FOREWORD INTRODUCTION

TRIPROPYLENE GLYCOL

CAS N°: 24800-440

SIDS Initial Assessment Report for SIAM 2

(Paris, 4-6 July 1994)

Chemical Name : Tripropylene glycol

CAS No: 24800-44-0

Sponsor Country: Japan

National SIDS Contact Point in Sponsor Country:
Mr. Yasuhisa Kawamura, Ministry of Foreign Affairs, Japan

History: As a high priority chemical for initial assessment, tripropylene glycol was selected in the framework of the HPV Programme.
At SIAM-2, conclusion was approved with comments.
Comments at SIAM-2: Rearrangement of the documents.

Deadline for circulation:
Date of Circulation:

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	24800-44-0
Chemical Name	Tripropylene glycol
Structural Formula	$HO[CH(CH_3)CH_2O]_3H$

CONCLUSIONS AND RECOMMENDATIONS

It is currently considered of low potential risk and low priority for further work.

SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE CONCLUSIONS AND RECOMMENDATIONS

Trypropylene glycol is a stable liquid with a production volume of ca. 600 tonnes/year in 1990 - 1993 in Japan. This chemical is used as an intermediate for resins in closed systems. It is stable in neutral and acidic solutions, and is considered to be "not readily biodegradable".

PECs have been calculated based on several models considering its physico-chemical properties (e.g. molecular weight, water solubility, vapour pressure and partition coefficient). The estimated concentrations were 9.7×10^{-11} mg/l (air), 8.3×10^{-6} mg/l (water), 3.0×10^{-5} mg/kg (soil), 5.0×10^{-5} mg/kg (sediment).

For the environment, various NOEC and LC_{50} values were gained from test results; LC_{50} = > 1,000 mg/l (acute fish); EC_{50} = > 1,000 mg/l (acute daphnia); EC_{50} = > 1,000 mg/l (acute algae); NOEC = > 1,000 mg/l (long-term daphnia reproduction). Therefore, the chemical does not have any remarkable ecotoxicity. Based on these values and considering the test duration the PNEC for aquatic organisms has been calculated as more than 10 mg/l.

The chemical does not have any remarkable ecotoxicity and its PEC/PNEC ratio is less than 1. Therefore, it is considered to be of low risk for the environment.

No monitoring data at work place have been available. Since the chemical is used as an intermediate in a closed system no data for consumer use are available.

Based on the physico-chemical properties, the level exposed indirectly through the environment was estimated as 5.9×10^{-5} mg/man/day. Also, the daily intake through drinking water is estimated as 2.8×10^{-7} mg/kg/day and through fish is calculated as 2.1×10^{-8} mg/kg/day. No data on occupational exposure are available. Neither monitoring data at work place nor data on consumer exposure have been reported.

The chemical showed no genotoxic effects in bacteria and chromosomal aberration test *in vitro*.

In a combined repeat dose and reproductive/developmental toxicity screening test, only salivation was observed at the highest dose (1000 mg/kg/day).
Also, increase in liver and kidney weights were observed in parental animals at that dose. From the view point of reproductive/developmental end-points, there were no effects observed related to mating, fertility and oestrus cycle and also for dams during the pregnancy and lactation period and for pups after their birth. Therefore, NOEL was 200 mg/kg/day for repeated dose toxicity as well as more than 1000 mg/kg/day for reproductive toxicity.

For human health, NOEL was estimated as 200 mg/kg/day and 1000 mg/kg/day for repeated dose and reproductive toxicity, respectively. The total exposed dose indirectly through the environment was estimated as 5.9×10^{-8} mg/man/day. Also, the daily intake through drinking water is estimated as 2.8×10^{-7} mg/kg/day and through fish is calculated as 2.1×10^{-8} mg/kg/day. For human health, margins of safety by indirect exposure from fish or drinking water are very large. Therefore, health risk is presumably low.

In conclusion, no further testing is needed at present considering its toxicity and exposure levels.

NATURE OF FURTHER WORK RECOMMENDED

FULL SIDS SUMMARY:

CAS NO: 24800-44-0		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point		Unknown	< -10 °C
2.2	Boiling Point		Unknown	267 °C at 1,013 hPa
2.3	Density		Unknown	6.6
2.4	Vapour Pressure		OECD TG 104	140 Pa at 25 °C
2.5	Partition Coefficient (Log Pow)		OECD TG 107	0.5 – 0.6 at 25 °C
2.6 A.	Water Solubility		Unknown	Miscible at 25 °C
B.	pH			No data available.
	pKa			No data available
2.12	Oxidation: Reduction Potential			No data available.
ENVIRONMENTAL FATE AND PATHWAY				
3.1.1	Photodegradation			No degradation
3.1.2	Stability in Water		OECD TG 111	Stable at pH 4.0, 7.0, 9.0
3.2	Monitoring Data			No data available
3.3	Transport and Distribution		Calculated (MNSEM model)	In Air 9.7E-11 mg/l In Water 8.3E-06 mg/l In Soil 3.0E-05 mg/kg In Sediment 5.0E-05 mg/kg
3.5	Biodegradation		OECD TG 301C	Not readily biodegradable: 1-2 % (BOD), 0 % (TOC), 0-3 % (GC) in 28 days
3.6	Bioaccumulation			No data available
ECOTOXICOLOGY				
4.1	Acute/Prolonged Toxicity to Fish	*Oryzias latipes*	OECD TG 203	LC_{50} (24hr): > 1,000 mg/L LC_{50}(96hr): > 1,000 mg/L
4.2	Acute Toxicity to Aquatic Invertebrates (*Daphnia*)	*Daphnia magna*	OECD TG 202	EC_{50} (24hr): > 1,000 mg/l
4.3	Toxicity to Aquatic Plants e.g. Algae	*Selenastrum capricornutum*	OECD TG 201	EC_{50} (72hr): > 1,000 mg/l NOEC: > 1,000 mg/l
4.5.2	Chronic Toxicity to Aquatic Invertebrates (*Daphnia*)	*Daphnia magna*	OECD TG 202	EC_{50} (21d, Immobility): >1,000 mg/l EC_{50} (21d, Reproduction) >1,000 mg/l NOEC (21d, Reproduction) >1,000 mg/l
4.6.1	Toxicity to Soil Dwelling Organisms			No data available.
4.6.2	Toxicity to Terrestrial Plants			No data available.

CAS NO: 24800-44-0		SPECIES	PROTOCOL	RESULTS
(4.6.3)	Toxicity to Other Non- Mammalian Terrestrial Species (Including Birds)			No data available
TOXICOLOGY				
5.1.1	Acute Oral Toxicity	Rat	OECD TG 401	LD_{50}: > 2,000 mg/kg
5.1.2	Acute Inhalation Toxicity			No data available.
5.1.3	Acute Dermal Toxicity			No data available
5.4	Repeated Dose Toxicity	Rat	OECD Combined Test	NOEL = 200 mg/kg/day
5.5	Genetic Toxicity In Vitro			
A.	Bacterial Test (Gene mutation)	*S. .typhimurium* *E. coli*	OECD Guidelines No.471 and 472 and Japanese Guideline	Negative in all bacterial strains with and without metabolic activation.
B.	Non-Bacterial In Vitro Test (Chromosomal aberrations)	CHL cells	OECD Guideline No.473 and Japanese Guideline	Negative with metabolic activation and without metabolic activation
5.6	Genetic Toxicity In Vivo			No data available
5.8	Toxicity to Reproduction	Rat	OECD Combined Test	NOEL Parental = 1,000 mg/kg/day NOEL F1 offspring = 1,000 mg/kg/day
5.9	Developmental Toxicity/ Teratogenicity			
5.11	Experience with Human Exposure			

SIDS Initial Assessment Report

1. Identity

OECD Name: Tripropylene glycol

Synonym:

CAS Number: 24800-44-0

Empirical Formula: $C_9H_{20}O_4$

Structural Formula:

$HO[CH(CH_3)CH_2O]_3H$

Degree of Purity: > 98 %

Major Impurities: Dipropylene glycol

Essential Additives: No additives

2. Exposure

2.1 General discussion

Trypropylene glycol is a stable liquid with a production volume of ca. 600 tonnes /year from 1990 - 1993 in Japan. It is used as an intermediate for resins in closed system. All wastes are incinerated. Tripropylene glycol seems to be released into water and air from its production sites after biological treatment. No specific monitoring data of the chemical is available.
This chemical is stable in neutral, acidic and alkaline solutions, and is considered as "not readily biodegradable".

2.2 Environmental exposure

a) Biodegradability:

If released into water, this substance is not readily biodegraded (MITI (I), corresponding to the OECD
301C: 1-2 % during 28 days based on BOD, 0 % based on TOC and 0 - 3 % based on GC analysis).

b) Hydrolysis as a function to pH:

The chemical is stable in water at pH 4, 7 and 9 (OECD TG 111).

c) Photodegradability (estimation)

No degradation is expected, because of lack of UV absorption.

d) Bioaccumulation:

No data are available.

e) Estimates of environmental fate, pathway and concentration:

The potential environmental distribution of tripropylene glycol obtained from a generic fugacity model, Mackay level III, under emission scenarios is shown in Table I. The results show that when 1,4- is released into water, the majority of the chemical is likely distributed into soil and sediment
PECs have been calculated based on several models (MNSEM, CHEMCAN, CHEMFRN) considering its physico-chemical properties (e.g. molecular weight, water solubility, vapour pressure and partition coefficient). The estimated concentrations of MNSEM model were 9.7×10^{-11} mg/l (air), 8.3×10^{-6} mg/l (water), 3.0×10^{-5} mg/kg (soil), 5.0×10^{-5} mg/kg (sediment). PEC_{global} was also calculated as 6.0×10^{-8} mg/l, based on a default scenario. No monitoring data at work place and environment have been reported. The chemical is used in closed system, and no data for consumer use are available. Based on the physico-chemical properties, the total exposure from the environment was estimated as 5.9×10^{-5} mg/man/day. Also, the daily intake through drinking water is estimated at 1.7×10^{-5} mg/kg/day and through fish it is calculated as 1.3×10^{-6} mg/kg/day.

Global situation:

Method: MNSEM 147S (Details are shown in Form-1 Annex)
Input data:

Molecular weight:	192.26
Water solubility:	1000000 [mg/l]
Vapor pressure:	1.05E+00 [mmHg]
Log Pow:	0.60

Results: Steady state mass and concentration calculated using MNSEM 147S

Air:	9.7E-11 [mg/l]
Water:	8.3E-06 [mg/l]
Soil:	3.0E-05 [mg/kg dry solid]
Sediment:	5.0E-05 [mg/kg dry solid]

Exposure dose

Inhalation of air:	2.0E-06 [mg/day]
Drinking water:	1.7E-05 [mg/day]
Ingestion of fish:	1.3E-06 [mg/day]
meat:	2.4E-11 [mg/day]
milk:	3.5E-11 [mg/day]
vegetation:	3.9E-05 [mg/day]

Total exposure dose: 5.9E-05 [mg/day]

Table 1. Comparison of calculated environmental concentration of tripropylene glycol using several models.

Model	Air[mg/l]	Water[mg/l]	Soil[mg/kg]	Sediment[mg/kg]
MNSEM	9.7E-11	8.3E-06	3.0E-05	5.0E-05
CHEMCAN2	1.6E-10	8.5E-06	1.4E-06	8.4E-06
CHEMFRAN	1.7E-11	8.5E-06	1.1E-07	8.4E-07

2.3 Consumer Exposure

No data on consumer exposure are available.

2.4 Occupational Exposure

No data on work place monitoring have been reported.

3. Toxicity

3.1 Human Toxicity

a) Acute toxicity

LD_{50} was 3,000 mg/kg in acute oral toxicity studies in rats. LD_{50} and LC_{50} values in acute inhalation and dermal toxicity study are not available.

b) Repeated toxicity

There is only one key study on repeated dose toxicity of tripropylene glycol. This chemical was studied for oral toxicity in rats according to the OECD combined repeated dose and reproductive/developmental toxicity test [OECD TG 422]. As the study was well controlled and conducted under GLP, this was appropriate to regard as a key study. Male and female SD rats were orally administered (gavage) at doses of 0, 8, 40, 200 and 1,000 mg/kg/day. In male rats, the administration period was two weeks prior to mating, 2 weeks of mating and 2 weeks after the completion of mating period. In female, in addition to maximum four weeks pre-mating and mating period, they were given through pregnant period until day 3 of post delivery.
In the clinical observation, salivation was observed in the 1,000 mg/kg male group. There were no differences in body weight gain, food consumption, clinical chemistry, or hematological parameters between the treated and control animals of both sexes. Increased absolute and relative liver weights, and increased relative kidney weight occurred in 1,000 mg/kg/day in males. Also, increased relative liver weight was observed in 1,000 mg/kg/day female group. In histopathological examinations, any changes which may have been caused by the test substance were not observed in the heart, kidneys, liver, thymus, testes, ovaries, epididymides, adrenal, brain or spleen in both sexes. The NOEL is considered to be 200 mg/kg/day for repeated dose toxicity.

c) Reproductive toxicity

Tripropylene glycol was studied for oral toxicity in rats according to the OECD combined repeated dose and reproductive/developmental toxicity test [OECD TG 422] at doses of 0, 8, 40, 200 and 1,000 mg/kg/day. Although this combined study was designed to investigate reproductive capability in parental generation as well as development in F_1 offspring, parameters to evaluate developmental toxicity were limited to only body weights at day 0 and day 4 after birth, and autopsy findings at day 4.
There were no effects on mating, fertility, and oestrus cycle or on dams during the pregnancy and lactation period. External examination of pups revealed no increase in appearance of abnormal pups. Body weight gain of pups was normal. Pups killed at postnatal day 4 showed no abnormal gross findings. The NOEL values for both parental and F_1 offspring in reproductive toxicity are considered to be 1,000 mg/kg/day.

d) Genetic toxicity

Bacterial test
Reverse gene mutation assay was conducted in line with Guidelines for Screening Mutagenicity Testing of Chemicals (Japan) and OECD Test Guidelines 471 and 472, using pre-incubation method. This study was well controlled and regarded as a key study.

Tripropylene glycol showed negative results in *Salmonella typhimurium* TA100, TA1535, TA98, TA1537 and *Escherichia coli* WP2 *uvr*A at concentrations up to 5 mg/plate with or without metabolic activation system (MHW, 1993).

Non-bacterial test *in vitro*
Chromosomal aberration test in line with Guidelines for Screening Mutagenicity Testing of Chemicals (Japan) and OECD Test Guideline 473 was conducted using cultured Chinese Hamster lung (CHL/IU) cells. This study was well controlled and regarded as a key study. The maximum concentration of the chemical was used with no apparent cytotoxic effect in continuous treatment. In short term treatment, it was set to 3.5 mg/ml because the concentration was equivalent to ca. 10 mM as required in test guidelines. Either structural chromosomal aberrations or polyproidy were not recognized up to a maximum concentration of 1.90 mg/ml under conditions of both continuous treatment and short-term treatment with or without an exogeneous metabolic activation system (MHW, 1993).

in vivo test
No data are available on *in vivo* genotoxic effects.

e) Other human health related information

None

3.2 Ecotoxicity

Tripropylene glycol has been tested in a limited number of aquatic species (*Selenastrum capricornutum*, *Daphnia magna* and *Oryzias latipes*), under OECD test guidelines [OECD TG 201, 202, 203, 204 and 211]. Acute and chronic toxicity data to test organisms for docosanoic acid are summarized in Table 2. No other ecotoxicological data are available. Various NOEC and LC_{50} values were gained from above tests; 96h LC_{50} = > 1,000 mg/l (acute fish); 24h EC_{50} = > 1,000 mg/l (acute daphnia); 72h EC_{50} = > 1,000 mg/l (acute algae); 21d NOEC = > 1,000 mg/l (long-term daphnia reproduction). Therefore, the chemical is considered to be non-toxic to fish, daphnids and algae and it does not have any remarkable ecotoxicity. Based on these values and considering the test duration, PNEC for aquatic organisms has been calculated as more than 10 mg/l. Environmental risk is presumably low.

Table 2. Acute and chronic toxicity data of tripropylene gycol to aquatic organisms.

Species	Endpoint[*1]	Conc. (mg/L)	Reference
Selenastrum capricornutum (algae)	Biomass: EC_{50} (72h)	> 1,000 mg/L	MOE, Japan. (1992)
Daphnia magna (water flea)	Mor: LC_{50}(24h) Rep: EC_{50}(21d) NOEC(21d)	> 1,000 mg/L > 1,000 mg/L > 1,000 mg/L	
Oryzias latipes (fish, Medaka)	Mor: LC_{50}(24h) Mor: LC_0(72h) Mor:LC50(96h)	> 1,000 mg/L > 1,000 mg/L > 1,000 mg/L	

Notes: [*1] Mor; mortality, Rep; reproduction.

4. Initial assessment

Trypropylene glycol is stable liquid and the production volume is ca. 600 tonnes/year in 1990 - 1993 in Japan. This chemical is used as an intermediate for resins in closed system. This chemical is stable in neutral and acidic solutions, and is considered to be "not readily biodegradable".

PECs have been calculated based on several models considering its physico-chemical properties (e.g. molecular weight, water solubility, vapour pressure and partition coefficient). The estimated concentrations were 9.7×10^{-11} mg/l (air), 8.3×10^{-6} mg/l (water), 3.0×10^{-5} mg/kg (soil), 5.0×10^{-5} mg/kg (sediment). No monitoring data at work place have been available. Since the chemical is used as an intermediate in closed system there is no data for consumer use.

Based on the physico-chemical properties, the level exposed indirectly through the environment was estimated as 5.9×10^{-5} mg/man/day. Also, the daily intake through drinking water is estimated as 2.8×10^{-7} mg/kg/day and through fish is calculated as 2.1×10^{-8} mg/kg/day. No data on occupational exposure are available. Neither monitoring data at work place nor data on consumer exposure have been reported.

For the environment, various NOEC and LC_{50} values were gained from test results; 96h LC_{50} = > 1,000 mg/l (acute fish); 24h EC_{50} = > 1,000 mg/l (acute daphnia); 72h EC_{50} = > 1,000 mg/l (acute algae); 21d NOEC = > 1,000 mg/l (long-term daphnia reproduction). Therefore, the chemical does not have any remarkable ecotoxicity. Based on these values and considering the test duration, PNEC for aquatic organisms has been calculated as more than 10 mg/l. The PEC/PNEC ratio is less than 1 Therefore it is considered to be low risk for the environment.

The chemical showed no genotoxic effects in bacteria and chromosomal aberration test *in vitro*.
In a combined repeat dose and reproductive/developmental toxicity test, only salivation was observed at the highest dose (1000 mg/kg/day). Also, increase of liver and kidney weights were observed in parental animals at the dose. From the view point of reproductive/developmental end-points, there were no effects observed related to mating, fertility and oestrus cycle and also for dams during the pregnancy and lactation period and for pups after their birth. Therefore, NOEL was 200 mg/kg/day for repeated dose toxicity as well as more than 1000 mg/kg/day for reproductive toxicity.
The total exposed dose indirectly through the environment was estimated as 5.9×10^{-8} mg/man/day.
Also, the daily intake through drinking water is estimated as 2.8×10^{-7} mg/kg/day and through fish is calculated as 2.1×10^{-8} mg/kg/day. For human health the margin of safety by indirect exposure from fish or drinking water are very large. Therefore, health risk is presumably low.

5. Overall recommendation and initial assessment

5.1 Conclusion

In conclusion, no further testing is needed at present considering its low toxicity and exposure levels.

5.2 Recommendation

None

6. REFERENCES

EA, Japan (1992) "Investigation on the Ecotoxicological Effects of OECD High Production Volume Chemicals", Office of Health Studies, Environmental Health Department, Environment Agency, Japan (HPV/SIDS Test conducted by EA, Japan)

EA and MITI, Japan (1993) Unpublished Report on Exposure Estimation (HPV/SIDS Test conducted by EA and MITI, Japan)

ECDIN database

Lyman, W.J., W. F. Reehl and D. H. Rosenblatt (1981) "Handbook of Chemical Property Estimation Method", McGraw Hill Book Co.

MHW, Japan (1993a) Unpublished Report on Acute Toxicity Test of Tripropylene glycol (HPV/SIDS Test conducted by MHW, Japan)

MHW, Japan (1993b) Unpublished Report on Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test of Tripropylene glycol. (HPV/SIDS Test conducted by MHW, Japan)

MHW, Japan (1993c) Unpublished Report on Mutagenicity Test of Tripropylene glycol. (HPV/SIDS Test conducted by MHW, Japan)

MITI, Japan : Unpublished data

MITI, Japan (1993) Unpublished Report (Test was performed in Chemicals Inspection and Testing Institute, Japan)

Sax, N.I. (1968) Dangerous Propertied of Industrial Materials, 3rd Ed., Reinhold Book Corporation, New York

SIDS DOSSIER
(Tripropylene glycol CAS No.: 24800-44-0)

Sponsor Country: Japan

S I D S P R O F I L E

1.01 A.	**CAS No.**	24800-44-0
1.01 C.	**CHEMICAL NAME (OECD Name)**	Tripropylene glycol
1.01 D.	**CAS DESCRIPTOR**	Not applicable
1.01 G.	**STRUCTURAL FORMULA**	$C_9H_{20}O_4$
	OTHER CHEMICAL IDENTITY INFORMATION	$HO[CH(CH_3)CH_2O]_3H$
1.5	**QUANTITY**	In Japan, approx 600 tonnes in 1990 – 1993.
1.7	**USE PATTERN**	(a) Intermediate for resin 99 %
1.9	**SOURCES AND LEVELS OF EXPOSURE**	1. Media of release: Water from a production site Quantities per media: Negligible small 2. Media of release: Air from a production site Quantities per media: Negligible small 3. Information on consumer exposure is not available.
ISSUES FOR DISCUSSION (IDENTIFY, IF ANY)		

SIDS SUMMARY

CAS NO: 24800-44-0		Information	OECD Study	GLP	Other Study	Estimation Method	Acceptable	SIDS Testing Required
STUDY		**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**
PHYSICAL-CHEMICAL DATA								
2.1	Melting Point	Y	N	N	Y	N	Y	N
2.2	Boiling Point	Y	N	N	Y	N	Y	N
2.3	Density	Y	N	N	Y	N	Y	N
2.4	Vapour Pressure	N						Y
2.5	Partition Coefficient	N						Y
2.6	Water Solubility	Y	N	N	Y	N	Y	N
	pH and pKa values	N						N
OTHER P/C STUDIES RECEIVED								
ENVIRONMENTAL FATE and PATHWAY								
3.1.1	Photodegradation	N						Y
3.1.2	Stability in water	N						Y
3.2	Monitoring data	N						N
3.3	Transport and Distribution	N						N
3.5	Biodegradation	N						Y
3.6	Bioaccumulation	N						N
OTHER ENV FATE STUDIES RECEIVED								
ECOTOXICITY								
4.1	Acute toxicity to Fish	N						Y
4.2	Acute toxicity to Daphnia	N						Y
4.3	Toxicity to Algae	N						Y
4.5.2	Chronic toxicity to Daphnia	N						Y
4.6.1	Toxicity to Soil dwelling organisms	N						N
4.6.2	Toxicity to Terrestrial plants	N						N
4.6.3	Toxicity to Birds	N						N
OTHER ECOTOXICITY STUDIES RECEIVED								
TOXICITY								
5.1.1	Acute Oral	Y	N	N	Y	N	Y	N
5.1.2	Acute Inhalation	N						N
5.1.3	Acute Dermal	N						N
5.4	Repeated Dose	N						Y
5.5	Genetic Toxicity *in vitro*							
	. Gene mutation	N						Y
	. Chromosomal aberration	N						Y
5.6	Genetic Toxicity *in vivo*	N						N
5.8	Reproduction Toxicity	N						Y
5.9	Development / Teratogenicity	N						Y
5.11	Human experience	N						N
OTHER TOXICITY STUDIES RECEIVED								

1. GENERAL INFORMATION

1.01 SUBSTANCE INFORMATION

A.	**CAS-Number**	24800-44-0
B.	**Name** *(IUPAC name)*	Tripropylene glycol
C.	**Name** *(OECD name)*	Propanol, (1-methyl-1,2-ethanediyl)bis(oxy)bis-
D.	**CAS Descriptor**	Not applicable
E.	**EINECS-Number**	246-466-0
F.	**Molecular Formula**	$C_9H_{20}O_4$
G.	**Structural Formula**	
		$HO[CH(CH_3)CH_2O]_3H$
H.	**Substance Group**	Not applicable
I.	**Substance Remark**	
J.	**Molecular Weight**	192.26

1.02 OECD INFORMATION

A. **Sponsor Country:** Japan

B. **Lead Organisation:**

Name of Lead Organisation:
Ministry of Health and Welfare (MHW)
Ministry of International Trade and Industry (MITI)
Environment Agency (EA)

Contact person:
Mr. Yasuhisa Kawamura
Director
Second International Organization Bureau
Ministry of Foreign Affairs

Address:
2-2-1 Kasumigaseki, Chiyoda-ku
Tokyo 100, Japan
TEL 81-3-3581-0018
FAX 81-3-3503-3136

C. **Name of responder** Same as above contact person

1.1 GENERAL SUBSTANCE INFORMATION

A. **Type of Substance**

element **[ ]**; inorganic **[ ]**; natural substance **[ ]**;
organic **[X]**; organometallic **[ ]**; petroleum product **[ ]**

B. Physical State

gaseous **[ ]**; liquid **[X]**; solid **[ ]**

C. Purity > 98 %

1.2 SYNONYMS [(Methylethylene)bis(oxy)]dipropanol

1.3 IMPURITIES Dipropylene glycol (1 - 1.05 %), Water (0.1 - 0.5 %)

1.4 ADDITIVES None

1.5 QUANTITY

Location	Production(tonnes)	Date
Japan	600	1990-1993

Reference: MITI, Japan

1.6 LABELLING AND CLASSIFICATION

Labelling None

Classification None

1.7 USE PATTERN

A. General

Type of Use:	**Category:**
Main industry use	Intermediate for resin 99 %
MITI, Japan	

B. Uses in Consumer Products None

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUE

Source	Number of workers	Frequency & duration
Maintenance	2	1 time/year
Filling	2	6 days/month

1.9 SOURCES OF EXPOSURE

(a)
Source: Media of release: Water from a production site
Quantities per media: Negligible small

(b)

Source:	Media of release: Air from a production site Quantities per media: Negligible small
Reference:	MITI, Japan

1.10 ADDITIONAL REMARKS

A. Options for disposal

Incineration

B. Other remarks None

2. PHYSICAL-CHEMICAL DATA

2.1 MELTING POINT

Value:	< -10 °C
Decomposition:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Sublimation:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Remarks:	None
Reference:	Unpublished company data

2.2 BOILING POINT

Value:	267 °C
Pressure:	1013 hPa
Decomposition:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Remarks:	None
Reference:	Sax, N.I. (1968)

2.3 DENSITY (Relative density)

Type:	Bulk density **[ ]**; Density **[ ]**; Relative Density **[X]**
Value:	6.6
Temperature:	
Method:	Unknown
GLP:	Yes [ ] No **[ ]** ? **[X]**
Remarks:	
Reference:	ECDIN database

2.4 VAPOUR PRESSURE

Value:	140 Pa
Temperature:	25 °C
Method:	calculated **[ ]**; measured **[X]** OECD Test Guideline 104 (Static Method)
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Remarks:	
Reference:	MITI, Japan (1993)

2.5 PARTITION COEFFICIENT $\log_{10}P_{ow}$

Log Pow:	0.5 - 0.6
Temperature:	25 °C
Method:	calculated **[ ]**; measured **[**X**]** OECD Test Guideline 117
GLP:	Yes **[X]** No **[ ]** ? **[ ]**

Remarks:	None
Reference:	MITI, Japan (1993)

2.6 WATER SOLUBILITY

A. Solubility

(a) **Preferred result**

Value:	Freely soluble
Temperature:	25 °C
Description:	Miscible**[X]**; Of very high solubility **[ ]**; Of high solubility **[ ]**; Soluble **[ ]**; Slightly soluble **[ ]**; Of low solubility **[ ]**; Of very low solubility **[ ]**; Not soluble **[ ]**
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Remarks:	Unknown
Reference:	Unpublished company data

B. pH Value, pKa Value Not applicable

2.7 FLASH POINT

Value:	142 °C
Type of test:	Closed cup **[ ]**; Open cup **[X]**; Other **[ ]**
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Remarks:	
Reference:	Unpublished company data

2.8 AUTO FLAMMABILITY

No studies located

2.9 FLAMMABILITY

No studies located

2.10 EXPLOSIVE PROPERTIES

No studies located

2.11 OXIDIZING PROPERTIES

No studies located

2.12 OXIDATION: REDUCTION POTENTIAL

No studies located

2.13 ADDITIONAL DATA

A. Partition co-efficient between soil/sediment and water (Kd)

No studies located

B. Other data

None

3. ENVIRONMENTAL FATE AND PATHWAYS

3.1 STABILITY

3.1.1 PHOTODEGRADATION

Type:	Air **[ ]**; Water **[X]**; Soil **[ ]**; Other **[ ]**
Light source:	Sun light **[X]**; Xenon lamp **[ ]**; Other **[ ]**
Results:	No degradation (No absorption) Half-life: Infinite
Reference	Lyman, et al. (1981)

3.1.2 STABILITY IN WATER

Type:	Abiotic (hydrolysis) **[X]**; biotic (sediment)**[ ]**
Half life:	Stable at pH 4, 7 and 9 at 25 °C
Method:	OECD Test Guideline 111
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Tripropylene glycol
Remarks:	None
Reference:	MITI, Unpublished Report (1993) (Test was performed in Chemicals Inspection and Testing Institute, Japan)

3.1.3 STABILITY IN SOIL

No studies located

3.2 MONITORING DATA (ENVIRONMENT)

No studies located

3.3 TRANSPORT AND DISTRIBUTION BETWEEN ENVIRONMENTAL COMPARTMENTS INCLUDING ESTIMATED ENVIRONMENTAL CONCENTRATIONS AND DISTRIBUTION PATHWAYS

3.3.1 TRANSPORT

No studies located

3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)

Media:	Air-biota [ ]; Air-biota-sediment-soil-water [ ]; Soil-biota [ ]; Water-air [ ]; Water-biota [ ]; Water-soil [ ]; Other [X] (Air-soil-water-sediment)
Method:	Fugacity level I [ ]; Fugacity level II [ ]; Fugacity level III [X]; Fugacity level IV [ ];Other(calculation) [ ];Other(measurement)[ ]

Results: Steady state mass and concentration calculated using MNSEM 147S

Air:	9.7E-11 [mg/l]
Water:	8.3E-06 [mg/l]
Soil:	3.0E-05 [mg/kg dry solid]
Sediment:	5.0E-05 [mg/kg dry solid]

Exposure dose

Inhalation of air:	2.0E-06 [mg/day]
Drinking water:	1.7E-05 [mg/day]
Ingestion of fish:	1.3E-06 [mg/day]
meat:	2.4E-11 [mg/day]
milk:	3.5E-11 [mg/day]
vegetation:	3.9E-05 [mg/day]

Total exposure dose: 5.9E-05 [mg/day]

Remarks: Input data:

Molecular weight:	192.26
Water solubility:	1000000 [mg/l]
Vapor pressure:	1.05E+00 [mmHg]
Log Pow:	0.60

MNSEM 147S is a slightly revised version of MNSEM 145I.
addition of air particle compartment to air phase
execution of calculation on a spreadsheet program

Comparison of calculated environmental concentration using several methods (Japanese environmental conditions are applied to the calculations.)

Model	Air[mg/l]	Water[mg/l]	Soil[mg/kg]	Sediment[mg/kg]
MNSEM	9.7E-11	8.3E-06	3.0E-05	5.0E-05
CHEMCAN2	1.6E-10	8.5E-06	1.4E-06	8.4E-06
CHEMFRAN	1.7E-11	8.5E-06	1.1E-07	8.4E-07

Reference: EA and MITI, Japan (1993)

3.4 IDENTIFICATION OF MAIN MODE OF DEGRADABILITY IN ACTUAL USE

No studies located

3.5 BIODEGRADATION

Type:	aerobic **[X]**; anaerobic **[ ]**
Inoculum:	adapted **[ ]**; non-adapted **[X]**;
Concentration of the chemical:	100 mg/l related to COD **[ ]**; DOC **[ ]**; Test substance **[X]**;
Medium:	water **[ ];** water-sediment **[ ];** soil **[ ];** sewage treatment others **[X]** (Japanese standard activated sludge)
Degradation:	Degree of degradation after 28 days 1, 2 and 2 % from BOD 0, 0 and 0 % from TOC analysis 0, 3 and 3 % from GC analysis

Results:	Readily biodeg. **[ ];** Inherently biodeg. **[ ]**; under test condition no biodegradation observed **[X]**, Other **[ ]**
Method:	OECD Test Guideline 301C
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Tripropylene glycol
Remarks:	None
Reference:	MITI, Japan (1993)

3.6 BOD_5,COD OR RATIO BOD_5/COD

No studies located

3.7 BIOACCUMULATION

No studies located

3.8 ADDITIONAL REMARKS None

A. Sewage treatment

B. Other information

4. ECOTOXICOLOGICAL DATA

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type of test:	static **[ ]**; semi-static **[X]**; flow-through **[ ]**; other **[ ]** open-system **[X]**; closed-system **[ ]**
Species:	*Oryzias latipes*
Exposure period:	96 hr
Results:	LC_{50} (24h) > 1,000 mg/l
	LC_{50} (48h) > 1,000 mg/l
	LC_{50} (72h) > 1,000 mg/l
	LC_{50} (96h) > 1,000 mg/l
	NOEC =
	LOEC =
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**
Method:	OECD Test Guideline 203 (1981)
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	Tripropylene glycol, purity = 97%
Remarks:	A group of 10 O*ryzias latipes* were exposed to 5 nominal Concentrations (95-1000 mg/l) and laboratory water control.
Reference:	EA, Japan (1992)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

A. Daphnia

Type of test:	static **[X]**; semi-static **[ ]**; flow-through **[ ]**; other **[ ]**; open-system **[X]**; closed-system **[ ]**
Species:	*Daphnia magna*
Exposure period:	24 hr
Results:	EC_{50} (24h)= > 1,000 mg/l
	EC_{50} (48h) =
	NOEC =
	LOEC =
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**
Method:	OECD Test Guideline 202 (1984)
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	Tripropylene glycol, purity = 97%
Remarks:	20 daphnids (4 replicates; 5 organisms per replicate) were exposed to 5 nominal concentrations (10-1000 mg/l), control of DMSO:HCO-40= 9:1 (320 mg/l) and laboratory water control.
Reference:	EA, Japan (1992)

B. Other aquatic organisms

No studies located

4.3 TOXICITY TO AQUATIC PLANTS e.g. Algae

Species:	*Selenastrum capricornutum* ATCC 22662
End-point:	Biomass **[X]**; Growth rate **[ ]**; Other **[ ]**

Exposure period:	72 hr	
Results:	Biomass:	EC_{50} (24h) =
		EC_{50} (72h) > 1,000 mg/l
		NOEC= > 1000 mg/l ($p < 0.05$)
		LOEC =

Analytical monitoring: Yes **[ ]** No **[X]** ? **[ ]**

Method:	OECD Test Guideline 201 (1984)
	open-system **[**X**]**; closed-system **[ ]**
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	Tripropylene glycol, purity = 97%
Remarks:	The EC_{50} values were calculated based on 5 nominal Concentrations (95-1000 mg/l) and laboratory water control.
Reference:	EA, Japan (1992)

4.4 TOXICITY TO BACTERIA

No studies located

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1. CHRONIC TOXICITY TO FISH

No studies located

4.5.2. CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Type of test:	static **[ ]**; semi-static **[**X**]**; flow-through **[ ]**; other **[ ]**; open-system **[X]**; closed-system **[ ]**	
Species:	*Daphnia magna*	
End-point:	Mortality **[X]**; Reproduction rate **[X]**; Other **[ ]**	
Exposure period:	21 day	
Results:	Mortality:	LC_{50} (24 h) > 1,000 mg/l
		LC_{50} (48h)
		LC_{50} (96 h) = > 1,000 mg/l
		LC_{50} (7 d) > 1,000 mg/l
		LC_{50} (14 d) > 1,000 mg/l
		LC_{50} (21 d) > 1,000 mg/l
		NOEC =
		LOEC =
	Reproduction:	EC_{50} (14 d) > 1,000 mg/l
		EC_{50} (21 d) > 1,000 mg/l
		NOEC = > 1,000 mg/l
		LOEC = > 1,000 mg/l
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**	
Method:	OECD Test Guideline 202 (1984)	
GLP:	Yes **[ ]** No **[X]** ? **[ ]**	
Test substance:	Tripropylene glycol, purity = 97%	
Remarks:	40 daphnids (4 replicates; 10 organisms per replicate) were exposed to 5 nominal concentrations (10-1000 mg/l), control of DMSO: HCO-40= 9:1 (320 mg/l) and laboratory water control.	
Reference:	EA, Japan (1992)	

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

No studies located

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

No studies located

4.6.3 TOXICITY TO OTHER NON MAMMALIAN TERRESTRIAL SPECIES (INCLUDING AVIAN)

No studies located

4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)

No studies located

4.8 BIOTRANSFORMATION AND KINETICS IN ENVIRONMENTAL SPECIES

No studies located

4.9 ADDITIONAL REMARKS

None

5. TOXICITY

5.1 ACUTE TOXICITY

5.1.1 ACUTE ORAL TOXICITY

(a)

Type :	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Rat
Value :	= 3,000 (mg/kg)
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Test substance:	Tripropylene glycol
Remarks:	
Reference:	Unpublished company data

(b)

Type :	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Rat (Crj:CD(SD))
Value :	> 2,000 mg/kg
Method:	Unknown
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Tripropylene glycol, Purity > 98 %
Remarks:	
Reference:	MHW, Japan (1993a)

5.1.2 ACUTE INHALATION TOXICITY

No studies located

5.1.3 ACUTE DERMAL TOXICITY

No studies located

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION

No studies located

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

No studies located

5.2.2 EYE IRRITATION/CORROSION

No studies located

5.3 SKIN SENSITISATION

No studies located

5.4 REPEATED DOSE TOXICITY

Species/strain:	Rat (Crj:CD(SD))
Sex:	Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration:	Oral (gavage)
Exposure period:	Males: 49 days including 14 days before mating Females: from 14 days before mating to day 3 of lactation
Frequency of treatment:	7 days/week
Post exposure observation period:	
Dose:	0, 8, 40, 200 or 1,000 mg/kg (12 animals/group)
Control group:	Yes **[X]**; No **[ ]**; No data **[ ]**; Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL:	200 mg/kg/day
LOEL:	1,000 mg/kg/day
Results:	In the clinical observation, salivation was observed in the 1,000 mg/kg male group. There were no differences in body weight gain, food consumption, clinical chemistry, or hematological parameters between the treated and control animals of both sexes. Increased absolute and relative liver weights, and increased relative kidney weight occurred in 1,000 mg/kg/day males group. Also, increased relative liver weight was observed in 1,000 mg/kg/day female group. In histopathological examinations, any changes which may have been caused by the test substance were not observed in the heart, kidneys, liver, thymus, testes, ovaries, epididymides, adrenal, brain or spleen in both sexes.
Method:	OECD Combined Repeat dose and Reproductive/Developmental Toxicity Test (1992)
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Purity: > 98 %
Reference:	MHW, Japan (1993b)

5.5 GENETIC TOXICITY IN VITRO

A. BACTERIAL TEST

(a)

Type :	Bacterial reverse mutation assay
System of testing:	
Species/strain:	*S. typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA 1538 *E. coli* uvrA
Concentration:	0, 312.5, 625, 1250, 2500 or 5000 µg/plate
Metabolic activation:	With **[ ]**; Without **[ ]**; With and Without **[X]**; No data **[ ]**
Results:	
Cytotoxicity conc:	With metabolic activation: 5000 µg/plate Without metabolic activation: 5000 µg/plate
Precipitation conc:	
Genotoxic effects:	+ ? -
	With metabolic activation: **[ ] [ ] [X]**
	Without metabolic activation: **[ ] [ ] [X]**
Method:	Japanese Guideline for Screening Mutagenicity testing of chemicals
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Teat substance:	Commercial, purity: > 98 %
Remarks:	Procedure: Plate method Plates/test: 3

Activation system: Liver S-9 fraction from Phenobarbital and 5,6-Benzoflavone pretreated male SD rats with NADPH-generating system
Media:Histidine selective
No. replicates: 2

Reference: MHW, Japan (1993c)

B. NON-BACTERIAL IN VITRO TEST

Type : Cytogenetics Assay
System of testing: Species/strain: Chinese hamster CHL cells
Concentration: 0, 0.48, 0.95, 1.90 mg/ml
Metabolic activation: With **[ ]**; Without **[ ]**; With and Without **[X]**; No data **[ ]**
Results:
Cytotoxicity conc: With metabolic activation:> 1.90 mg/ml
Without metabolic activation: > 1.90 mg/ml
Precipitation conc:
Genotoxic effects:

	+	?	-
With metabolic activation:	**[ ]**	**[ ]**	**[X]**
Without metabolic activation:	**[ ]**	**[ ]**	**[X]**

Method: Japanese Guideline for Screening Mutagenicity testing of chemicals
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: Purity > 98 %
Remarks: Plates/test:2
Activation system: S-9 fraction from the liver of Phenobarbital and 5,6-Benzoflavone induced male SD derived rats with NADPH-generating system
No. replicates: 1
Reference: MHW, Japan (1993c)

5.6 GENETIC TOXICITY IN VIVO

No studies located

5.7 CARCINOGENICITY

No studies located

5.8 TOXICITY TO REPRODUCTION

Type: Fertility **[ ]**; One generation study **[ ]**; Two generation study **[ ]**; Other **[X]**
Species/strain: Rat (slc:SD)
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration: Oral (gavage)
Exposure period: Males: 49 days including 14 days before mating
Females: from 14 days before mating to day 3 of lactation.
Frequency of treatment:7 days/week
Postexposure observation period:
Premating exposure period: male: 14 days, female: 14 days
Duration of the test;
Doses: 0, 8, 40, 200 or 1,000 mg/kg (12 /animals/sex/ group)
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**

NOEL Parental :	1,000 mg/kg/day
NOEL F1 Offspring:	1,000 mg/kg/day
NOEL F2 Offspring:	N/A
Results:	There were no effects on mating, fertility, and oestrus cycle or on dams during the pregnancy and lactation period. External examination of pups revealed no increase in appearance of abnormal pups. Body weight gain of pups was normal. Pups killed at postnatal day 4 showed no abnormal gross findings. General parental toxicity: see section 5.4.
Method:	Combined Repeated Dose and Reproductive/Developmental Toxicity Test
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Commercial, purity > 98 %
Remarks:	None
Reference:	MHW, Japan (1993b)

5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

No studies located

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

No studies located

B. Toxicodynamics, toxicokinetics

No studies located

5.11 EXPERIENCE WITH HUMAN EXPOSURE

None

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