HUNTSMAN

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Regulatory Compliance Specialist

201-16248

April 27, 2006

U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA. 22116
Attn: Chemical Right-to-Know Program

Re: HPV Challenge Program, AR-201
Oxirane, reaction products with ammonia, distillation residue
CAS Registry Number 68953-70-8

Huntsman Petrochemical Corporation is pleased to submit the enclosed Test Plan and Robust Summaries for ***Oxirane, reaction products with ammonia, distillation residue,*** CAS Registry Number 68953-70-8 as part of our commitment to the EPA High Production Volume Challenge Program, AR-201.

Based on a review of available data elements, including physical/chemical properties and results of biological and toxicological studies, we believe that no further testing is necessary to complete the dossier.

Please contact me at 281-719-4754 if there are questions relating to this submission.

Sincerely yours,

Donald A. Lederer, Jr.

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201-16248

Oxirane, reaction products with ammonia, distillation residue

CAS Number 68953-70-S

USEPA HPV Challenge Program Submission

March 30, 2006

Submitted by:

Huntsman Petrochemical Corporation
INEOS Oxide, a division of INEOS Americas LLC

Prepared by:
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I. Introduction

Huntsman Petrochemical Corporation and INEOS Oxide, a division of INEOS Americas, LLC have voluntarily committed to develop screening level health effects data, environmental fate and effect data, and physical chemical test data for the distillation residue from the reaction of oxirane with ammonia (CAS # 68953-70-8) under the Environmental Protection Agency's High Production Volume Challenge Program.

This organic amine stream is the resulting distillation residue from alkanolamines production. In this process, ethylene oxide is reacted with ammonia to form mono-, di- and tri- ethanolamines. These fractions are removed by distillation. The remaining distillation residue is CAS# 68953-70-8. This material typically contains at least 80% TEA, less than 1% DEA, with the remainder as higher boiling amine reaction products.

CAS# 68953-70-8 is used mainly as a concrete additive as a corrosion inhibitor for steel reinforcements. Environmental and occupational exposures are expected to be minimal.

Data Availability and Quality Summary

	Data Available	Data Adeauate	Testing Recommended
Melting point	TEA	Yes	No
Boiling point	Yes	Yes	No
Vapor Pressure	Yes	Yes	No
Partition Coefficient	TEA	Yes	No
Water Solubility	Yes	Yes	No
Stability in Water	TEA	No	No
Transport	TEA	Yes	No
Photodegradation	No	Yes	No
Biodegradation	TEA	Yes	No
Acute Toxicity to Fish	TEA	Yes	No
Acute Toxicity to Invertabrates	TEA	Yes	No
Acute Toxicity to Aquatic Plants	TEA	Yes	No
Acute Tox – oral	**Yes**	**Yes**	**No**
Acute Tox – inhalation	TEA	**Yes**	**No**
Acute Tox – dermal	Yes	**Yes**	**No**
Gene Tox – MN	Yes	**Yes**	**No**
Gene Tox *in vitro* – Ames	Yes	**Yes**	**No**
Gene Tox *in vitro* – *UDS*	Yes	**Yes**	**No**
Repeat dose- oral, dermal, inhalation	TEA	**Yes**	**No**
Reproductive toxicity	TEA	**Yes**	**No**
Developmental tox	TEA	**Yes**	**No**

II. Use of Triethanolamine Data for CAS Number 68953-70-8 Endpoints

As described above, CAS# 68953-70-8 is the distillation residue from alkanolamines production and it typically contains at least 80% triethanolamine (TEA). Because of this relatively high percentage of TEA, the toxicity of CAS# 68953-70-8 would be expected to be very similar to that of commercial TEA. This data summary and test plan includes available data on CAS# 68953-70-8, compares that data to TEA data for the same endpoints, and uses TEA data as a surrogate for other endpoints.

Endpoint	CAS# 68953-70-8	TEA
Boiling point	372 C	335 c
Vapor Pressure	<0.1 mmHg	<0.1 mmHg
Water Solubility	Miscible	Miscible
Acute Tox – oral	>5000 mg/kg	>5000 mg/kg
Acute Tox – dermal	>3000 mg/kg	>2000 mg/kg
Gene Tox ***in vivo – MN***	Negative	
- Drosophila SLRL		Negative
Gene Tox ***in vitro*** – Ames	Negative	Negative
Gene Tox ***in vitro – UDS***	Negative	Negative

III. Test Plan and Rationale

A. Physical Chemical Data

The physical/chemical data for CAS# 68953-70-s are found in material safety data sheets. The underlying data were not reviewed, but additional testing is not justified. Transport between environmental compartments has been estimated using EPA software (EPIWIN Level III). The stability of CAS# 68953-70-8 in water has not been tested, but TEA was stable in two river water samples for 7 or 10 days.

Recommended testing: None

B. Ecotoxicity

CAS# 68953-70-8 or TEA lack chromophoric functional groups for participation in photodegradation at environmentally relevant wavelengths; thus there are no photodegradation data and none are needed. Data on biodegradation of CAS# 68953-70-8 are not available; however, in reactions with mixed liquor activated sludge from a municipal wastewater treatment facility, TEA biodegrades with an estimated half-life of 0.02 to 0.1 days. (Because this study was not included in the TEA IUCLID, it is

included in the CAS# 68953-70-8 IUCLID.) Data on acute fish, invertebrate and plant toxicity for CAS# 68953-70-8 were not found, but data on TEA are available to cover this endpoint. Acute fish toxicity studies *(Carassius auratus, Lepomis macrochirus, Leuciscus idus, and Pimephales promelas)* are included in the TEA IUCLID data set; acute fish LC_{50}s are > 450 mg/l to >11,800 mg/l. An acute toxicity study of TEA to *ceriodaphnia dubia* (water flea) was not included in the TEA IUCLID, so is included in the IUCLID for CAS# 68953-70-8; the EC_{50} for 48 hour exposure was 610 mg/l. The toxicity of TEA to *Scenedesmus subspicatus* (Green algae) was not included in the TEA IUCLID, so is included in the IUCLID for CAS# 68953-70-8; the EC_{50} for 48 hour exposure, based on decreased biomass, was 470 mg/l in a static cell multiplication inhibition test.

Recommended ecotoxicity testing: None

C. Mammalian Toxicity

Reliable acute toxicity tests are available on CAS# 68953-70-8 and TEA. CAS# 68953-70-8 is practically nontoxic following acute oral exposure in a test that meets OECD and EPA test guidelines; the LD_{50} is >5000 mg/kg. The dermal LD_{50} is >3000 mg/kg, in a test that meets OECD and EPA test guidelines. LD_{50}s for TEA were similar. No further testing is recommended.

Repeated dose testing of CAS# 68953-70-8 data are not available, but subchronic (l-3 month) studies of TEA by oral, inhalation, and dermal exposure are available. A one month inhalation study of TEA is included in the TEA IUCLID (p. 33); exposure of rats 6 hr/d, 5 d/wk for 4 wk to an aerosol of TEA at 20, 100 and 500 mg/m^3 revealed no adverse effects except slight inflammation of mucosa of the larynx. TEA in the feed of rats for 91 days at up to 1000 mg/kg body weight (included in TEA IUCLID, p. 35) resulted in no treatment-related effects. Dermal application (studies included in TEA IUCLID, p. 37, 41) of TEA to rats at 125 to 2000 mg/kg/day for 91 days or mice at 250 to 4000 mg/kg/day for 91 days resulted in no systemic toxicity, but slight inflammation at the exposure site. No further testing is recommended.

CAS# 68953-70-8 was negative in an Ames (in vitro bacterial mutation) assay, a rat hepatocyte UDS (in vitro DNA damage and repair) assay and a micronucleus (in vivo genotoxicity) assay in mice. TEA was also negative in five Ames assays, two *Bacillus subtilis* recombination assays, two E. coli mutation assays, one *Saccharomyces cerevisae* mutation assay, two *in vitro* chromosomal aberration assays, one *in vitro* sister chromatid exchange assay, two *in vitro UDS* assays, one *in vitro* CHO cell transformation assay, and one *in vivo* sex-linked recessive lethal mutation assay in *Drosophila melanogaster*. No further testing is recommended.

TEA has been reported not to increase tumors in rats in a 2 yr drinking water study (TEA IUCLID, p. 50) or in an 18 month study in mice (TEA IUCLID, p. 51). No increase in tumors was found in mice exposed to TEA for two years at 40 or 450

mg/kg/day body weight in the feed (TEA IUCLID, p. 51). No increase in tumors was found following dermal application for 14-18 months in two separate studies (TEA IUCLID, p. 49).

No reproduction studies have been found for either CAS# 68953-70-8 or TEA; however, no toxicity to reproductive organs has been reported in any of the repeated-dose toxicity studies of TEA. Therefore, reproductive toxicity is unlikely for CAS# 68953-70-8. No further testing is recommended.

No change in maternal mortality, number of viable litters, litter size, percent survival of pups, or birth weight or weight gain of pups was found when mice were dosed with TEA by gavage at 1125 mg/kg on gestation days 6-15 and evaluated on post pat-turn day 3 (TEA IUCLID, p. 53). No increase in malformations was seen when hair dyes containing TEA (30 mg/kg/day) were applied to the skin of rats on gestation days 1, 4, 7, 10, 13, 16, and 19 (TEA IUCLID, p. 54). No further testing is recommended.

Recommended Testing: None

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IUCLID

Data Set

Existing Chemical	: ID: 68953-70-a
CAS No.	: 68953-70-a
Producer related part	
Company	: ToxWorks
Creation date	: 01.11.2005
Substance related part	
Company	: ToxWorks
Creation date	: 01.11.2005
Status	:
Memo	:
Printing date	: 01.12.2005
Revision date	:
Date of last update	: 01.12.2005
Number of pages	: 22
Chapter (profile)	: Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	: Reliability: without reliability, **1,** 2, 3, 4
Flags (profile)	: Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety **Dataset,** Risk Assessment, Directive **67/548/EEC, SIDS**

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	manufacturer
Name	:	Huntsman Corp
Contact person	:	Mr. Ray Papciak
Date	:	
Street	:	10003 Woodloch Forest Drive
Town	:	77380 The Woodlands, Texas
Country	:	United States
Phone	:	281-719-6094
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

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Type	:	manufacturer
Name	:	INEOS Americas LLC
Contact person	:	Ms. Dana Morisse-Arnold
Date	:	
Street	:	2305 Brazosport Blvd.
Town	:	77541 Freeport, TX
Country		United States
Phone		979-415-8511
Telefax		
Telex	:	
Cedex		
Email	:	
Homepage	:	

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1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	Oxirane, reaction products with ammonia, distn, residue
Smiles Code		
Molecular formula	:	
Molecular weight	:	
Petrol class	:	

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1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	
Substance type	:	organic
Physical status	:	liquid
Purity	:	
Colour	:	amber to dark brown
Odour	:	slight ammonia
Remark	:	Product is a distillation residue which contains at least 80% triethanolamine, less than 1% diethanolamine, and the remainder being higher amines.

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1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Alkanolamine 5503

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Amine 1-N

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1.3 IMPURITIES

Purity	:	typical for marketed substance
CAS-No	:	
EC-No	:	
EINECS-Name	:	
Molecular formula	:	
Value	:	

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1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.8 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

08.11.2005

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

2.2 BOILING POINT

Value	: ca. 372 °C at
Decomposition	:
Method	: other
Year	:
GLP	: no data
Test substance	:

Remark : from MSDS
01.11.2005

2.3 DENSITY

Type	: density
Value	: ca. 1.12 g/cm³ at 20°C
Method	: other
Year	:
GLP	: no data
Test substance	:

Remark : from MSDS
01.11.2005

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	: < .1 hPa at 20 °C
Decomposition	:
Method	: other (measured)
Year	
GLP	: no data
Test substance	:

Remark : from MSDS
23.11.2005

2.5 PARTITION COEFFICIENT

Partition coefficient	:
Log pow	: < at °C
pH value	

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2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	at °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	

Remark : completely soluble in water; from MSDS 01.11.2005

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.6 AUTO FLAMMABILITY

2.9 **FLAMMABILITY**

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

3.1.2 STABILITY IN WATER

Type	:	abiotic
	:	at °C
	:	> 7 day(s) at 25 °C
	:	at °C
Deg. product	:	
Method	:	
Year	:	1992
GLP	:	yes
Test substance	:	other TS: TEA
Method	:	As part of biodegradation study of TEA in two river water samples, control samples containing TEA and formaldehyde to deactivate microorganisms. Samples were analyzed for TEA over 7 or 10 days.
Result	:	Recovery of added radioactive TEA was greater than 90% up to 7 days in a water sample from one river and greater than 95% in the sample from another river after 10 days. pH in both river samples was 7.7
Reliability	:	(2) valid with restrictions Control samples from biodegradation study; conducted under GLP, but not according to standard water stability study.

01.12.2005 **(14)**

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	
Air	:	.0266 % (Fugacity Model Level I)
Water	:	45.9 % (Fugacity Model Level I)
Soil	:	54 % (Fugacity Model Level I)
Biota	:	% (Fugacity Model Level II/III)
Soil	:	.0766 % (Fugacity Model Level II/III)
Method	:	
Year	:	2005
Remark	:	Model based on TEA.
Reliability	:	(2) valid with restrictions EPA model calculations

01.12.2005 **(2)**

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	industrial sewage
Concentration	:	.6 mg/l related to Test substance 5.4 mg/l related to Test substance
Contact time	:	
Degradation	:	(±) % after
Result	:	inherently biodegradable
Deg. product	:	yes
Method	:	
Year	:	1992
GLP	:	yes
Test substance	:	other TS: TEA
Method	:	The biodegradation of TEA was tested in the presence of activated sewage sludge from a wastewater treatment plant. The sludge was aerated for 48 hours before use. After the addition of the activated sludge mixed liquor and TEA, the sample tubes were sealed with rubber stoppers with carbon dioxide traps. Cultures were analyzed periodically for the disappearance of TEA and formation of degradation products, including carbon dioxide. Recovery of applied radioactive TEA was between 74 and 92%. Cultures were sampled until all TEA had disappeared.
Result	:	Half-life = 0.02 to 0.1 day. The rate of degradation was 1500 mg TEA/mg solids/ hr for the low TEA concnetration and 4800 mg TEA/mg solids/ hr for the high TEA concnetration. Also tested biodegradation in sandy loam surface soil - half life = 0.5 to 1.8 days for concentrations of 1.4 to 2000 mg/kg. Biodegradation in two river waters: average half-life = 1.2 days for TEA concentrations of 0.099 and 0.489 mg/l.
Reliability	:	(1) valid without restriction Standard methodology; well reported.

01.12.2005 (14)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Ceriodaphnia sp. (Crustacea)
Exposure period	:	48 hour(s)
Unit		mg/l
EC50	:	= 610 calculated
Analytical monitoring	:	no
Method	:	other: NSW EPA procedure
Year	:	1999
GLP	:	no data
Test substance	:	other TS: TEA

Reliability : (1) valid without restriction
Well-reported and uses standard procedure

01.12.2005 (13)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	growth rate
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC10	:	= 110 calculated
EC50	:	= 750 calculated
Limit test	:	
Analytical monitoring	:	no
Method	:	other: Din 38 412, Part 9, 1988
Year	:	1988
GLP	:	no data
Test substance	:	other TS: TEA

Method Culture medium was seeded with 1000 algae cells/ml and incubated at 25 C for 48 hours under controlled lighting. TEA was added at 16-2000 mg/l.

Reliability : (2) valid with restrictions
No data on GLP; method and results described briefly.

01.12.2005 (5)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.6 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals		10
Vehicle		
Doses	:	5000 mg/kg
Method	:	OECD Guide-line 401 "Acute Oral Toxicity"
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Method : Five male (209-229 g) and 5 female (145-177 g) Sprague-Dawley rats were fasted overnight and dosed by gavage with 1000 mg/kg of the undiluted test material. They were observed for signs of toxicity at 1 and 4 hours after dosing and once daily for the next 14 days. Body weights were recorded on days 0, 7, and 14. After 14 days all rats were euthanized by carbon dioxide inhalation and necropised.

Result : Signs of toxicity included piloerection, salivation and diarrhea in 1 to 3 rats on the day of dosing. Poor grooming was seen in up to 5 rats through day 3. No rats died during the 14 days of observation. Body weights on days 7 and 14 post-dosing appeared normal. Mottled kidneys were observed in males at necropsy; no visble lesions were seen in females.

Reliability : (1) valid without restriction
Meets guidelines and GLP requiements.

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Type	:	LD50
Value	:	> 2000 mg/kg bw
Species	:	rat
Strain	:	Fischer 344
Sex		female
Number of animals	:	3
Vehicle		
Doses	:	2000 mg/kg
Method	:	
Year		1995
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Method : The study used common methodology, but did not describe in sufficient detail to ascribe to a published standard. Animals were administered the test material by gavage and observed for 14 days.

Result : There was no effect on body weight and no clinical signs of toxicity were seen. There were no deaths.

Reliability (2) valid with restrictions
The report does not identify a Guideline or GLP status, but corresponds with another GLP study.

01.12.2005 (4)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type		LD50
Value	:	> 3000 mg/kg bw
Species	:	rabbit
Strain	:	New Zealand white
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	3000 mg/kg
Method	:	OECD Guide-line 402 "Acute dermal Toxicity
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1 .1 - 1.4
Method	:	Approximately 24 hours before dosing, the fur was removed from the trunks of 5 male and 5 female rabbits weighing between 2147 and 2586 grams. The test substance was spread evenly (area not specified) on intact skin and covered with gauze. The trunk was wrapped with rubber dam and an elastic bandage for 24 hours.
Result	:	Diarrhea was observed in 3 of 10 rabbits on days 1 and 2 after dosing; no other signs of toxicity were seen. Moderate to severe erythema was present at the test site in all animals upon removal of the test site coverings, One female had necrosis of the skin. No erythema was present by day 3. There were no deaths during the 14 days of observation. Body weights on days 7 and 14 post-dosing appear normal. No lesions were seen during necropsy.
Reliability	:	(1) valid without restriction Meets guideline and GLP requirements

03.11.2005 (6)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	undiluted
Exposure	:	Occlusive
Exposure time	:	24 hour(s)
Number of animals	:	6
Vehicle	:	
PDII	:	1.62
Result	:	slightly irritating
Classification	:	not irritating
Method	:	EPA OPP 81-5
Year		1990
GLP	:	yes
Test substance		as prescribed by 1.1 - 1.4
Method	:	Trunks of 3 male and 3 female rabbits (2246 - 2645 grams) were clipped free of hair. The test material was applied to 1 abraded and 2 intact sites on the dorsal trunk of each rabbit. Exposure at 1 intact site was for 4 hours; exposure at the other intact site and the abraded site was for 24 hours. Sites were scored for erythema and edema at 24, 48 and 72 hours after the

end of the exposure periods. The 4 hour exposure was in compliance with OECD method 404 and the 24 hour exposure in compliance with EPA 81-5.

Result : Following 4 hours of exposure, there **was** very slight erythema on 2 of 6 rabbits, but no edema. After 72 hours, no erythema or edema was seen, The **PII** for 4 hours of exposure to intact sites was 0.25. Following 24 hours of exposure, slight to severe erthema was observed on all rabbits; there was slight edema on 5 of 6. Erythema and edema was gone from the intact sites by 48 hours, but did not completely clear from the abraded sites in all animals until day 9. The **PII** from 24 hours of exposure (intact and abraded combined) was 1.62.

Reliability : (1) valid without restriction
Meets guideline and GLP requirements

23.11.2005 **(8)**

Species : rabbit
Concentration : undiluted
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 1
Vehicle :
PDII
Result : slightly irritating
Classification : not irritating
Method :
Year : 1995
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Method : Test material applied to intact skin for 5 consecutive days and to abraded skin 3 times. Sites were observed for irritation.

Result : No erythema or edema was seen at the intact site and slight erythema was seen at the adraded site.

Reliability : (2) valid with restrictions
The report does not provide **suffiicient** details to determine if a Guideline or GLP were followed

23.11.2005 (3)

5.2.2 EYE **IRRITATION**

Species : rabbit
Concentration : undiluted
Dose : .1 ml
Exposure time
Comment : not rinsed
Number of animals : 6
Vehicle : none
Result : moderately irritating
Classification : irritating
Method : EPA OPP 81-4
Year : 1991
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : 0.1 ml test material instilled in lower eyelid; eyelids held closed for approximately 1 second. Eyes were not washed. Scored after **24, 48** and 72 hours according to Draize scale. Number of rabbits scored as positive according to US Federal Hazardous substances Act Regulations at 16 CFR 1500.42 was recorded. Report includes Draize score and number positive.

Result : There was no **corneal** opacity in any rabbit at any time. Iris irritation was

observed in 4 of 6 rabbits 1 hour after instillation, but was not present in any rabbits after 24 hours. Conjunctival redness, grade 2 or 3, was observed in all 6 rabbits after 1 hour, in 5 rabbits after 24 hours, in 1 rabbit after 48 hours, but not after 72 hours. Conjunctival swelling, grade 2 or higher, was observed in all six rabbits 1 hour after dosing, but was not present after 24 hours. The mean score using the Draize scale was 18.2 of possible 110.

Reliability : (1) valid without restriction
Meets guideline and GLP requirements

01.12.2005 (9)

Species : rabbit
Concentration : undiluted
Dose : .1 ml
Exposure time : 1 hour(s)
Comment :
Number of animals : 1
Vehicle : none
Result : slightly irritating
Classification : not irritating
Method :
Year : 1995
GLP : no data
Test substance : as prescribed by 1 .1 - 1.4

Method : Instilled into both eyes, one washed after 30 seconds; the other was washed after 1 hr.
Result : Slight conjunctival redness and swelling for first 24 hours. No irritation after 48 or 72 hours.
Reliability : (2) valid with restrictions
This was a limited study that did not meet guidelines and no data on GLP

01.12.2005 (3)

5.3 SENSITIZATION

Type : Buehler Test
Species : guinea pig
Concentration : 1st: Induction undiluted occlusive epicutaneous
2nd: Challenge undiluted occlusive epicutaneous
3rd:
Number of animals : 35
Vehicle :
Result : not sensitizing
Classification : not sensitizing
Method : EPA OPP 81-6
Year : 1990
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Male and female Hartley Guinea pigs (300 to 500 grams) were obtained from USDA registered dealer and housed according to NRC Guidelines. The left shoulder of each animal was clipped free of hair 24 hrs before weekly application of 0.3 ml of the undiluted test material or DNCB (1-chloro-2,4-dinitrobenzene) and the animals held in restrainers during exposure. The test material was applied to 10 males and 10 females beneath a 25 mm Hill Top Chamber (Hill Top Research, Inc., Cincinnati, OH) and covered with a dental dam. DNCB, positive control at 0.3% in 80% in ethanol/20% water, was aplied similarly to 2 males and 3 females. The patch and dam were held in place with clips attached to the sides of the animal restrainer. After 6 hours, the dams and patches were removed.

Thirteen days after the third induction exposure, each animal was challenged by 0.3 ml undiluted test material, or 0.3% DNCB in acetone on a naive site on the left flank as described above. 24 hours after the challenge exposure, the test sites were depilated with Neet Cream Hair Remover for 30 minutes. After 2 hours, the sites were graded. The grading was repeated 24 hours later.

Scores greater than slight patchy erythema were regarded as evidence of sensitization.

Result : All five positive control (DNCB) guinea pigs showed evidence of sensitization (severe erythema). No erythema was evident in any guinea pig following 3 induction and 1 challenge exposure to undiluted test material. Thus, the test material is considered not a sensitizer.

Reliability : (1) valid without restriction
meets guideline and GLP requirements

03.11.2005 **(1)**

5.4 REPEATED DOSE TOXICITY

5.5 GENETIC TOXICITY 'IN VITRO

Type : Ames test
System of testing : TA98, TA100, TA1538
Test concentration : 167, 500, 1670, 5000, 7500, and 10,000 ug/plate
Cycotoxic concentr. : >10,000 ug/plate
Metabolic activation : with and without
Result : negative
Method : EPA OPPTS 870.5265
Year : 1990
GLP : yes
Test substance : as prescribed by 1 .1 - 1.4

Method : The test material or positive control was mixed with top agar and poured over minimal glucose plates in triplicate for each dose tested. Plates were incubated in the dark at 37 C for 48 hr. Plates were scored for revertant colonies. Positive controls were as follows: -S9: TA100 and TA1535 - sodium azide; TA1537 - 9-aminoacridine; TA98 and TA1538 - 2-nitrofluorene;

A positive result was defined as a dose-dependent statistically significant increase in revertants with at least one concentration that is double the value of the negative control.

Result : All positive controls produced more than double the mutant frequencies of the negative controls. Statistically significant increases that were less than double and not dose dependent were seen with the test material in strains TA100 and TA1535 without activation and in TA1538 with activation. In repeated tests, they did not produce increases. Thus, the laboratory concluded that the test material was not mutagenic.

Reliability : (1) valid without restriction
meets guideline and GLP requirements

01.12.2005 **(12)**

Type : Unscheduled DNA synthesis
System of testing : Rat heaptocyte primary culture
Test concentration : 0.5, 5, 25, 50, and 5000 ug/ml
Cycotoxic concentr. : 750 ug/ml
Metabolic activation : without

Result	:	negative
Method	:	EPA OPPTS 870.5550
Year	:	1991
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	The liver of an anesthetized male F344 rat was perfused with EGTA, followed by collagenase. The liver was excised, the capsular membrane opened and hepatocytes detached by gently brushing with a camel's hair brush. Cells were centrifuged and suspended in calf serum. Aliquots of 1 x 10^5 viable hepatocytes were inocuclated into 12 well cluster dishes and allowed to attach to coverslips for 2 hours. The cultures were incubated for 18-20 hours with the test material and [3H]-thymidine. Cells were swollen and washed; then dipped in NTB-2 photographic emulsion in the dark and stored in the dark for 1 week. Autoradiographs were developed in D19 and stained with Harris Alum hematoxylin. Slides were evaluated for a net increase in black silver grains over the nucleus by counting 150 hepatocytes.
Result	:	The dose levels of 750 to 5000 ug/ml were not scored as there was excess cytotoxicity. At 100 and 500 ug/ml, the net nuclear grain (NNG) counts were slightly greater than the negative control values: 0.5+/-6.2 and 2.4+/-6.1, respectively. NNG between O-5 are generally considered a marginal response. The test was repeated at concentrations between 50 and 600 ug/ml. None had increased NNG counts. The investigators concluded that the test was negative.
Reliability	:	(1) valid without restriction meets guideline and GLP requirements

03.11.2005 **(11)**

5.6 **GENETIC TOXICITY 'IN VIVO'**

Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	CD-I
Route of admin.	:	i.p.
Exposure period	:	single dose; assayed at 24, 48 and 72 hours post dosing
Doses	:	1000 mg/kg
Result	:	negative
Method	:	EPA OTS 798.5395
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method		A preliminary toxicity test was conducted using 2 male and 2 female CD-I mice at 500, 750, 1000, 1500 amd 5000 mg/kg ip in distilled water. 1 of 4 dosed at 1500 and 3 of 4 dosed at 5000 mg/kg died. Fifteen males and 15 female 8-week old CD-I mice were dosed once ip at 1000 mg/kg; 5 of each sex were sacrificed after 24, 48, and 72 hours. Five males and 5 females were also exposed to 0.5 mg/kg triethylenemelamine in saline by ip injection, as positive controls. Following sacrifice, both femurs were removed from each mouse and marrow removed into fetal bovine serum. The suspension was centrifuged and a small drop of the cell pellet was smeared on a glass slide, dried and stained with modified Wrights Stain Pak 4481. Slides were evaluated for micronuclei in 1000 polychomatic erythrocytes.
Result		The positive control resulted in 3.5% of PCEs with micronuclei. Treatment of mice with the test material did not result in increased micronuclei, compared to control. Incidences of micronuclei were 0.04% for negative control mice and 0.02%, 0.03%, and 0.04% for mice treated with the test

material at 1000 mg/kg and sacrificed after 24, 48, and 72 hours, respectively. The test material did not change the ratio fo PCEs to NCEs.

Reliability : (1) valid without restriction
meets guideline and GLP requirements

01.12.2005 (10)

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES .

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.8 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT