201-16677A

HIGH PRODUCTION VOLUME (HPV)

CHALLENGE PROGRAM

FINAL SUBMISSION

For

Isooctadecanoic Acid Reaction Products with TEPA
(CAS No. 68784-17-8)

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

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LIST OF MEMBER COMPANIES IN THE
HEALTH and ENVIRONMENTAL REGULATORY TASK GROUP

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

Chevron Oronite Company, LLC

Afton Chemical Company (formerly Ethyl Corporation)

Infineum

The Lubrizol Corporation

The Health and Environmental Regulatory Task Group (HERTG) of the American Chemistry Council's Petroleum Additives Panel hereby submits for review and public comment its final submission dossier for isooctadecanoic acid reaction products with TEPA (CAS Numbers 68784-17-8) to the Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program.

Fate and Transport Characteristics. Based on the physicochemical properties and molecular structure, the HERTG concluded that isooctadecanoic acid reaction products with TEPA was most likely to partition to soils. To verify this conclusion, the HERTG calculated fugacity data on isooctadecanoic acid reaction products with TEPA. Since this material lacks any readily hydrolyzable moieties, hydrolysis modeling was considered unnecessary. Isooctadecanoic acid reaction products with TEPA was subjected to biodegradability testing and found to be poorly biodegradable. The HERTG developed computer modeled data that indicated isooctadecanoic acid reaction products with TEPA does not possess the potential to photodegrade.

Aquatic Toxicology. Data on acute fish toxicity, acute invertebrate toxicity, and algal toxicity were reviewed. The findings of the available studies indicated isooctadecanoic acid reaction products with TEPA possesses significant acute toxicity to algae but does not cause significant toxicity to fish or daphnia. However, the effect of isooctadecanoic acid reaction products with TEPA to the algae was algistatic.

Mammalian Toxicology - Acute. Data on acute mammalian toxicity (oral and dermal) were reviewed. Oral and dermal LD_{50} levels for isooctadecanoic acid reaction products with TEPA were very high, indicating essentially no toxicity.

Mammalian Toxicology - Subchronic Toxicity. The HERTG conducted a repeated-dose study in rats for isooctadecanoic acid reaction products with TEPA. After administration of isooctadecanoic acid reaction products with TEPA, there was no significant toxicity observed at any dose level. This illustrates that isooctadecanoic acid reaction products with TEPA possesses a very low order of repeated-dose toxicity to mammals.

Mammalian Toxicology - Reproductive and Developmental Toxicity. The HERTG investigated the reproductive and developmental toxicity of isooctadecanoic acid reaction products with TEPA. Exposure of rats to isooctadecanoic acid reaction products with TEPA did not impact fertility or reproduction in rats. Additionally, this material did not cause any developmental effects in offspring, thus indicating isooctadecanoic acid reaction products with TEPA does not cause reproductive or developmental toxicity.

Mammalian Toxicology - Mutagenicity. Bacterial reverse mutation assay test data was available for isooctadecanoic acid reaction products with TEPA and the results were negative, both with and without metabolic activation. Isooctadecanoic acid reaction products with TEPA was also tested in an *in vitro* chromosomal aberration assay. The results were negative for clastogenicity, both with and without metabolic activation.

Conclusion. Based on the physiochemical, environmental fate, aquatic toxicology and mammalian toxicology studies completed and reviewed for this submission, the HERTG concluded that isooctadecanoic acid reaction products with TEPA does posses toxicity but only to algae (via an algistatic effect) but the overall risk is low to mammals, fish, and aquatic invertebrates. As this final submission was completed, the HERTG carefully evaluated the number of animals necessary for testing and the conditions to which animals might be exposed. Thus, a minimal amount of testing involving the use of animals was employed. As a result, HERTG believes that the concerns of some non-governmental organizations about animal welfare were fully considered and the use of animals for this final submission was minimized.

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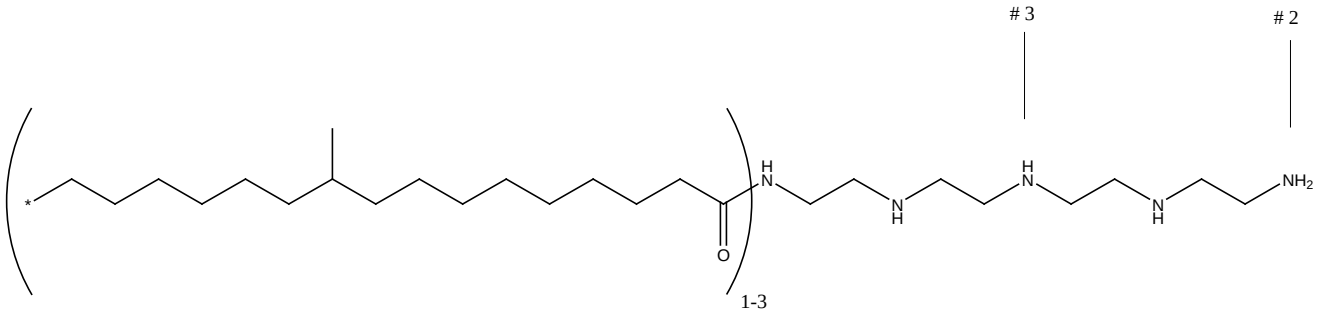
1.0 INTRODUCTION

In March 1999, the Health and Environmental Regulatory Task Group (HERTG) of the American Chemistry Council's Petroleum Additives Panel committed to review certain chemicals listed under the Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program. This final submission follows up on that commitment, and sets forth how the HERTG fulfilled the Screening Information Data Sets (SIDS) requirements for isooctadecanoic acid reaction products with TEPA (CAS No. 68784-17-8). The chemical name, CAS Registry Number, and chemical structure are shown in Figure 1.

Figure 1. CHEMICAL STRUCTURE OF ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA



Isooctadecanoic acid reaction products with TEPA (CAS No. 68784-17-8)

In preparing this final submission 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. Where additional data was needed, testing was completed to meet the SIDS requirements.

2.0 USE AND 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 facilitates formulation of 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.

3.0 PHYSIOCHEMICAL PROPERTIES

The physiochemical properties of isooctadecanoic acid reaction products with TEPA are shown in Table 1, below.

TABLE 1. PHYSIOCHEMICAL PROPERTIES OF ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA

Physical/Chemical Characteristics	Study Results
Melting Point	Not Applicable
Boiling Point	589.1^{o} C [1]
Vapor Pressure	1.62 x 10^{-12} mm Hg [1]
Partition Coefficient	6.3 (OECD 117 method)
Water Solubility	5.19 ± 0.78 mg/L (OECD 105 method)

[1] Modeled value for monosubstituted CAS # 68784-17-8 using EpiWin version 3.12 software

4.0 ENVIRONMENTAL FATE DATA

4.1 Biodegradability

Previously, a modified Sturm test (OECD Guideline 301B) was used to evaluate the biodegradability of isooctadecanoic acid reaction products with TEPA. After 29 days, the extent of biodegradation was 5.0 ± 1.6 % based on total carbon dioxide production. The available data were considered adequate and reliable.

4.2 Hydrolysis

There are no published or unpublished hydrolysis studies on isooctadecanoic acid reaction products with TEPA. However, isooctadecanoic acid reaction products with TEPA does not possess any readily hydrolyzable moieties and as a result, this material is unlikely to undergo hydrolysis. Therefore, hydrolysis modeling was considered unnecessary.

4.3 Photodegradation

There are no published or unpublished photodegradation studies of isooctadecanoic acid reaction products with TEPA. The Atmospheric Oxidation Potential (AOP) of this substance was characterized using the modeling program AOPWIN. The data indicated that this material has a low potential for photodegradation (Table 2).

4.4 Fugacity Modeling

There are no published or unpublished fugacity data for isooctadecanoic acid reaction products with TEPA. The relative distribution among environmental compartments was evaluated using Level III Fugacity modeling. The modeling indicated this material will primarily partition to soils.

TABLE 2. ENVIRONMENTAL FATE DATA FOR ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA

Environmental Fate	Study Results
Biodegradation	5.0 ± 1.6 % at 29 days (OECD 301B)
Photodegradation[1]	AOPWIN Model Estimation OH- Rate Constant (cm3/molec-sec) = 320.3×10^{-12} Half-life = 0.033 days
Fugacity[1]	Mass distribution (%) Air 6.18×10^{-10} Water 9.81 Soil 81.6 Sediment 8.63

[1] Modeled values using EpiWin version 3.12.

5.0 ECOTOXICOLOGY DATA

5.1 Fish Acute Toxicity

Available data indicated the 96 hour LC_{50} of isooctadecanoic acid reaction products with TEPA for rainbow trout (Oncorhynchus mykiss) was > 1,000 mg/L and the no observed effect concentration (NOEC) was 1,000 mg/L. Water accommodated fractions (WAF) were used to expose the fish to the test material. The data was considered adequate and reliable.

5.2 Invertebrates Acute Toxicity

Available data showed the 48 hour EC_{50} of isooctadecanoic acid reaction products with TEPA for (*Daphnia magna*) was 150 mg/L and the no observed effect concentration (NOEC) was 100 mg/L. WAF preparations were used to expose the daphnia to the test material. The data was considered adequate and reliable.

5.3 Algal Toxicity

Previously, the 96 hour EL_{50} of isooctadecanoic acid reaction products with TEPA determined in unicellular green algae was 1.0 – 1.4 mg/L WAF and the 72 and 96 hour NOEL was 1.0 mg/L WAF. However, the effect of the test material to the algae was algistatic. The available algal toxicity data was considered adequate and reliable.

TABLE 3. AQUATIC TOXICITY DATA FOR ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA

Ecotoxicity study	Study Results
Acute Toxicity to Fish (OECD 203) (*Pimephales promelas*)	96-hour LC_{50} > 1,000 mg/L WAF NOEC = 1,000 mg/L WAF
Acute Toxicity to Invertebrates (OECD 202) (*Daphnia magna*)	48-hour EC50 = 150 mg/L WAF NOEC = 100 mg/L WAF
Acute Toxicity to Algae (OECD 201)	EL_{50} (96 hrs) = 1.0 – 1.4 mg/L WAF NOEL = 1.0 mg/L WAF

WAF: Water accommodated fraction

6.0 MAMMALIAN TOXICOLOGY DATA

6.1 Acute Mammalian Toxicity

Acute oral and dermal toxicity studies were available for isooctadecanoic acid reaction products with TEPA. The LD_{50} in rats (oral) and rabbits (dermal) were >5 g/kg and > 2 g/kg, respectively. These studies were reviewed and considered reliable.

6.2 Repeated-dose Toxicity

A repeat dose toxicity study for isooctadecanoic acid reaction products with TEPA was reviewed. Up to and including the high dose of 1,000 mg/kg/day, this material did not cause significant toxicity to rats. The results are shown in Table 4 and this study was considered adequate and reliable.

6.3 Reproductive and Developmental Toxicity

The HERTG conducted a reproductive and developmental screening study (OECD 421) in rats on isooctadecanoic acid reaction products with TEPA. Administration of this material did not impact fertility or reproduction and did not cause developmental toxicity (data shown in Table 4) and this study was considered adequate and reliable.

TABLE 4. MAMMALIAN TOXICITY DATA FOR ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA

Mammalian Toxicity	Study Results
Acute Toxicity	Rat Oral LD_{50} >5 g/kg Rabbit Dermal LD_{50} >2 g/kg
Repeat Dose Toxicity	Oral gavage 28-day study in rats (OECD 407) NOEL = 1000 mg/kg/day Significant findings: **All doses (100, 500, and 1000 mg/kg/day)** -No adverse effect observed (body and organ weights, clinical chemistry, hematology, clinical observations, functional observation battery, motor activity, or histology)
Reproductive and Developmental Toxicity	Reproductive and developmental screen (OECD 421) – Oral gavage and rats Reproductive NOEC = 1000 mg/kg/day (highest dose) Significant findings: Administration of isooctadecanoic acid reaction product with TEPA did not adversely impact fertility/reproduction in rats after administration of any dose (150, 450, or 1000 mg/kg/day) Litter sizes, fertility indices, pup weights and pup survival were similar between controls and all dose groups. Additionally, administration of isooctadecanoic acid reaction product with TEPA did not cause any developmental toxicity effects at any dose

7.0 GENETIC TOXICOLOGY DATA

7.1 Mutagenicity

An adequate and reliable bacterial reverse mutation study was performed for isooctadecanoic acid reaction products with TEPA. The material was not mutagenic in any strain in the presence or absence of metabolic activation.

7.1 Clastogenicity

A chromosomal aberration study (OECD 473) was conducted in human peripheral blood lymphocytes. Isooctadecanoic acid reaction products with TEPA exposure did not result in an

increased rate of chromosomal aberrations or endoreduplication in the presence or absence of metabolic activation.

TABLE 5. SUMMARY OF DATA FOR ISOOCTADECANOIC ACID REACTION PRODUCTS WITH TEPA

CAS Number	Environmental Fate					Ecotoxicity		
	Physical Chem	Photodeg	Hydrolysis	Fugacity	Biodeg	Acute Fish Toxicity	Acute Invert Toxicity	Algal Toxicity
68784-17-8	A/C	C	D	C	A	A	A	A

CAS Number	Human Health Effects				
	Acute Toxicity	Point Mutations	Chrom Effects	Sub-chronic	Repro/ Develop
68784-17-8	A	A	A	A	A

A Adequate data available
C Computer modeling completed
D Technical discussion completed