solutions. Samples were assayed according to EPA Method 415.1
Nominal Test Substance Concentration Levels	Control, 1, 10, 100 and 1,000 mg/L WAF loading rates. (Range find study) Control and 1,000 mg/L WAF loading rates. (Main study)
Test Concentration Preparation	Individual water accommodated fractions (WAFs) were prepared for each test level and renewed daily. A measured weight of test material was added to a measured volume of dilution water (15-L) in a glass vessel (20-L) and stirred for 24 hours. Stirring accomplished using a magnetic stir bar. Mixing speed adjusted such that a vortex formed between 30 to 50% of the distance to the bottom. Following the mixing period, the test solutions were allowed to stand for 1 hour before the water phase was removed. The siphoned water phase (i.e., WAF) was used in the aquatic toxicity test.
Exposure Period	96 hours

Exposure Conditions	Static renewal test conditions.
Vehicle	None
Statistical Analysis	None required based on the results.
Dose Rangefinding Study	Yes
Test Chambers	20-liter glass aquaria containing 15 liters of test solution
Diluent Water	Dechlorinated well water adjusted to the appropriate hardness of 40 to 48 mg/L as $CaCO_3$. The water was passed through activated carbon, a particle filter, and then an ultraviolet sterilizer, and then it was stored in a polyethylene tank where it was aerated.
Diluent Water Chemistry	Conductivity 200 µohms/cm Dissolved Oxygen: 6.5-9.4 mg/L pH: 7.8 Hardness: 40 mg/L $CaCO_3$ Alkalinity: 7 mg/L $CaCO_3$
Photoperiod	16-h light per day using cool-white fluorescent lights with an intensity of 2 uEin^{-1}/m^{-2}.
Temperature Range	11.7-12.4^{o} C ^{O}C
Positive Control	No
Remarks field for test conditions	Pretreatment: none, fish held for a minimum of 14 days before testing. No feeding 48 hours prior to and during the test. All organisms were observed for mortality and the number of individuals exhibiting clinical signs of toxicity or abnormal behavior at 3, 24, 48, 72, and 96 hours after initiation of test material exposure.
Results	Range find study: All fish survived the completion of the 96-hour observation period. No undissolved test material was seen on the surface of the test vessels during the entire aquatic toxicity test. Main Study: The treated test chambers were slightly cloudy during the test. At 1000 mg/L one fish was dead at 72 hours. All of the remaining fish (29) survived the 96-hour exposure period. At 48 hours one fish exposed to the WAF was swimming erratically and gasping. No other effects were noted. Control fish were unremarkable. The 24, 48, 72 and 96 hour LC50s were >1000 mg/L WAF. The 96-hour NOEC was 1000 mg/L WAF. Analytical Monitoring: TOC levels were between none detected and 1 mg/L in the control and 2.0 mg/L at the 1,000 mg/L loading. TOC levels were not considered to be indicative of actual test material concentrations and results are therefore based on nominal loading rates. Statistical results: Statistical analysis of survival data was not warranted.
Conclusions	The 24, 48, 72 and 96 hour LC50s were >1000 mg/L WAF. The 96 hour NOEC

	was 1000 mg/L WAF
Data Quality	(1) Reliable without restriction (Klimish Code)
References	Unpublished confidential business information
Other	Updated: 4/07/2003

2.2 Acute Toxicity to Aquatic Invertebrates (e.g. Daphnia)

Robust Summary 9-Daphnia - 1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Purity – 95% active 5%HRLBO
Method	
Method/Guideline followed	Test protocol followed US EPA Toxic Substances Control Act Test Guideline #797.1300 (1985, 1987), OECD Guideline for Testing of Chemicals #202 *Daphnia* sp. Acute Immobilization Test and Reproduction Test (1984).
Test Type	Static renewal acute toxicity test
GLP (Y/N)	Y
Year (Study Performed)	1993
Species/Strain	*Daphnia magna*
Analytical Monitoring	Total organic carbon (TOC) measurements of initial (0-h) test solutions and at 24 hours post initiation of exposure.
Exposure Period (unit)	48 hours
Statistical methods	Statistical analysis of the survival data was performed using standard techniques. The binomial (24 hours) or probit (48 hours) method was used to calculate LC50 values. The NOEC, no observed effect concentration, was defined as the highest concentration tested at and below which there was no toxicant-related immobilization or physical and/or behavioral abnormalities.
Remarks field for test conditions (fill as applicable)	Juvenile daphnids less than 24-hours old were produced from laboratory in-house culture. Individual water accommodated fractions (WAFs) were prepared for each test level and renewed daily. A measured weight of test material was added to a measured volume of dilution water in a glass vessel and stirred for 24 hours. Stirring was accomplished using a Teflon coated magnetic stir bar. Following the mixing period, the test solutions were allowed to stand for 60 minutes before the water phase was gently siphoned from the mixing vessel into corresponding replicate test vessels (300 mL culture dishes containing 250 mL of test solution). Twenty daphnids, less than 24 hours old were distributed into each concentration (10 daphnids/replicate). At 24 hours the test solutions were replaced with newly prepared WAF and all surviving daphnids were carefully transferred into the corresponding test vessel. Daphnids were not fed during exposure. Control test chambers were handled in an identical fashion. Light cycles were maintained at 16-hour light per day with an intensity of 5 $uEin^{-1}m^{-2}$ at the surface of the culture solutions. Test solutions

	were maintained at 20 ± 1 C. Dilution water was dechlorinated tap water adjusted to the approximate hardness of 160-180 mg/L as $CaCO_3$.
Test Concentrations	100, 170, 280, 460 and 770 mg/L WAF
RangeFinding Study	1, 10, 100 and 1000 mg/L WAF
Results	
Remarks	Water chemistry: Dissolved oxygen: 7.6 – 9.0 mg/L; pH: 8.1 - 8.9; conductivity: 540 – 610 µohms/cm. Total Organic Carbon measurements were 2 mg/L in the 100 and 770 mg/L test concentration solutions prestudy. Analysis of 24-hour test solutions resulted in measurements of 3 mg/L and 4 mg/L in the 100 and 770 mg/L test concentration solution. TOC analysis of the control solutions at 0 and 24 hours resulted in measurements of 1 mg/L and 3 mg/L respectively. Throughout the exposure period small suspended particles were present in each WAF treated test vessel. At least 90% survival occurred in all control test vessels and no control sub lethal effects were noted during the test. Based on observed mortality in the WAF treated groups, the 24-hour daphnid LC50 was 160 mg/L WAF and the 24-hour EC50 was 150 mg/L. The 48-hour LC50 and EC50 values were both 150 mg/L WAF. The 48 hour NOEC was 100 mg/L.
Conclusions	24-hour daphnid LC50 was 160 mg/L WAF and the 24-hour EC50 was 150 mg/L. The 48-hour LC50 and EC50 values were both 150 mg/L WAF. The 48 hour NOEC was 100 mg/L.
Data Quality	Reliable without restriction (Klimisch Code)
References	Unpublished confidential business information
Other	Updated: 4/07/2003

2.3 Toxicity to Aquatic Plants (e.g. Algae)

Robust Summary 9-Algae- 1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material purity not provided.
Method	
Method/Guideline followed	OECD Guideline for Testing of Chemicals #201 Alga, Growth Inhibition Test (1984).
Test Type	Static acute toxicity test (Water Accommodated Fraction- WAF)
GLP (Y/N)	Y
Year (Study Performed)	1993
Species/Strain	Freshwater algae, *Selenastrum capricornutum*
Number of cells/mL	10,000 cells/mL in three replicate cultures/test concentration.
Exposure period/duration	96 hours
Range find test	Yes
Analytical monitoring	Total organic carbon (TOC) measured at the beginning and end of the test according to EPA Method 415.1.
Statistical methods	Binominal/nonlinear interpolation method was used to calculate EC50 values. A parametric t test was used to calculate the no observed effect concentrations.
Remarks field for test conditions (fill as applicable)	Test Species: Selenastrum capricornutum cultures obtained from the university of Texas at Austin. Loading Concentrations: Range find Study: 1, 10, 100 and 1000 mg/L loading rate WAF. Main Study: 1, 2, 4, 8 and 16 mg/L loading rate WAF. Test System: The WAF was prepared only at the beginning of the test. A measured weight of test material was added to a measured volume of culture medium (10-L) in a glass vessel and stirred for 24 hours. Stirring accomplished using a magnetic stirrer. Mixing speed was adjusted such that the vortex extended from the surface to approximately 30% - 50% of the depth of the mixing vessel. Following the mixing period, the test solutions were allowed to stand for one hour. The WAF was removed from each concentration by siphoning. The siphoned water phase (i.e., WAF) was used for the aquatic toxicity test. Test Conditions: A static test was conducted; i.e., there was no daily renewal of test solution. Three 100-mL replicates per treatment, inoculum ~10,000 cells/mL. During the test all treatment and control flasks were randomly placed on an orbital shaker adjusted to approximately 100 cycles per minute under

	constant light (24 hours/day) for 96 hours. Cell densities were determined at 0, 24, 48, 72 and 96 hours. pH was determined at 0 and 96 hours. The target test temperature was 24.0^{o} C. The culture media was as specified in the guideline.
Results	During the study water quality data were as follows: pH: 7.6-10.9 TOC: None detected No observations were given concerning visual appearance of WAF or presence/absence of undissolved material. The control algae population grew well during the test, resulting in an average of 1,467,000 cells/mL in the control. The 24, 48, 72 and 96 hour EC50 values for algae exposed to the WAF of the test material ranged from 1.0 –1.3 mg/L based on the number of cells/mL and from 1.0 to 1.4 mg/mL based on average specific cell growth. The 72 and 96 hour EC50s were as follows: 72 hours 1.2 mg/L WAF (based on cells/ml) 72 hours 1.3 mg/L WAF (specific growth rate) 96 hours 1.3 mg/L WAF (based on cells/ml) 96 hours 1.4 mg/L WAF (specific growth rate) The 72 and 96 hour NOECs were as follows: 72 hours 1.0 mg/L WAF (based on cells/ml) 72 hours 1.0 mg/L WAF (specific growth rate) 96 hours 1.0 mg/L WAF (based on cells/ml) 96 hours 1.0 mg/L WAF (specific growth rate) The regrowth of inhibited cultures from the 2 mg/L WAF test level revealed that the effect at this concentration was algistatic. Control culture pH increased from 7.7 at 0 hour to 7.9 at 96 hours. This is consistent with the guideline. In the test cultures pH increased over the 96 hour test period following a concentration dependent pattern. Greater increases were observed at lower concentrations. Decreases in pH were observed at the three highest concentrations. This was attributed to a greater number of viable cells at lower concentrations with greater utilization of carbonates and bicarbonates from respiration.
Conclusions	The 24, 48, 72 and 96 hour EC50 values for algae exposed to the WAF of the test material ranged from 1.0 –1.3 mg/L based on the number of cells/mL and from 1.0 to 1.4 mg/mL based on average specific cell growth. The effect of the test material to the algae was algistatic.
Data Quality	(1) Reliable without restriction
References	Confidential business information.
Other	Updated: 4/07/2003

3. Toxicity

3.1 Acute Toxicity

3.1.1 Acute Oral Toxicity

Robust Summary 9-Acute Oral -1

Test Substance	
CAS #	CAS# 68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material dosed as received, purity 95% active 5%HRLBO
Method	
Method/Guideline followed	EPA FIFRA 81-1 (November 1982)
Test Type	Acute oral toxicity
GLP (Y/N)	Y
Year (Study Performed)	1985
Species/Strain	Rats/Sprague-Dawley strain
Sex	Male and Female
No. of animals/dose	5/sex
Vehicle	None
Route of administration	Oral (intragastric)
Dose level	5.0 g/kg
Dose volume	Not provided
Control group included	Yes
Remarks field for test conditions	A single dose of the undiluted test material was administered intragastrically to five fasted (over night) male and female rats at each treatment level. A control group consisting of 5 animals/sex was included. The animals were observed for signs of toxicity or behavioral changes frequently on the day of dosing and twice daily thereafter (once daily on weekends). Individual weights were recorded on the day of dosing, on days 2 and 7 and at termination. All animals were euthanized at the conclusion of the observation period. Gross autopsies were performed on all animals after 14 days. Abnormal tissues were evaluated microscopically.
Results	LD50 > 5.0 g/kg (males and females)
Remarks	No mortality was observed. Reduced food consumption was observed in one treated male 24 hours after dosing. No other signs of toxicity were observed. There were no significant treatment related necropsy findings in any of the animals. Bilateral dilated renal pelvis was observed in a treated male and female. Upon microscopic examination, moderate hydronephrosis with mild tubular regeneration

	was observed in the male and trace hydronephrosis was observed in the female. This is a common congenital finding observed in laboratory rats and was not associated with treatment.
Conclusions	The test article, when administered as received to male and female Sprague-Dawley rats, had an acute oral LD50 of > 5.0 g/kg (males and females.).
Data Quality	Reliable without restriction (Klimisch Code)
References	Unpublished confidential business information
Other	Updated: 3/31/2003

3.1.3 Acute Dermal Toxicity

Robust Summary 9-Acute Dermal-1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material purity – 95% active 5%HRLBO
Method	
Method/Guideline followed	OECD Guideline 402
Test Type	Acute dermal toxicity (Limit Test)
GLP (Y/N)	Y
Year (Study Performed)	1986
Species/Strain	Rabbits/New Zealand White
Sex	Male and female
No. of animals/sex/group	5
Vehicle	None
Route of administration	Dermal
Dose level	2 g/kg
Specific Gravity	Not provided
Control group included	Yes
Remarks field for test conditions	Approximately 24 hours prior to topical application of the test material, the hair of each animal was closely clipped. A single dose of 2 g/kg of the undiluted test material was administered dermally to five male and female animals. The test material was kept in contact with the skin for a period of 24 consecutive hours under a plastic sheet. Collars were used to prevent oral ingestion. After 24 hours, the remaining test material had hardened and could not be removed with mineral oil, acetone or ethanol. The test material remained on the animals until the skin to which the test material was adhered flaked away between days 7 and 14. The animals were observed for signs of toxicity or behavioral changes frequently on the day of dosing and twice daily thereafter (once daily on weekends). The skin at the application site was evaluated for irritation at 1, 7 and 14 days according to the Draize method. Individual weights were recorded on the day of dosing, on days 2 and 7 and at termination. All animals were euthanized at the conclusion of the observation period. Gross autopsies were performed on all animals after 14 days. Sections of skin from each animal and any abnormal tissues were evaluated microscopically.

Results	The test article, when administered dermally as received to 5 male and 5 female New Zealand white rabbits, had an acute dermal LD50 of greater than 2.0 g/kg. Moderate to severe dermal irritation was observed in the treated animals.
Remarks	No mortality was observed. Reduced food consumption was observed in four treated animals of each sex from day 1 to day 7. Body weights were unremarkable. Reddened nictitating membranes with yellow ocular discharge were observed in two females in the treated group. All treated animals were normal by Day 8. Reddened nictitating membranes with brown or yellow ocular discharge were observed in one control male from day 2 to day 8. After 24 hours, the remaining test material had hardened and could not be removed with mineral oil, acetone or ethanol. Skin irritation ranged from well defined to moderate erythema and edema in the treated animals. By day 7 the skin in the application site had thickened and cracked with severe erythema and eschars between the cracks. Between days 7 and 14 the skin and test material flaked away leaving normal appearing skin at the application site. Skin irritation on day 14 in the treated animals consisted of a pinpoint eschar and slight erythema with no edema. The only findings observed in the controls were attributed to the tape and possible scratching. Microscopic compound related lesions in the skin consisted of trace to mild hyperkeratosis, epidermal crusting, dermal inflammation and acanthosis. Findings in the control group were much more focal or multifocal rather than diffuse and did not occur in every rabbit.
Conclusions	The test article, when administered dermally as received to 5 male and 5 female New Zealand white rabbits, had an acute dermal LD50 of greater than 2.0 g/kg. Moderate to severe dermal irritation was observed in the treated animals.
Data Quality	Reliable without restriction (Klimisch Code)
References	Unpublished confidential business information
Other	Updated: April 3, 2003

3.3 Genetic Toxicity:

Robust Summary 9-Gentox-1

Test Substance	
CAS #	68784-17-8
Chemical Name	Isooctadecanoic acid reaction products with TEPA
Remarks	Test material purity – 95% active 5% HRLBO
Method	
Method/Guideline followed	Similar to OECD Guideline 471
Test Type	Bacterial Reverse Mutation Assay
GLP (Y/N)	Y
Year (Study Performed)	1986
Test System	*Salmonella typhimurium*
Strains Tested	*Salmonella typhimurium* tester strains TA98, TA100, TA1535, TA1537
Exposure Method	Plate incorporation
Test Substance Doses/concentration levels	0.1, 0.33, 1.0, 3.3, and 10 mg/plate with and without activation
Metabolic Activation	With and without (S9 fraction mix of livers of Aroclor 1254 pretreated Sprague Dawley rats)
Vehicle	Acetone
Tester strain, activation status, Positive Controls and concentration level	TA98 +S9 2-aminoanthracene 2 ug/plate TA98 -S9 2-nitrofluorene 10 ug/plate TA100 +S9 2-aminoanthracene 2 ug/plate TA100 -S9 sodium azide 1 ug/plate TA1535 +S9 2-aminoanthracene 2 ug/plate TA1535 -S9 sodium azide 1 ug/plate TA1537 +S9 2-aminoanthracene 2 ug/plate TA1537 -S9 9-aminoacridine 50 ug/plate
Vehicle Control	Acetone
Statistical Analysis	Mean revertant colony count and standard deviation were determined for each dose point.
Dose Rangefinding Study	Yes
S9 Optimization Study	Yes
Dose confirmation	Yes
Remarks field for test conditions	This study was conducted prior to the development of OECD Guideline No. 471. This study deviates from the guideline in that Tester Strain E. coli WP2 urvA Tester Strain called for in the guideline was not included. There were two treatment sets for each tester strain, with (+S9) and without (-S9) metabolic activation. Each of the tester strains was

	dosed with five concentrations of test substance, vehicle control, and a positive control. Three plates/dose group/strain/treatment set were evaluated. 100 ul of test material, positive control or vehicle control were added to each plate along with 100 ul of tester strain, S9 mix (if needed) and 2.0-2.5 ml of top agar. This was overlaid onto the surface of minimal bottom agar in a petri dish. Due to unusual toxicity results observed in the first experiment, the amount of solvent/test material delivered to each plate was reduced to 50 ul in the second experiment. Plates were incubated for 48 hours at 37^{o}C. The numbers of revertant colonies were counted with an automated colony counter. The test material was considered positive if two consecutive dose levels (or the highest non-toxic dose level) produced responses at least twice (2.5 fold for TA1535 and 1537) that of the negative/solvent control and these dose levels exhibited a dose response. Study results were confirmed in a second independent assay.
Results	The test substance was not mutagenic in this assay with or without metabolic activation.
Remarks	The test material was completely miscible with acetone but was not completely miscible with the top agar at $\geq$ 0.1 mg/plate. In the first experiment, in which the test material or solvent was delivered at 100 ul/plate, cytotoxicity was observed in TA 98, 100 and 1535 (1 and 3.3 mg/plate) and TA1537 (3.3 mg/plate) with metabolic activation. Test material precipitation occurred at all dose levels and interfered with cytotoxicity evaluations at the highest dose tested (10 mg/plate). Precipitation with little or no cytotoxicity was observed at all concentrations tested in the second experiment. No reproducible increases in mutation frequency were observed in any tester strain with or without metabolic activation. The positive control for each respective test strain exhibited an appropriate response (with or without S9) over the mean value of the vehicle control for a given strain, confirming the expected positive control response.
Conclusions	Under the conditions of this study, the test material was not mutagenic.
Data Quality	Reliable without restriction (Klimisch Code).
References	Unpublished confidential business information
Other	Updated: April 3, 2003