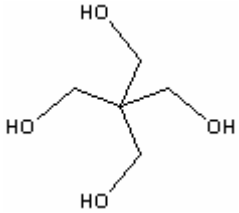
FOREWORD INTRODUCTION

PENTAERYTRITOL

CAS N°: 115-77-5

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	115-77-5
Chemical Name	Pentaerythritol
Structural formula	

CONCLUSIONS AND RECOMMENDATIONS

Environment

Although the chemical is not readily biodegradable, toxicity to aquatic organisms is very low. PEC/PNEC ratio is less than 1 based on the local exposure scenario in the Sponsor country. Therefore, it is currently considered of low potential risk and low priority for further work.

Human health

The chemical caused only soft faeces and diarrhoea in a repeated dose study. The chemical is not considered as an irritant to skin and eyes. Within the Sponsor country exposure is well controlled in a closed system. Estimated daily intake via indirect exposures is considered to be low. As margin of safety for indirect exposure is more than 500,000, 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

Pentaerythritol is a stable solid and the production volume was ca. 25,000 tonnes/year in 1996 and 1997 in Japan. The chemical is used as intermediate for Alkyd resin, Rosin ester, Explosive and Lubricants. No consumer use is reported. The chemical is classified as 'Biodegradable'. The bioconcentration factor ranged from 0.3 – 2.1.

The potential environmental distribution of pentaerythritol obtained from a generic fugacity model (Mackey level III) showed the chemical will be distributed mainly to water and soil. Predicted environmental concentration (PEC_{local}) of the chemical was estimated as 4.3×10^{-3} mg/l and 5.1×10^{-5} mg/l from Japanese local exposure scenario.

The main route of occupational exposure is inhalation with limited workers during bag filling operation. The average concentration in the atmosphere was measured at production sites as 8.5 mg/m^3 (range 0.35-20.3 mg/m^3) and the daily intake as the worst case was estimated as 1.2 mg/kg/day. There is no available information on the consumer use. For indirect exposure via the environment, the daily intakes through drinking water and fish are estimated as 1.43×10^{-4} mg/day and 1.35×10^{-5} mg/kg/day, respectively, based on PEC_{local} of 4.30×10^{-3} mg/l.

Predicted No Effect Concentration (PNEC) of the chemical was determined using a *Daphnia*

magna 48 h immobility data (600 mg/l). The assessment factor of 1000 used to an acute toxicity data to determine PNEC, according to the OECD Provisional Guidance for Initial Assessment of Aquatic Effects, because only one acute toxicity data is available among algae, cladocera and fishes. Thus, PNEC of the chemical is determined as 0.6 mg/l, tentatively. Thus, PEC / PNEC is 0.0072. Effects of the chemical on aquatic ecosystems are of low concern at present.

Pentaerythritol was not mutagenic in bacterial and chromosomal aberration tests in vitro. The chemical is not considered as an irritant to the skin and the eyes, nor as a sensitizer. In a combined repeat dose and reproductive/developmental toxicity screening test, both male and female rats showed only soft faeces and diarrhoea. The chemical did not show any toxicity to parents and offsprings. The no observed effect levels were 100 mg/kg/day for repeated dose toxicity and 1000 mg/kg/day for reproductive/developmental toxicity.

For human health, the risk for workers is expected to be low because the margin of safety is 83.3 as the worst case. The risks for consumer and the general population through indirect exposure are also assumed to be low because a margin of safety through drinking water or fish is calculated to be 6.98×10^5 or 7.38×10^6. Therefore, it is currently considered of low potential risk and low priority for further work.

IF FURTHER WORK IS RECOMMENDED, SUMMARISE ITS NATURE

FULL SIDS SUMMARY

CAS NO: 115-77-5		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point		unknown	260 °C
2.2	Boiling Point			
2.3	Density			
2.4	Vapour Pressure		OECD TG 104	< 1.3 x 10^2 Pa at 20 °C
2.5	Partition Coefficient (Log Pow)		OECD TG 107	< 0.3 at 25°C
2.6 A.	Water Solubility		OECD TG 105	25 g/L at 25°C
B.	pH			
	pKa			No ionizable functional group
2.12	Oxidation: Reduction Potential			
ENVIRONMENTAL FATE AND PATHWAY				
3.1.1	Photodegradation			
3.1.2	Stability in Water		OECD TG 111	Stable at pH 4, 7 and 9 at 25 °C
3.2	Monitoring Data			
3.3	Transport and Distribution			
3.5	Biodegradation		OECD TG 301C	Not readily biodegradable
3.7	Bioaccumulation	Carp	OECD TG 305C	BCF 0.3 – 0.6 at 10 m/L 0.4 – 2.1 at 1 mg/L
ECOTOXICOLOGY				
4.1	Acute/Prolonged Toxicity to Fish	*Oryzias latipes*	OECD TG 203	LC_{50}(48hr)= >100 mg/l LC_{50}(72hr)= >100 mg/l LC_{50}(96hr)= >100mg/l
4.2	Acute Toxicity to Aquatic Invertebrates *Daphnia*	*Daphnia magna*	Unknown	EC_{50}(48hr)= 600 mg/l
4.3	Toxicity to Aquatic Plants e.g. Algae	*Selenastrum capricornutum*	OECD TG 201	EC_{50}(72hr,Biomas) >1000 mg/l NOEC > 1000 mg/l
4.5.2	Chronic Toxicity to Aquatic Invertebrates (*Daphnia*)	*Daphnia magna*	OECD TG 202	EC_{50}(21d,Repro) >1000 mg/l NOEC > 1000 mg/l
4.6.1	Toxicity to Soil Dwelling Organisms			
4.6.2	Toxicity to Terrestrial Plants			

4.6.3	Toxicity to Other Non-Mammalian Terrestrial Species (Including Birds)			
TOXICOLOGY				
5.1.1	Acute Oral Toxicity		OECD 401	LD_{50} = > 2000 mg/kg
5.1.2	Acute Inhalation Toxicity	Rat	Other (unknown)	LC_0 = 11 g/m^3/6 hr (as a mixture)
5.1.3	Acute Dermal Toxicity	Rabbit	Other	LC_0 = 10 g/kg
5.4	Repeated Dose Toxicity	Rat	OECD Combined	NOEL = 100 mg/kg
5.5	Genetic Toxicity In Vitro			
A.	Bacterial Test (Gene mutation)	S. typhimurium E. coli WP2	Japanese TG	- (With metabolic activation) - (Without metabolic activation)
B.	Non-Bacterial In Vitro Test (Chromosomal aberrations)	Chinese hamster CHL cells	Japanese TG	- (With metabolic activation) - (Without metabolic activation)
5.6	Genetic Toxicity In Vivo			No data
5.8	Toxicity to Reproduction	Rat	OECD combined	NOEL =1000 mg/kg
5.9	Developmental Toxicity/ Teratogenicity			No data
5.11	Experience with Human Exposure			No data

[Note] Data beyond SIDS requirements can be added if the items are relevant to the assessment of the chemical, e.g. corrosiveness/irritation, carcinogenicity.

COVER PAGE
SIDS Initial Assessment Report
for
8th SIAM

(France, October 28-30, 1998)

Chemical Name:	Pentaerythritol
CAS No:	115-77-5
Sponsor Country:	Japan

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

HISTORY:

SIDS Testing Plan were reviewed in SIDS Review Process, where the following SIDS Testing Plan was agreed:

no testing ( )

testing (X)

- Vapour pressure
- Octanol/water partition coefficient
- Water solubility
- Stability in water
- Biodegradation
- Acute toxicity to fish, daphnia and algae
- Chronic toxicity to daphnia
- Combined repeat dose and reproductive toxicity test
- Gene mutation
- Chromosomal aberration test in vitro

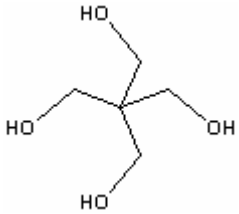
Deadline for circulation: July 31, 1998
Date of Circulation: October 5, 1998
(To all National SIDS Contact Points and the OECD Secretariat)

SIDS INITIAL ASSESSMENT REPORT

Pentaerythritol
(CAS No. 115 - 77 - 5)

1. IDENTITY

- OECD Name: Pentaerythritol
- Synonym: 2,2-bis(hydroxymethyl)-1,3-Propanediol; Hercules P 6; Monopentaerythritol; PE 200; Tetramethylolmethane; THME; PETP; Pentaertyhritol; Tetrakis(hydroxymethyl)methane
- CAS Number: 115-77-5
- Empirical Formula: $C_5H_{12}O_4$
- Structural Formula:



- Degree of Purity: 94-95 %
- Major Impurity: Bispentamonoformal (4%), Dipentaerythritol, Tripentaerythritol
- Essential Additives: None
- Physical-chemical properties
  - Melting Point: 260 °C
  - Vapour pressure: < 1.3 x 10_2 Pa at 20 °C
  - Water solubility: 27 g/L
  - Log Pow: < 0.3

2. GENERAL INFORMATION ON EXPOSURE

2.1 Production and import

24,074 tonnes/year in 1996 in Japan
27,513 tonnes/year in 1997 in Japan

2.2 Use pattern

Intermediate in closed system.
Intermediate for Alkyd resin, rosin ester, explosives, lubricants

2.3 Other information

3. ENVIRONMENT

3.1 Environmental Exposure

3.1.1 General Discussion

Pentaerythritol is not readily biodegradable according to data obtained in Japan (OECD 301C: 13.2 % after 28d). However, there are numerous data on biodegradability of this chemical ranging from 0% after 28 days (ref. 1) to 97% after 12 days (ref. 2). Direct photodegradation is not expected because pentaerythritol has not absorption band in UV and VIS region.

Bioaccumulation potential of pentaerythritol is very low (OECD 305C: BCF 0.3 –2.1).

The potential environmental distribution of pentaerythritol obtained from Mackay level III fugacity model is shown in Table 1. The results show that, if pentaerythritol is released into water, it is unlikely to be distributed into other compartments. If pentaerythritol is released into air or soil, it is likely to be transported to water.

Table 1
Environmental distribution of pentaerythritol
Using a generic level III fugacity model.

Compartment	Release 100% to air	Release 100% to water	Release 100% to soil
Air	52.1 %	1.0 %	1.5 %
Water	36.2 %	98.5 %	29.8 %
Soil	11.5 %	0.2 %	68.5 %
Sediment	0.1 %	0.3 %	0.1 %

Pentaerythritol is used in closed systems as an intermediate and is not included in consumer products.

3.1.2 Predicted Environmental Concentration

As Pentaerythritol is produced under well controlled closed systems, the amount of release to air phase is negligibly small. The waste of pentaerythritol from the production sites is released to water phase after treated in their own wastewater treatment plant. Therefore, Predicted Environmental Concentration (PEC) will be calculated only for the water environment.

Local exposure

a) According to report from a Japanese manufacturer (A), 42,000 kg/year (measured) of Pentaerythritol was released with 2.1 x 10^8 L/year of effluent into the centralized wastewater treatment plant. Wastewater treated in centralized wastewater treatment plant was released with 1.1 x 10^{11} L/year of effluent into a bay in 1995. During the both treatment plants, removal rate was estimated to be negligible. Dilution factors for two steps are estimated to be 520 and 90 (See Appendix 1). Local Predicted Environmental Concentration (PEC_{local}) is calculated to be 4.3 x 10^{-3} mg/L, employing the following calculation model.

Amount of release (4.2 x 10^{10} mg/y)
Volume of effluent (2.1 x 10^8 L/y) x Dilution Factor (520) x Dilution Factor (90)

b) According to report from another Japanese manufacture (B), 500kg/year (estimated) of pentaerythritol was released with 1.5 x 10^{10} L/year of effluent into a bay in 1995. Local Predicted

Environmental Concentration (PEC_{local}) is calculated to be 5.1 x 10^{-5} mg/L, employing the following calculation model and dilution factor of 660 (See Appendix 1).

Amount of release (5 x 10^{8} mg/y)
Volume of effluent (1.5 x 10^{10} L/y) x Dilution Factor (660)

3.2 Effects on the Environments

3.2.1 Effects on aquatic organisms

Acute and chronic toxicity data of pentaerythritol to aquatic organisms are summarized below (Table 2). Toxicity of this chemical to aquatic organisms is very low, because all the toxicity data are higher than 100 mg/l. Predicted No Effect Concentration (PNEC) of this chemical was determined using a *Daphnia magna* 48 h immobility data (600 mg/l) found in a reference (Table 2). The assessment factor of 1000 is used to an acute toxicity data to determine PNEC, according to the OECD Provisional Guidance for Initial Assessment of Aquatic Effects (EXCH/MANUAL/96-4-5.DOC/May 1996), because only one acute toxicity data is available among algae, cladocera and fishes.

From acute toxicity data: PNEC = 600/ 1000 = 0.6 mg/l

Thus, PNEC of pentaerythritol is determined as 0.6 mg/l, tentatively.

Table 1
Acute and chronic toxicity data of pentaerythritol to aquaticorganisms at different trophic levels. The data (ref. 1)) by the Environmental Agency of Japan were tested based on OECD Test Guide Lines.

Species	Endpoint	Conc. (mg/l)	Remarks
Selenastrum capricornutum (algae)	Gro 72 h EC50	>1000	a, 3)
	do. 72 h NOEC	> 1000	c, 3)
Daphnia magna (Water flea)	Imm 24 h EC50	>1000	a, 3)
	Rep 21 d NOEC	>1000	c, 3)
	Imm 48 h EC50	600	a, 4), A
	Mor 48 h LC50	33600	a, 5)
Oryzias latipes (fish, Medaka)	Mor 24 h LC50	>100	a, 3)
	Mor 48 h LC50	> 100	a, 3)
	Mor 72 h LC50	> 100	a, 3)
	Mor 96 h LC50	> 100	a, 3)

Notes: Gro; growth, Mor; mortality, Rep; reproduction,
No. 3- 5), Reference number, A), C); selected as the lowest value respectively among the acute or chronic toxicity data of algae, cladocera (water flea) and fishes to determine PNEC of pentaerythritol.

3.2.2 Terrestrial effects

No data available.

3.2.3 Other effects

No data available.

3.3 Initial Assessment for the Environment

PNEC of this chemical is calculated as 0.6 mg/l, tentatively.

The highest PEC from Japanese local exposure scenario (manufacturer A) is 4.3×10^{-3} mg/l.

Thus, PEC_{local} / PNEC = 4.3×10^{-3}/ 0.6 = 0.0072 < 1

Effects of this chemical on aquatic ecosystems is at low concern at present.

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

References

1) Struijis, J., Stoltenkamp, J. (1980) Headspace determination of evolved carbon dioxide in a biodegradability screening test. Ecotoxicol. Environ. Saf., 19, 204-211.

2) Gerike, P., Sebesta, G., Herkelmann, H. (1979) A correlation study of biodegrada-Bility determination with various chemicals in various tests. Ecotoxicol. Environ. Saf., 3, 159-173.

3) Toxicity data by the Environment Agency of Japan. The tests were conducted based on OECD Test Guide Lines.

4) Walton, J.R, and Davis, E.M. (1980) Toxicology and fate of selected chemicals in aquatic ecosystems. University of Texas, School of Public Health, Inst. of Environ, Health, Houston, TX: 91 p.

5) Bringmann, G. and Kuhn, R. (1982) Results of toxic action of water pollutants on Daphnia magna Straus tested by an improved standardized procedure. Z. Wasser Abwasser-Forsch. 15 (1), 1-6 (GER) (ENG ABS)

4. HUMAN HEALTH

4. 1 Human Exposure

4. 1. 1 Occupational exposure

Pentaerythritol is produced in closed systems. Occupational exposure in production sites is expected in bag filling operation. The major route of exposure is considered to be inhalation. The bag filling operation was done for 8 hours per day using automatic filling machine with local exhaust ventilation. The workers wear goggles, protective gloves, and dust masks. The atmosphere concentrations at bag filling operation area were measured at a production facility, using light scattering dust monitor. The average daily intake without protection equipment such as mask was calculated as 1.2 mg/kg/day from the average atmosphere concentration of 8.5 mg/m^3 (maximum value; 20.3 mg/m^3 and minimum value; 0.35 mg/m^3), body weight of 70 kg and respiratory volume of 1.25 m^3/hour.

4. 1. 2 Consumer exposure

There are no available data.

4. 1. 3 Indirect exposure via the environment

As pentaerythritol is persistent but very low bioaccumulative such as the bioconcentration factor of 0.3-2.1, the exposure to the general population via the environment would be possible through mainly drinking water processed from surface.

Based on the physical chemical properties of this chemical (e.g. high water solubility), a significant removal during the processing is not expected. Therefore, the concentration in drinking water should be estimated to be equal to the highest local predicted environmental concentration (PEC) of 4.30×10^{-3} mg/l. The daily intake through drinking water is calculated as 1.43×10^{-4} mg/kg/day (2 l/day, 60 kg b.w.).

Using the highest bioconcentration factor of 2.1 obtained by tests, the concentration of this chemical in fish can be calculated as follows:

$$PEC_{fish} = (4.30 \times 10^{-3} \text{ mg/l}) \times 2.1 = 9.03 \times 10^{-6} \text{ mg/g-wet}$$

As a daily intake of fish in Japan is estimated to be 90 g for 60 kg body weight person, a daily intake of this chemical will be 1.35×10^{-5} mg/kg/day.

4. 2 Effects on Human Health

a) Acute toxicity

Oral:

Rats: LD_{50}: >2000 mg/kg (diarrhea) [SIDS data]

Mice: LD_{50}: 25500 mg/kg as a mixture of 88 % mono- and 12 % dipentaerythritol.

Guinea pigs: LD_{50}: 11300 mg/kg as a mixture of 88 % mono- and 12 % dipentaerythritol.

Inhalation:

Rats: LC_0: 11 g/m^3/6 hours [SIDS data]
No toxic effects were observed at dose of 11 g/m^3 as a mixture of 88 % mono- and 12 % dipentaerythritol for 6 hours.

Dermal:

Rabbits: LC_0: 10 g/kg [SIDS data]
A single 24-hour application of 10 g/kg of aqueous paste by the closed patch technique on intact and abraded skin showed no symptoms. There is no evidence for percutaneous absorption.

b) Irritation

A saturated aqueous solution of pentaerythritol instilled into the rabbit eye. As a result, no irritation or inflammation was observed. However, instillation of a 50 % aqueous suspension into the conjunctival sac resulted in slightly irritating. The signs of ocular irritation resolved within 24 hours.

Applying a saturated aqueous solution of the technical grade once daily for 10 days to rabbit skin resulted in no significant irritation.

c) Sensitisation

There are no available data. However, Berlin (1994) considered that pentaerythritol might not sensitize the skin, because an application of a saturated water solution of this chemical in skin irritation study for 10 days resulted in no significant irritation.

d) Repeated toxicity

[SIDS data] Oral toxicity study of pentaerythritol was performed in SD(Crj:CD) rats by an OECD combined repeat dose and reproductive/ developmental toxicity screening test at doses of 0 (vehicle: 0.5 % CMC-Na), 100, 300, 1000 mg/kg/day.

Soft feces were noted in both sexes of the 300 and 1000 mg/kg groups, and diarrhea was noted in males of the 300 and 1000 mg/kg groups and females of the 1000 mg/kg group. Water consumption increased in males of the 1000 mg/kg group. No effects were observed in body weights, food consumption, urinalysis, hematology, blood chemistry, organ weight, autopsy or histopathology findings. NOEL was considered to be 100 mg/kg/day based on gastrointestinal changes.

Oral administration study by gavage for 28 days was performed (daily) in F344 rats at doses of 0 (vehicle; water), 1000 mg/kg/day. No toxic effect was observed. Therefore, NOEL was considered to be 1000 mg/kg/day.

Inhalation toxicity study for 90 days was performed in rats, guinea pigs and dogs at a concentration of 8 g/m^3 (as a mixture of 88 % mono- and 12 % dipentaerythritol), 6 hours/day. No effect was observed in reaction, body weights, mortality, hematologic studies, and gross and microscopic pathologic studies. A concentration of 8 g/m^3 was NOEL for three experimental animals.

e) Reproductive/developmental toxicity

[SIDS data] Oral toxicity study of pentaerythritol was performed in SD(Crj:CD) rats by an OECD combined repeat dose and reproductive/ developmental toxicity screening test at doses of 0 (vehicle: 0.5 % CMC-Na), 100, 300, 1000 mg/kg/day.

No effects were observed on the following items: for dams, reproductive ability, organ weights, histopathological appearance of the reproductive organs, delivery or maternal behavior, and for offspring, viability, clinical signs, body weight changes or autopsy findings. The NOELs for reproductive and developmental performances were considered to be 1000 mg/kg/day.

f) Genetic toxicity

[SIDS data] Gene reverse mutation was negative in S. Typhimurium TA100, TA98, TA1535, TA1537, and Escherichia coli WP2 uvrA with and without metabolic activation. Neither structural chromosomal aberrations nor polyploidy were induced in CHL/IU cells up to the concentration of 1.4 mg/ml, in the absence or presence of an exogenous metabolic activation system.

4.3 Initial Assessment for Human Health

Pentaerythritol was not mutagenic in bacterial and chromosomal aberration tests in vitro. NOEL was 100 mg/kg/day for repeat dose toxicity and 1000 mg/kg/day for reproductive/developmental toxicity. There are no available information on consumer use. This chemical is not considered as an irritant to skin and eyes, nor sensitizer.

Pentaerythritol is used in a closed system at industries and the exposure route for human is an inhalation in limited workers. The daily intake through inhalation is calculated as 1.2 mg/kg/day as the worst case, based on the average atmosphere concentration of 8.5 mg/m^3. Although the margin of safety is 83.3, heath risk is considered to be probably low, because workers always wear protective equipment during the operation. Furthermore, in inhalation animal studies, NOEL was reported to be 8 g/m^3 (6 hour/day, 90 days) as a mixture for rats, guinea pigs and dogs. In USA, a limit value of ACGIH TLV-TWA is 10 mg/m^3 (1996).

As for indirect exposure via environment, PEC_{local} of 4.30 $x10^{-3}$ mg/l from local exposure scenario was used for the estimation. The daily intakes through drinking water and fish are calculated as 1.43 x 10^{-4} mg/kg/day and 1.35 x 10^{-5} mg/kg/day, respectively. Since margin of safety is very large, such as 6.98 x 10^5 from drinking water and 7.38 x 10^6 from fish, health risk is extremely low.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

Although pentaerythritol is not readily biodegradable, toxicity to aquatic organisms is very low. PEC/PNEC ratio is less than 1 based on the local exposure scenario in the Sponsor country. Therefore, it is currently considered of low potential risk and low priority for further work.

Pentaerythritol is low toxic in a repeated dose study (i.e. soft feces, diarrhea). This chemical is not considered as an irritant to skin and eyes. Estimated daily intake through occupational and indirect exposures is considered to be low. As margin of safety is very large, it is currently considered of low potential human risk and low priority for further work.

5.2 Recommendations

No recommendation

6. REFERENCES

Berlin,K., Arbete och Hlsa, 24, 1-7 (1994).

Appendix 1

Method for Prediction of environmental concentration of pollutant in surface water

1. Predicted environmental concentration in the local environment (PEC_{local}) with effluent release into river

When decomposition, precipitation and vaporization of pollutant can be ignored, it is used that simplified equation by complete mixing model shown with equation (1) to calculate predicted environmental concentration in the local environment(PEC_{local}) as for release effluent into river.

$$PEC_{local}\ (mg/L) = \frac{Co\ Q + Cs\ Qs}{Q + Qs} \quad (1)$$

Where
Co: Concentration of pollutant in upper stream of release point (mg/L)
Cs: Concentration of pollutant in effluent (mg/L)
Q : Flow rate of river(m^3/day)
Qs: Flow rate of effluent released into river(m^3/ day)

At the equation (1), when Co can be considered as 0, dilution factor of pollutant in the river(R) can be shown with following equation.

$$R = Cs/C = (Q + Qs) / Qs \quad (2)$$

As the worst case, it is used to employ a flow rate at dry season as flow rate of river (Q). When flow rate at dry season is indistinct, it is estimated using the following equation in Japan.

$$\text{flow rate at dry season} = \text{mean flow late} / 2.5 \quad (3)$$

2. Predicted environmental concentration in the local environment (PEC_{local}) with effluent release into sea.

For prediction of concentration of pollutant in the sea water with effluent, it is employed generally Joseph-Sendner equation (4). This equation is one of analytic solution led under the following conditions from diffusion equation.

① It is adopted large area of sea or lake.
② The flow rate of effluent and concentration of pollutant in the effluent are constant, and distribution of concentration is able to regard as equilibrium state.
③ Effluent is distributed uniformly to vertical direction, and it spreads in a semicircle or segment to horizontal direction.
④ Diffusion coefficient of pollutant at the sea is in proportion to distance from release point of effluent.
⑤ There is not any effect of tidal current.
⑥ Decomposition of pollutant can be ignored.

$$C(x) = (C_s - C(r))\left(1 - \exp\left(-\frac{Q_s}{\theta d p}\left(\frac{1}{x} - \frac{1}{r}\right)\right)\right) + C(r) \qquad (4)$$

Where
C(x): Concentration of pollutant at distance x(m) from release point
Cs : Concentration of pollutant in effluent
C(r) : Concentration of pollutant at distance r(m) from release point
Qs : Flow rate of effluent(m^3/day)
θ : Opening angle of seacoast(rad.)
d : Thickness of diffusion layer(m)
P : Diffusion velocity(m/day) (1.0 $\pm$ 0.5 cm/sec.)

When C(x) is 0 at r=∞ and density stratification is ignored for simplification, Joseph-Sendner equation(4) is simplified to equation(5)

$$C(x) = C_s\left(1 - \exp\left(-\frac{Q_s}{\theta d p x}\right)\right) \qquad (5)$$

Because of $Q_s/\theta d p x \ll 1$ except vicinity of release point, dilution factor in distance x from release point R(x) can be shown with equation(6).

$$R(x) = C_s/C(x) = \theta d p x/Q_s \qquad (6)$$

When it is employed following parameters in equation (6) as default, dilution factor R can be shown with equation (7).
P = 1 cm/sec(860m/day)
θ = 3.14
d = 10m
x = 1000m

$$R = 2.7 \times 10^7/Q_s \qquad (7)$$

Qs: volume of effluent(m^3/day)

REVISED OECD HPV FORM 1

SIDS DOSSIER
ON THE HPV PHASE 4 CHEMICAL

Pentaerythritol

CAS No. 115 - 77 -5

Sponsor Country : Japan
Date: October 5, 1998

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4.6 TOXICITY TO TERRESTRIAL ORGANISMS
4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS
4.6.2 TOXICITY TO TERRESTRIAL PLANTS
4.6.3 TOXICITY TO OTHER NON-MAMMALIAN TERRESTRIAL SPECIES (INCLUDING BIRDS)
4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)
4.8 BIOTRANSFORMATION AND KINETICS
4.9 ADDITIONAL REMARKS

5. TOXICITY

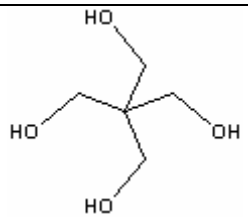
5.1 * ACUTE TOXICITY
5.1.1 ACUTE ORAL TOXICITY
5.1.2 ACUTE INHALATION TOXICITY
5.1.3 ACUTE DERMAL TOXICITY
5.1.4 ACUTE TOXICITY BY OTHER ROUTES OF ADMINISTRATION
5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION
5.2.2 EYE IRRITATION/CORROSION
5.3 SKIN SENSITISATION
5.4 * REPEATED DOSE TOXICITY
5.5 * GENETIC TOXICITY IN VITRO
A. BACTERIAL TEST
B. NON-BACTERIAL IN VITRO TEST
5.6 * GENETIC TOXICITY IN VIVO
5.7 CARCINOGENICITY
5.8 * TOXICITY TO REPRODUCTION
5.9 * DEVELOPMENTAL TOXICITY / TERATOGENICITY
5.10 OTHER RELEVANT INFORMATION
A. SPECIFIC TOXICITIES (NEUROTOXICITY, IMMUNOTOXICITY etc.)
B. TOXICODYNAMICS, TOXICOKINETICS
5.11 * EXPERIENCE WITH HUMAN EXPOSURE

6. REFERENCES

Note: *;Data elements in the SIDS
†;Data elements specially required for inorganic chemicals

S I D S P R O F I L E
DATE: October 5, 1998

1.01 A.	**CAS No.**	115 - 77 –5
1.01 C.	**CHEMICAL NAME (OECD Name)**	Pentaerythritol
1.01 D.	**CAS DESCRIPTOR**	
1.01 G.	**STRUCTURAL FORMULA**	
	OTHER CHEMICAL IDENTITY INFORMATION	
1.5	**QUANTITY**	In Japan, 24,074 tonnes/year in 1996 27,513 tonnes/year in 1997
1.7	**USE PATTERN**	Intermediate in closed system. Intermediate for Alkyd resin, rosin ester, explosives, lubricants
1.9	**SOURCES AND LEVELS OF EXPOSURE**	(a) 42,000 kg/year into a bay in 1955. (b) 500 tonnes/year into a bay in 1955.
ISSUES FOR DISCUSSION (IDENTIFY, IF ANY)	SIDS testing required: Vapour pressure Partition coefficient Water solubility Stability in water Biodegradation Acute toxicity to fish, daphnia and algae Chronic toxicity to daphnia Combined repeat dose and reproductive toxicity Gene mutation Chromosomal aberration	

SIDS SUMMARY

CAS NO: 115-77-5		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	N						N
2.3	Density	N						N
2.4	Vapour Pressure	N						Y
2.5	Partition Coefficient	N						Y
2.6	Water Solubility	N						Y
	pH and pKa values	N						N
2.12	Oxidation: Reduction potential	N						N
	OTHER P/C STUDIES RECEIVED							
ENVIRONMENTAL FATE and PATHWAY								
3.1.1	Photodegradation	N						N
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
	OTHER ENV FATE STUDIES RECEIVED							
ECOTOXICITY								
4.1	Acute toxicity to Fish	N		N				Y
4.2	Acute toxicity to Daphnia	Y		N				Y
4.3	Toxicity to Algae	N		N				Y
4.5.2	Chronic toxicity to Daphnia	N		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	Y	N	N	Y	N	Y	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						N
5.11	Human experience	N						N
	OTHER TOXICITY STUDIES RECEIVED							

1. GENERAL INFORMATION

1.01 SUBSTANCE INFORMATION

***A. Cas number** 115 - 77 - 5

B. Name *(IUPAC name)*

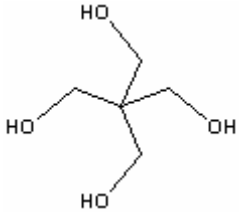
***C. Name** *(OECD name)* Pentaerythritol

†D. CAS Descriptor

E. EINECS-Number 204-104-9

F. Molecular Formula $C_5H_{12}O_4$

***G. Structural Formula**



H. Substance Group

I. Substance Remark

J. Molecular Weight 136.15

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)
Environmental Agency (EA)
Ministry of Labour (MOL)

Contact person: Mr.kenichi Suganuma
Director, Second International Organization Bureau
Ministry of Forein Affairs

Address:

Street: 2-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100 Japan
Tel: 81-3-3581-0018
Fax: 81-3-3503-3136

C. Name of responder

Name: 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 *(at 20°C and 1.013 hPa)*

gaseous **[ ]**; liquid **[ ]**; solid **[x]**

C. Purity 94 – 95 %

1.2 SYNONYMS 2,2-bis(hydroxymethyl)-1,3-Propanediol; Hercules P 6; Monopentaerythritol; PE 200; Tetramethylolmethane; THME; PETP; Pentaertyhritol; Tetrakis(hydroxymethyl)methane

1.3 IMPURITIES

Name: Bispentamonoformal (4%), Dipentaerythritol, Tripentaerythritol

***1.5 QUANTITY**

Remarks: 24,074 t/y in 1996
27,513 t/y in 1997
Reference: MITI

1.6 LABELLING AND CLASSIFICATION

***1.7 USE PATTERN**

A. General

	Type of Use:	**Category:**
(a)	main industrial use	Intermediate Intermediate in closed system Intermediate for Alkyd resin, Rosin ester, Explosive, Lubricants

Remarks: (a) None

Reference: MITI

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUE

None

***1.9 SOURCES OF EXPOSURE**

In Japan, pentaerythritol is produced by 2 companies.

(a)
Source: Media of release: Bay through centralized wastewater treatment plant

Quantities per media: 42,000kg/year in 1995 (measured)
Remarks:
Reference: MITI, Japan

(b)
Source: Media of release: Bay
Quantities per media:. 500kg/year in 1995 (estimated)
Remarks:
Reference: MITI, Japan

2. PHYSICAL-CHEMICAL DATA

*2.1 MELTING POINT

Value: 260 °C
Decomposition: Yes **[ ]** No **[x]** Ambiguous **[ ]**
Sublimation: Yes **[x]** No **[ ]** Ambiguous **[ ]**
Method:
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks:
Reference: Lange's Handbook of Chemistry (13th edition)

*2.4 VAPOUR PRESSURE

Value: $< 1.3 \times 10^2$ Pa
Temperature: 20 °C
Method: calculated **[ ]**; measured **[x]**
GLP: Yes **[ ]** No **[ ]** ? **[x]**
Remarks:
Reference: The Sigma-Aldrich Library of Regulatory and Safety Data

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

Log Pow: < 0.3
Temperature: 25 °C
Method: calculated **[ ]**; measured **[x]**
OECD TG 117
GLP: Yes **[x]** No **[ ]** ? **[ ]**
Remarks:
Reference: MITI, JAPAN.

*2.6 WATER SOLUBILITY

A. Solubility

Value: 25 g/L
Temperature: 25 °C
Description: Miscible **[ ]**; Of very high solubility **[x]**;
Of high solubility **[ ]**; Soluble **[ ]**; Slightly soluble **[ ]**;
Of low solubility **[ ]**; Of very low solubility **[ ]**; Not soluble **[ ]**
Method: OECD TG 105
GLP: Yes **[x]** No **[ ]** ? **[ ]**
Remarks:
Reference: MITI, JAPAN.

B. pH Value, pKa Value

pH Value: No ionizable functional group

3. ENVIRONMENTAL FATE AND PATHWAYS

3.1 STABILITY

*3.1.2 STABILITY IN WATER

Type: Abiotic (hydrolysis) **[x]**; biotic (sediment)**[ ]**
Degradation: Stable at pH 4, 7 and 9 at 25 °C
Method: OECD TG 111
GLP: Yes **[x]** No **[ ]** ? **[ ]**
Test substance: Pentaerythritol, purity: 99 %
Remarks:
Reference: MITI, JAPAN.

*3.2 MONITORING DATA (ENVIRONMENTAL)

No studies located

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

*3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)

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

Compartment	Release 100% to air	Release 100% to water	Release 100% to soil
Air	52.1 %	1.0 %	1.5 %
Water	36.2 %	98.5 %	29.8 %
Soil	11.5 %	0.2 %	68.5 %
Sediment	0.1 %	0.3 %	0.1 %

Remarks: Appendix 1
Reference:

*3.5 BIODEGRADATION

Type: aerobic **[x]**; anaerobic **[ ]**
Inoculum: adapted **[ ]**; non-adapted **[x]**;
Concentration of the chemical: related to COD **[ ]**; DOC **[ ]**; test substance **[x]**
Medium: water **[x];** water-sediment **[ ];** soil **[ ];** sewage treatment **[ ]**
Degradation: 13.2 % after 25 days
Results: readily biodeg. **[ ];** inherently biodeg. **[ ]**; under test condition no biodegradation observed **[x]**, other **[ ]**
Method: OECD TG 301C

GLP:	Yes **[x]** No **[ ]** ? **[ ]**
Test substance:	Pentaerythritol, purity: 99 %
Remarks:	
Reference:	MITI, JAPAN.

3.7 BIOACCUMULATION

Species:	Carp (Cyprinus carpio)
Exposure period:	6 weeks
Temperature:	25 °C
Concentration:	(1) 10 m/L
	(2) 1 mg/L
BCF:	(1) 0.3 – 0.6
	(2) 0.4 – 2.1
Method:	OECD TG 305C
Type of test:	calculated **[ ]**; measured **[x]**
	static **[ ]**; semi-static **[ ]**; flow-through **[x]**; other *(e.g. field test)* **[ ]**
GLP:	Yes **[x]** No **[ ]** ? **[ ]**
Test substance:	Pentaerythritol , purity: 99 %
Remarks:	
Reference:	MITI, JAPAN.

4. ECOTOXICITY

*4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type of test:	static **[ ]**; semi-static **[X]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**
	open-system **[X]**; closed-system **[ ]**
Species:	*Oryzias latipes* (Himedaka)
Exposure period:	96 h
Results:	LC_{50} (24h) = > 100 mg/l
	LC_{50} (48h) = > 100 mg/l
	LC_{50} (72h) = > 100 mg/l
	LC_{50} (96h) = > 100 mg/l
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**
Method:	OECD TG 203 (1992)
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	As prescribed by 1.1 - 1.4, purity: 95%
Remarks:	Group of ten Himedaka were exposed to nominal concentration of 100 mg/l and laboratory water control.
Reference:	Environment Agency of JAPAN (1995)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

*A. Daphnia

Type of test:	static **[ ]**; semi-static **[X]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**;
	open-system **[X]**; closed-system **[ ]**
Species:	*Daphnia Magna*.
Exposure period:	48 h
Results:	EC_{50} (48h) = >1000 mg/l
	NOEC = 1.0 mg/l
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**
Method:	OECD TG 202

GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	As prescribed by 1.1 - 1.4 , purity: 95 %
Remarks:	20 daphnids (4 replicates; 5 organisms per replicate) were exposed to nominal concentrations of 100, 180, 320, 560 and 1000 mg/l and laboratory water control.
Reference:	Environment Agency of JAPAN (1995)

B. Other aquatic organisms

***4.3 TOXICITY TO AQUATIC PLANTS, e.g. algae**

Species:	*Selenastrum capricornutum* ATCC 22662	
Endpoint:	Biomass **[X]**; Growth rate **[ ]**; Other **[ ]**	
Exposure period:	72 h	
Results:	Biomass	$EC_{50\ (72h)}$ = >1000 mg/l NOEC = >1000 mg/l
Analytical monitoring:	Yes **[X]** No **[ ]** ? **[ ]**	
Method:	OECD TG 201 (1984) open-system **[ ]**; closed-system **[X]**	
GLP:	Yes **[ ]** No **[X]** ? **[ ]**	
Test substance:	purity: 99.9 %	
Remarks:	Static test. The EC_{50} value for growth rate (% inhibition) was calculated based on 5 nominal concentrations (100, 180, 320, 560 and 1000 mg/l) . Minimal amount of Tween 80 - acetone (1:1) or DMSO - HCO-40 (9:1) is used as solubilizer.	
Reference:	Environment Agency of JAPAN (1995)	

4.4 TOXICITY TO BACTERIA

No data

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1 CHRONIC TOXICITY TO FISH

No data

(*)4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Type of test:	static **[ ]**; semi-static **[X]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**; open-system **[X]**; closed-system **[ ]**	
Species:	*Daphnia Magna*	
Endpoint:	Mortality **[ ]**; Reproduction rate **[X]**; Other **[X]**	
Exposure period:	21 d	
Results:	Reproduction rate:	$EC_{50\ (21\ d)}$ = >1000 mg/l NOEC = >1000 mg/l
	Immobility:	$EC_{50(48h)}$ = >1000 mg/l $EC_{50\ (21\ d)}$ = >1000 mg/l
Analytical monitoring:	Yes **[ ]** No **[X]** ? **[ ]**	
Method:	OECD TG 202(1984)	
GLP:	Yes **[ ]** No **[X]** ? **[ ]**	
Test substance:	As prescribed by 1.1 - 1.4 , purity: 95 %	

Remarks:	40 daphnids (4 replicate; 10 daphnids per replicate) were exposed to 5 concentrations (10, 32, 100, 320, 1000 mg/l) in dechlorinated tap water (pH : 7.6 to 8.0; Hardness : 48 to 111 mg/l)
Reference:	Environment Agency of JAPAN (1995)

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

No data

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

No data

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

No data

4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)

No data

4.8 BIOTRANSFORMATION AND KINETICS

No data

4.9 ADDITIONAL REMARKS

5. TOXICITY

***5.1 ACUTE TOXICITY**

5.1.1 ACUTE ORAL TOXICITY

Type:	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Rats/Crj:CD (SD)
Value:	>2000 mg/kg b.w. Discriminating dose: 0, 500, 1000, 2000 mg/kg b.w.
Method:	OECD Test Guideline 401
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	purity: 92.7 %
Remarks:	No deaths occurred and no changes were observed except for diarrhea and soft feces at doses of 1000 and 2000 mg/kg b.w..
Reference:	MHW, Japan (1996)

Type:	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Mice
Value:	25500 mg/kg b.w. as a mixture
Method:	Other
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	a mixture of 88 % mono- and 12 % dipentaerythritol

Remarks:	Ataxia, tremors, and loss of righting reflex.
Reference:	M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

Type:	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Guinea pigs
Value:	11300 mg/kg b.w. as a mixture
Method:	Other
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	a mixture of 88 % mono- and 12 % dipentaerythritol
Remarks:	Ataxia, tremors, and loss of righting reflex.
Reference:	M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

5.1.2 ACUTE INHALATION TOXICITY

Type:	LC_0 **[X]**; LC_{100} **[ ]**; LC_{50} **[ ]**; LCL_0 **[ ]**; Other **[ ]**
Species/strain:	Rats
Exposure time:	6 hours
Value:	11 g/m^3 (dust: particle sizes, 0.9-40 μ) as a mixture
Method:	Other
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	a mixture of 88 % mono- and 12 % dipentaerythritol
Remarks:	No toxic effect
Reference:	M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

5.1.3 ACUTE DERMAL TOXICITY

Type:	LD_0 **[X]**; LD_{100} **[ ]**; LD_{50} **[ ]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Rabbits
Value:	10 g/kg
Method:	Other
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	purity: unknown
Remarks:	A single application of aqueous paste for 24 hours by the closed patch technique on intact and abraded skin showed no symptoms. There is no evidence for percutaneous absorption.
Reference:	Toxicologic Data Bulletin T-110. Hercules Powder Company, Inc., Wilmington, DE (1964)

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION

No data are available

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

Species/strain:	Rabbits
Results:	Highly corrosive **[ ]**; Corrosive **[ ]**; Highly irritating **[ ]**; Irritating **[ ]**; Moderate irritating **[ ]**; Slightly irritating **[ ]**; Not irritating **[X]**
Classification:	Highly corrosive (causes severe burns) **[ ]**; Corrosive (causes burns) **[ ]**; Irritating **[ ]**; Not irritating **[ ]**
Method:	Other
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Test substance:	purity: unknown

Remarks: Applying a saturated aqueous solution of technical grade once daily for 10 days
Reference: Berlow,E. *et al*.,The Pentaerythritols, pp.39-40. American Chemical Society Monograph 136. Reinhold Pub. Co., New York (1958)

5.2.2 EYE IRRITATION/CORROSION

Species/strain: Rabbits
Results: Highly corrosive **[ ]**; Corrosive **[ ]**; Highly irritating **[ ]**; Irritating **[ ]**; Moderate irritating **[ ]**; Slightly irritating **[X]**; Not irritating **[ ]**
Classification: Irritating **[ ]**; Not irritating **[ ]**; Risk of serious damage to eyes **[ ]**
Method: Other
GLP: Yes **[ ]** No **[**X**]** ? **[ ]**
Test substance: purity: unknown
Remarks: A 50 % aqueous suspension was instilled into the conjunctival sac. The signs of ocular irritation resolved within 24 hours. However, instillation of a saturated aqueous solution resulted in no irritation or inflammation.
Reference: Toxicologic Data Bulletin T-110. Hercules Powder Company, Inc., Wilmington, DE (1964)

5.3 SKIN SENSITISATION

No data are available.

*5.4 REPEATED DOSE TOXICITY

Species/strain: Rats/Crj:CD (SD)
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration: Oral (by gavage)
Exposure period: Male: 46 days
Female: from 14 days before mating to day 3 of lactation
Frequency of treatment: Daily
Post exposure observation period: 1 day
Dose: 100, 300, 1000 mg/kg/day
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**; 0.5 % CMC-Na solution
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL: 100 mg/kg
LOEL: 300 mg/kg
Results: Soft feces (in the 300 and 1000 mg/kg groups), diarrhea (in males of the 300 and 1000 mg/kg groups and females of the 1000 mg/kg group), and the increase of water consumption (in males of the 1000 mg/kg group).
Method: OECD Combined Repeat Dose and Reproductive Toxicity Screening Test
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: purity: 92.7 %
Reference: MHW, Japan (1996)

Species/strain: F344 rats
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration: Oral (by gavage)
Exposure period: 28 days
Frequency of treatment: Daily
Post exposure observation period:
Dose: 1000 mg/kg/day

Control group: Yes **[X]**; No **[ ]**; No data **[ ]**; water
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL: 1000 mg/kg
LOEL:
Results: No toxic effect
Method: Other
GLP: Yes **[ ]** No **[**X**]** ? **[ ]**
Test substance: purity: 96.4 %
Reference: Hayashi et al., Eisei-Sikenjo-Hokoku, 110, 32-36 (1992)
Species/strain: Rats
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[X]**
Route of Administration: Oral
Exposure period: 90 days
Frequency of treatment: Daily
Post exposure observation period:
Dose: 0.2, 1.0, 5.0 % as a mixture (in the dry diet)
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL: 1.0 %
LOEL: 5.0 %
Results: Severe diarrhea, enlarged cecums, and increased cecum to body weight ratios at the 5 % dietary level only.
Method: Other
GLP: Yes **[ ]** No **[**X**]** ? **[ ]**
Test substance: a mixture of 88 % mono- and 12 % dipentaerythritol
Reference: M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

Species/strain: Rats
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[X]**
Route of Administration: Inhalation
Exposure period: 90 days
Frequency of treatment: 6 hours/day
Post exposure observation period:
Dose: 8 g/m^3 (dust) as a mixture
Control group: Yes **[ ]**; No **[ ]**; No data **[X]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL: 8 g/m^3
LOEL:
Results: No toxic effect
Method: Other
GLP: Yes **[ ]** No **[**X**]** ? **[ ]**
Test substance: a mixture of 88 % mono- and 12 % dipentaerythritol
Reference: M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

Species/strain: Guinea pigs
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[X]**
Route of Administration: Inhalation
Exposure period: 90 days
Frequency of treatment: 6 hours/day
Post exposure observation period:
Dose: 8 g/m^3 (dust)
Control group: Yes **[ ]**; No **[ ]**; No data **[X]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL: 8 g/m^3
LOEL:

Results: No effect
Method: Other
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: a mixture of 88 % mono- and 12 % dipentaerythritol
Reference: M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

Species/strain: Dogs
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[X]**
Route of Administration: Inhalation
Exposure period: 90 days
Frequency of treatment: 6 hours/day
Post exposure observation period:
Dose: 8 g/m^3 (dust) as a mixture
Control group: Yes **[ ]**; No **[ ]**; No data **[X]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL: 8 g/m^3
LOEL:
Results: No effect
Method: Other
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: a mixture of 88 % mono- and 12 % dipentaerythritol
Reference: M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

*5.5 GENETIC TOXICITY IN VITRO

A. BACTERIAL TEST

Type: Bacterial reverse mutation assay
System of testing: *S.typhimurium* TA100, TA1535, TA98, TA1537
E.coli WP2 uvrA (SD)
Concentration: -S9: 0, 312.5, 625, 1250, 2500, 5000 µg/plate
+S9: same as -S9
Metabolic activation: With **[ ]**; Without **[ ]**; With and Without **[X]**; No data **[ ]**
S-9: Rat liver, induced with phenobarbital and 5,6-benzoflavone
Results:
Cytotoxicity conc: With metabolic activation: Not observed
Without metabolic activation: Not observed
Precipitation conc:
Genotoxic effects:

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

Method: Guideline for Screening Mutagenicity Testing of Chemicals (Japan)
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: purity: 92.7 %
Remarks: Positive controls:-S9, AF-2 (TA100, WP2, TA98), sodium azide (TA1535) and 9-aminoacridine (TA1537)
+S9, 2-aminoanthracene (all strains)
Reference: MHW, Japan (1996)

B. NON-BACTERIAL IN VITRO TEST

Type: Chromosomal aberration.
System of testing: Chinese hamster lung (CHL/IU) cells
Concentration: -S9 (continuous treatment): 0, 0.4, 0.7, 1.4 mg/ml
-S9 (short-term treatment): 0, 0.4, 0.7, 1.4 mg/ml

+S9 (short-term treatment): 0, 0.4, 0.7, 1.4 mg/ml
Metabolic activation: With **[ ]**; Without **[ ]**; With and Without **[X]**; No data **[ ]**
S-9: Rat liver, induced with phenobarbital and 5,6-benzoflavone
Results:
Cytotoxicity conc: With metabolic activation: Not observed
Without metabolic activation: Not observed
Precipitation conc:
Genotoxic effects:

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

Method: Guidelines for Screening Mutagenicity Testings of Chemicals (Japan)
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: purity: 92.7 %
Remarks: Positive controls: -S9, Mitomycin C
+S9, Cyclophosphamide
Reference: MHW, Japan (1996)

* 5.6 GENETIC TOXICITY IN VIVO

No data are available.

5.7 CARCINOGENICITY

No data are available.

*5.8 TOXICITY TO REPRODUCTION

Type: Fertility **[ ]**; One-generation study **[ ]**; Two-generation study **[ ]**; Other **[X]**
Species/strain: Rats/Crj:CD (SD)
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration: Oral (by gavage)
Exposure period: Male: 46 days
Female: from 14 days before mating to Day 3 of lactation
Frequency of treatment: Daily
Post exposure observation period: 1 day
Premating exposure period: male: 14 days, female: 14 days
Duration of the test:
Dose: 100, 300, 1000 mg/kg/day
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**; 0.5 % CMC-Na solution
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL Parental: 1000 mg/kg
NOEL F1 Offspring: 1000 mg/kg
NOEL F2 Offspring:
Results: No toxicity for parents and offsprings
Method: OECD Combined Repeat Dose and Reproductive Toxicity Screening Test
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: purity: 92.7 %
Remarks:
Reference: MHW, Japan (1996)

*5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

No data are available.

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

No data are available.

B. Toxicodynamics, toxicokinetics

No data are available.

* 5.11 EXPERIENCE WITH HUMAN EXPOSURE

Results: Source: Pentaerythritol production plant (flexible container packing)
Number of Workers Exposed: 2
Frequency and duration: 5 days/week, 8 hours/day
Emission Measured: 8.5 mg/m^3

Remarks: Measured as total dust using light scattering dust monitor
Reference: Japanese Manufacturing Company (confidential) 1997

6. REFERENCES

Hayashi et al., Eisei-Sikenjo-Hokoku, 110, 32-36 (1992)
MHW, Japan (1996)
M.L.Keplinger and J.H.Kay, *Toxicol.Appl.Pharmacol*., 6, 351 (1964)

Appendix 1

Pentaerythritol

scenario 1

	emission rate	conc.	Amount	percent	transformation rate [kg/h]	
	[kg/h]	[g/m^3]	[kg]	[%]	reaction	advection
air	1,000	8.0.E-06	8.0.E+04	52.1	1.0E+02	8.0.E+02
water	0	2.8.E-03	5.6.E+04	36.2	3.4E+01	5.6.E+01
soil	0	1.1.E-02	1.8.E+04	11.5	1.1E+01	
sediment		1.8.E-03	1.8.E+02	0.1	1.1E-01	3.6.E-03
		total amount	1.5.E+05			

scenario 2

	emission rate	conc.	Amount	percent	transformation rate [kg/h]	
	[kg/h]	[g/m^3]	[kg]	[%]	reaction	advection
air	0	5.9.E-07	5.9.E+03	1.0	7.4.E+00	5.9.E+01
water	1000	2.9.E-02	5.8.E+05	98.5	3.5.E+02	5.8.E+02
soil	0	8.2.E-04	1.3.E+03	0.2	8.0.E-01	
sediment		1.9.E-02	1.9.E+03	0.3	1.2.E+00	3.8.E-02
		total amount	5.9.E+05			

scenario 3

	emission rate	conc.	Amount	percent	transformation rate [kg/h]	
	[kg/h]	[g/m^3]	[kg]	[%]	reaction	advection
air	0	1.4.E-06	1.4.E+04	1.5	1.8.E+01	1.4.E+02
water	0	1.4.E-02	2.8.E+05	29.8	1.7.E+02	2.8.E+02
soil	1000	4.0.E-01	6.4.E+05	68.5	3.9.E+02	
sediment		9.1.E-03	9.1.E+02	0.1	5.6.E-01	1.8.E-02
		total amount	9.3.E+05			

scenario 4

	emission rate	conc.	Amount	percent	transformation rate [kg/h]	
	[kg/h]	[g/m^3]	[kg]	[%]	reaction	advection
air	600	5.1.E-06	5.1.E+04	14.2	6.4.E+01	5.1.E+02
water	300	1.2.E-02	2.3.E+05	64.9	1.4.E+02	2.3.E+02
soil	100	4.7.E-02	7.5.E+04	20.7	4.6.E+01	
sediment		7.6.E-03	7.6.E+02	0.2	4.7.E-01	1.5.E-02
		total amount	3.6.E+05			

Physico-chemical parameter

molecular weight		136.15	Measured
melting point °C		260	Measured
vapor pressure [Pa]		1.30E+02	Dummy
water solubility [g/m^3]		27000	Measured
log Kow		0.3	Dummy
half life [h]	in air	550	Estimated
	in water	1128	Estimated
	in soil	1128	Estimated
	in sediment	1128	Estimated

Temp. [°C]	25

Environmetal parameter

		volume	depth	area	organic	lipid content	density	residence
		[m^3]	[m]	[m^2]	carbon [-]	[-]	[kg/m^3]	time [h]
bulk air	air	1.0E+13					1.2	100
	particles	2.0E+03						
	total	1.0E+13	1000	1E+10				
bulk water	water	2.0E+10					1000	1000
	particles	1.0E+06			0.04		1500	
	fish	2.0E+05				0.05	1000	
	total	2.0E+10	10	2E+09				
bulk soil	air	3.2E+08					1.2	
	water	4.8E+08					1000	
	solid	8.0E+08			0.04		2400	
	total	1.6E+09	0.2	8E+09				
bulk sediment	water	8.0E+07					1000	
	solid	2.0E+07			0.06		2400	50000
	total	1.0E+08	0.05	2E+09				

Intermedia Transport Parameters [m/h]

air side air-water MTC	5	soil air boundary layer MTC	5
water side air water MTC	0.05	sediment-water MTC	1E-04
rain rate	1E-04	sediment deposition	5E-07
aerosol deposition	6E-10	sediment resuspension	2E-07
soil air phase diffusion MTC	0.02	soil water runoff	5E-05
soil water phase diffusion MTC	1E-05	soil solid runoff	1E-08

EXTRACT FROM IRPTC LEGAL FILES

file: 17.01 LEGAL rn : 100252
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : ARG type : REG

subject	specification	descriptor
AIR	OCC	MPC

8H-TWA: 10MG/M3 (APPLIES TO TOTAL DUST WITHOUT ASBESTOS AND WITH A SILICA CONTENT OF < 1%).
entry date: OCT 1991 effective date: 29MAY1991

title: LIMIT VALUES FOR CHEMICAL SUBSTANCES IN THE WORKING ENVIRONMENT-RESOLUTION NO. 444/1991 OF THE MINISTRY OF WORK AND SOCIAL SECURITY (AMENDING REGULATION DECREE NO. 351/1979 UNDER LAW NO. 19587/1972: HYGIENE AND SAFETY AT WORK)
original : ARGOB*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA(ARGENTIAN OFFICIAL BULLETIN), 24170 , I , 1 , 1979
amendment: ARGOB*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA(ARGENTIAN OFFICIAL BULLETIN), 27145 , I , 4 , 1991

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file: 17.01 LEGAL rn : 300236
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : CAN type : REG

subject	specification	descriptor
AIR	OCC	TLV

Nuisance particulate - TWA: 10 mg/m3 total dust or 5 mg/m3 respirable dust. Prescribed by the Canada Occupational Safety and Health Regulations, under the Canada Labour Code (administered by the Department of Employment and Immigration). The regulations state that no employee shall be exposed to a concentration of an airborne chemical agent in excess of the value for that chemical agent adopted by ACGIH (American Conference of Governmental Industrial Hygienists) in its publication entitled: "Threshold Limit Value and Biological Exposure Indices for 1985-86". The regulations also state that the employer shall, where a person is about to enter a confined space, appoint a qualified person to verify by means of tests that the concentration of any chemical agent or combination of chemical agents will not result in the exposure of the person to a concentration in excess of the value indicated above. These regulations prescribe standards whose enforcement will provide a safe and healthy workplace.
entry date: OCT 1994 effective date: 24MCH1994

amendment: CAGAAK, CANADA GAZETTE PART II, 128 , 7 , 1513 , 1994

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file: 17.01 LEGAL rn : 523573
!!! WARNING - not original IRPTC record - WARNING !!!
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : DEU type : REG

subject	specification	descriptor
AQ USE	INDST	CLASS RQR

This substance is classified as moderately hazardous to water (Water Hazard Class: WHC 1). (There are 3 water hazard classes: WHC 3 = severely hazardous; WHC 2 = hazardous; WHC 1 = moderately hazardous; and the classification as "not hazardous to water"). The purpose of the classification is to identify the technical requirements of industrial plants which handle substances hazardous to water.
entry date: SEP 2001 effective date: 01JUN1999

title: Administrative Order relating to Substances Hazardous to Water (Verwaltungsvorschrift wassergefaehrdende Stoffe)
original : BUANZ*, Bundesanzeiger, 51 , 98a , 1 , 1999

****

file: 17.01 LEGAL rn : 1010015
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : MEX type : REG

subject	specification	descriptor
AIR	OCC	MXL

AT ANY WORKPLACE WHERE THIS SUBSTANCE IS PRODUCED, STORED OR HANDLED A MAXIMUM PERMISSIBLE LEVEL OF 10MG/M3 MUST BE OBSERVED OR 20MG/M3 FOR 15 MINUTES, FOUR TIMES A DAY WITH INTERVALS OF AT LEAST 1 HOUR. THERE SHOULD BE NO TOXIC IMPURITIES PRESENT.
entry date: DEC 1991 effective date: 28MAY1984

title: INSTRUCTION NO.10 RELATED TO SECURITY AND HYGIENIC CONDITIONS AT WORKPLACES. (INSTRUCTIVO NO. 10, RELATIVO A LAS CONDICIONES DE SEGURIDAD E HIGIENE DE LOS CENTROS DE TRABAJO).
original : DOMEX*, DIARIO OFICIAL, , , , 1984

****

file: 17.01 LEGAL rn : 1105628
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :pentaerythrite
cas no :115-77-5 rtecs no :RZ2490000
area : RUS type : REG

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 --------------------------------
|subject|specification|descriptor|
|-------+-------------+----------|
| AIR   |    OCC      |   MAC    |
|       |             |   CLASS  |
 --------------------------------
CLV: 4.0MG/M3 (AEROSOL) HAZ. CLASS: III
entry date: MAY 1990                          effective date:   MAR1989

amendment: PDKAD*, PREDELNO DOPUSTIMYE KONTSENTRATSII VREDNYKH
           VESHCHESTV V VOZDUKHERABOCHEI ZONY (MAXIMUM ALLOWABLE
           CONCENTRATIONS OF HARMFUL SUBSTANCES IN OCCUPATIONAL AIR),
           4952-89 , , , 1989


                                  *******


file: 17.01 LEGAL   rn : 1122830
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name    :Pentaerythritol
reported name  :Pentaerythritol
cas no         :115-77-5            rtecs no       :RZ2490000
area          : RUS                 type          : REG
 --------------------------------
|subject|specification|descriptor|
|-------+-------------+----------|
| AQ    |    SURF     |   MAC    |
|       |             |   CLASS  |
 --------------------------------
0.1MG/L HAZARD CLASS: II
entry date: JUL 1990                          effective date:  1JAN1989

amendment: SPNPV*, SANITARNYE PRAVILA I NORMY OKHRANY POVERKHNOSTNYKH
           VOD OT ZAGRIAZNENIA (HEALTH REGULATION AND STANDARDS OF
           SURFACE WATER PROTECTION FROM CONTAMINATION), 4630-88 , , ,
           1988


                                  *******


file: 17.01 LEGAL   rn : 1340171
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name    :Pentaerythritol
reported name  :Pentaerythritol
cas no         :115-77-5            rtecs no       :RZ2490000
area          : USA                 type          : REC
 --------------------------------
|subject|specification|descriptor|
|-------+-------------+----------|
| AIR   |    OCC      |   TLV    |
 --------------------------------
Time Weighted Avg (TWA) 10 MG/M3; the value is for total dust containing
no asbestos & <1% crystalline silica.; Summary - THIS THRESHOLD LIMIT
VALUE IS INTENDED FOR USE IN THE PRACTICE OF INDUSTRIAL HYGIENE AS A
GUIDELINE OR RECOMMENDATION IN THE CONTROL OF POTENTIAL HEALTH HAZARDS.
entry date: DEC 1991                          effective date:      1989

title: THRESHOLD LIMIT VALUES
original : ACGIH*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL
           HYGIENISTS, , , 11 , 1989
```

amendment: ACGIH*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL HYGIENISTS, , , 11 , 1991

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file: 17.01 LEGAL rn : 1408421
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : EEC type : REG

subject	specification	descriptor
FOOD		RQR
GOODS		MXL
GOODS		PRMT

THE SUBSTANCE IS INCLUDED IN THE LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES, WHICH SHALL BE USED FOR THE MANUFACTURE OF PLASTICS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS. THE USE OF THE SUBSTANCE IS SUBJECT TO THE RESTRICTIONS SPECIFIED THEREIN. PLASTIC MATERIALS AND ARTICLES SHALL NOT TRANSFER THEIR CONSTITUENTS TO FOODSTUFFS IN QUANTITIES EXCEEDING 10MG/DM2 OF SURFACE AREA OF MATERIAL OR ARTICLE OR 60 MG/KG OF FOODSTUFFS IN THE SPECIFIED CASES. VERIFICATION OF COMPLIANCE WITH THE MIGRATION LIMITS SHALL BE CARRIED OUT IN ACCORDANCE WITH DIRECTIVES 82/711/EEC AND 85/572/EEC.
entry date: SEP 1995 effective date: 01JAN1991

title: COMMISSION DIRECTIVE OF 23 FEBRUARY 1990 RELATING TO PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS (90/128/EEC)
original : OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L75 , , 19 , 1990
amendment: OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L90 , , 26 , 1993

****

file: 17.01 LEGAL rn : 1470472
!!! WARNING - not original IRPTC record - WARNING !!!
systematic name:1,3-Propanediol, 2,2-bis(hydroxymethyl)-
common name :Pentaerythritol
reported name :Pentaerythritol
cas no :115-77-5 rtecs no :RZ2490000
area : EEC type : REG

subject	specification	descriptor
MANUF	INDST	CLASS
IMPRT	INDST	CLASS

The substance is included in a list of existing substances produced or imported within the Community in quantities exceeding 1000 tonnes per year. - A system of data reporting by any manufacturer who has produced or any importer who has imported the substance, as such or in a preparation, in quanities exceeding 10 tonnes per year is established.
entry date: AUG 1999 effective date: 04JUN1993

title: Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances
original : OJECFC, Official Journal of the European Communities, L84 , , 1 , 1993