RECEIVED
OPPT CBIC
2007 JAN 29 AM 8:12

DIMETHYLOLPROPIONIC ACID (CAS NO. 4767-03-7): TEST PLAN

Submitted to the US Environmental Protection Agency

By

GEO Specialty Chemicals

DATE: January 2007

SUMMARY

GEO Specialty Chemicals (GEO) has sponsored Dimethylolpropionic acid (DMPA; CAS No. 4767-03-7) under the EPA's High Production Volume (HPV) Program. This document provides the Test Plan and summaries of existing data for this substance.

1.0 INTRODUCTION

GEO has voluntarily committed to participate in the Environmental Protection Agency's (EPA) High Production Volume chemicals (HPV) challenge program, to assess the health and environmental hazards, including selected physical chemical characteristics of Dimethylolpropionic acid (DMPA; CAS No. 4767-03-7).

An evaluation of the available data and proposed test plan are included in this document. Summaries of the available data for DMPA are provided in Appendix 1.

The objective of this test plan is to evaluate the available data and determine what additional data, if any, are needed to adequately characterize the physical properties, environmental fate, and human health and environmental hazards of DMPA. It is proposed that additional studies be conducted as shown in Table 1.

Table 1: PROPOSED TESTING FOR DMPA

Endpoint	Data
Physical Chemical Properties	
Melting Point	A
Vapor Pressure	A
Boiling Point	NA
Partition Coefficient	A
Water Solubility	A
Environmental Fate	
Hydrolysis	Test (OECD TG 111)
Photodegradation	A
Biodegradation	Test (OECD TG 301)
Environmental Transport	A
Ecotoxicity	
Acute Fish	Test (OECD TG 203)
Acute Daphnia	Test (OECD TG 202)
Acute Algae	Test (OECD TG 201)
Mammalian toxicity	
Acute Oral	A
Repeated Dose	Test (OECD TG 422)
Genotoxicity (*in vitro* -bacteria)	A
Genotoxicity (*in vivo*)	A
Reproductive/Developmental	Test (OECD TG 422)

NA: not applicable; substance is a solid
A= Adequate data
Test = Testing proposed

2.0 POTENTIAL USE AND EXPOSURE

The use of DMPA is regulated by the FDA as follows:
- cleared under 21 CFR 175.105 - Adhesives (as comonomer of special polyurethane resins);
- cleared under 21 CFR 176.170 - Components of paper and board in contact with aqueous and fatty foods (as comonomer of special polyester resins);

- cleared under 21 CFR 178.180 - Components of paper and board in contact with dry foods (as comonomer of special polyester resins)

3.0 EVALUATION OF EXISTING DATA AND PROPOSED TESTING

Chemical/Physical Properties:

The physical chemical properties of the substance are provided in Table 2.

Table 2: PHYSICAL/CHEMICAL PROPERTIES DMPA

Endpoint	Result
Melting Point	189-191C
Vapor Pressure	1 hPa at 160 C
Boiling Point	N A (solid)
Partition Coefficient	-0.95
Water Solubility	11 mg/L

Recommendation: No additional testing is proposed.

Environmental Fate:

Environmental fate data are available for the sponsored substance. EPIWIN was used to predict the photodegradation and environmental distribution (Table 3). DMPA is expected to be readily biodegradable based on information located in a safety data sheet. However, details of the study conduct are not available; a biodegradation study is proposed for the sponsored substance. Hydrolysis data were not located for DMPA.

Table 3: ENVIRONMENTAL FATE PROPERTIES FOR DMPA

Endpoint	Result
Photodegradation	OVERALL OH Rate Constant = 9.0090 E-12 cm3/molecule-sec HALF-LIFE = 1.187 Days
Hydrolysis	Not determined
Environmental distribution (%)	Air = 8.86e-005 Water =40.5 Soil = 59.5 Sediment = 0.0645
Biodegradation	Readily biodegradable

Recommendation: A hydrolysis test (OECD TG 111) and biodegradation study (OECD TG 301) are proposed.

Aquatic Toxicity

Acute aquatic toxicity data are available for fish, daphnia or algae, but details of the studies are not available.

Table 4: ENVIRONMENTAL EFFECTS DATA FOR DMPA

Endpoint	Result
Acute toxicity to fish	48 hr LC0 > 5000 mg/L
Acute toxicity to Daphnia	24 hr EC50 = 38900 mg/L
Acute toxicity to algae	7 d EC3 = 16500 mg/L

Recommendation: Acute aquatic toxicity studies with fish, daphnia and algae (OECD TG 203, 202, and 201) are proposed.

Acute Mammalian Toxicity
The acute oral LD50 of DMPA in rats is > 2000 mg/kg/bw.

Recommendation: No additional testing is necessary.

Repeated Dose/ Reproductive/Developmental Toxicity
No data are available regarding the repeated dose toxicity, reproductive toxicity or developmental effects of the sponsored substance.

Recommendation: A combined repeat dose with developmental and reproductive screen (OECD TG 422) by the oral gavage route of exposure is proposed.

Mutagenicity Assays
DMPA was negative for mutagenicity in a bacterial reverse mutation assay conducted following OECD TG 471. DMPA was not clastogenic in an in vitro chromosome aberration assay conducted following OECD TG 473. DMPA was not mutagenic at the TK-locus of mouse lymphoma L5178y cells in a mammalian cell gene mutation assay conducted following OECD TG 476.

Recommendation: No additional testing is proposed.

APPENDIX 1

ROBUST SUMMARIES