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COURTNEY M. PRICE  
VICE PRESIDENT  
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Chemistry  
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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](mailto: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**

**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 physicochemical 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

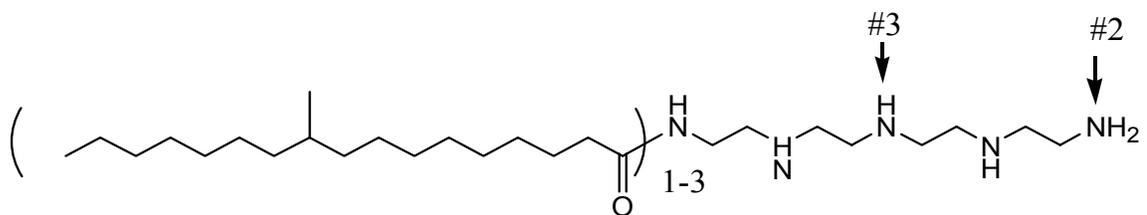
The substance that is the subject of this test plan is used as a petroleum additive in petroleum base stocks. The chemical name, CAS Registry Number, molecular weight and chemical structure for this substance are presented below.

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 then mixed into gasoline at gasoline to oil ratios of 50 to 100:1.

#### 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
<b>Physical/Chemical Characteristics</b>		
<i>Melting Point</i>	Not Applicable	No
<i>Boiling Point</i>	No Data Located	Yes
<i>Vapor Pressure</i>	No Data Located	Yes
<i>Water Solubility</i>	No Data Located	Yes
<i>Partition Coefficient</i>	No Data Located	Yes
<b>Environmental Fate</b>		
<i>Biodegradation</i>	<10% at 28 days	No
<i>Hydrolysis</i>	No Data Located	Yes
<i>Photodegradation</i>	No Data Located	Yes
<i>Fugacity</i>	No Data Located	Yes
<b>Ecotoxicity</b>		
<i>Acute Toxicity to Fish</i>	96 hr LC50: >1000 mg/L WAF 96 NOEC: 1000 mg/L WAF	No
<i>Acute Toxicity to Invertebrates</i>	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
<i>Acute Toxicity to Algae</i>	96 hr EC50: 1.0-1.4 mg/L WAF 72 and 96 hr NOEC: 1.0 mg/L WAF	No
<b>Mammalian Toxicity</b>		
<i>Acute Toxicity</i>	Oral LD50 > 5 g/kg (rat) Dermal LD50 > 2 g/kg (rabbit)	No
<i>Repeated Dose Toxicity</i>	No Data Located	Yes
<i>Developmental Toxicity</i>	No Data Located	Yes
<i>Reproductive Toxicity</i>	No Data Located	Yes
<b>Genotoxicity</b>		
<i>Gene Mutation</i>	Not Mutagenic	No
<i>Chromosomal Aberration</i>	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<sup>1</sup>, 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<sub>2</sub> 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<sub>2</sub> 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

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<sup>1</sup> 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<sup>2</sup>, 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<sub>50</sub> in Rainbow trout is > 1000 mg/L WAF. The 96-hour NOEC is 1000 mg/L WAF.

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<sup>2</sup> 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<sub>50</sub>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<sub>50</sub> 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<sub>50</sub> in rats is greater than 5 g/kg indicating a low concern for toxicity.
- OECD Test Guideline 402 (*Acute Dermal Toxicity*): The LD<sub>50</sub> 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.