魚類急性毒性試験

1.供試物質の概要

名　称	日　本　名	ペンタエリスリトール		
	英　　名	Pentaerythritol		
	一般名・商品名			
構造式			分子式・示性式	
			分　子　量	136.15
			水への溶解度	
			蒸　気　圧	
入手先	和光純薬工業株式会社		製 造 年 月 日	1993 年 5 月 日
	TEL　　(　　)		ロ ッ ト 番 号	AMP7703
純　度	95%　　不純物：			
その他の物性等				

2.供試魚の概要

種名及び系統名	ヒメダカ		
由　来	機関育種		
飼育方法	馴致結果：死亡 0％ 餌の種類：テトラミン　　量：適量／回　給餌頻度：　1回／日		
平均体長	2.1 ± 0.1cm（n＝20）	平均体重	0.096 ±0.015g（n＝20）

3.試験条件

試験温度	23.0 ±　　0.2 ℃	
希釈水	供給源	脱塩素水道水
	水　質	pH： 7.5　　Ca／Mg比： 2.9　　Na／K比： 2.3 硬度： 37　　アルカリ度： 33 その他： 水質測定年月日：　　1994 年　1 月　27 日

試験溶液	状　態	無色透明
	保管方法	冷蔵庫（冷暗所）
	調製方法	希釈水に直接溶解
飼育方法	半止水式	
	半止水式の場合	換水方法：全量交換　　頻度：１回／１日
	流水式の場合	
光　源	蛍光灯	照光周期：１６Ｌ８Ｄ

4．試験結果

（１）　魚類急性毒性試験結果（→様式3-1）

5．その他、特記事項

（様式3-1）　　魚類急性毒性試験結果（限度試験）

供試物質名　：ペンタエリスリトール
試験実施期間：１９９３年１０月　４日　～１９９３年１０月　８日　（　　４日間）
試験実施機関：福岡県保健環境研究所
濃度公比　　：

区分	溶液量	物質濃度	助剤濃度	試験開始時			２４時間			４８時間			７２時間			９６時間		
	L	mg/L	mg/L	供試魚数	ｐＨ	ＤＯ mg/L	生存数	ｐＨ	ＤＯ mg/L	生存数	ｐＨ	ＤＯ mg/L	生存数	ｐＨ	ＤＯ mg/L	生存数	ｐＨ	ＤＯ mg/L
対照	2	0	0	10	7.3	7.5	10	7.1 7.4	6.2 7.7	10	7.1 7.4	6.2 7.7	10	7.1 7.4	5.9 7.8	10	7.0	6.1
助剤対照																		
1	2	100	0	10	7.6	7.5	10	7.2 7.5	6.1 7.5	10	7.1 7.5	6.1 7.7	10	7.1 7.5	6.1 7.7	10	7.1	6.1
2																		
3																		
4																		
5																		
観察事																		

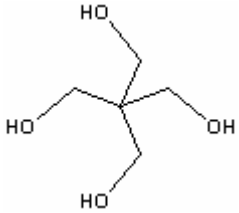
＊　　供試物質濃度を測定した場合、その値を（　）の中に入れて物質濃度欄に記入すること。
＊＊　ｐＨ，ＤＯは上段に換水前、下段に換水後の測定値を記入すること。

試験開始後９６時間で大部分の魚が生存した最高濃度	＞ 100 mg/L
試験開始後４８時間で大部分の魚が死亡した最低濃度	＞ 100 mg/L

【本試験の設定濃度及び設定根拠】

公比	設定濃度区（mg/L）					設定根拠
	1	2	3	4	5	
						限度試験結果より本試験不要

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

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.