SIDS INITIAL ASSESSMENT PROFILE

24800-44-0			
Tripropylene glycol			
HO[CH(CH ₃)CH ₂ O] ₃ H			
CONCLUSIONS AND RECOMMENDATIONS			
-			

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 LC₅₀ values were gained from test results; LC₅₀ = > 1,000 mg/l (acute fish); EC₅₀ = > 1,000 mg/l (acute daphnia); EC₅₀ = > 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

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 $LC_{50} = > 1,000 \text{ mg/l}$ (acute fish); 24h $EC_{50} = > 1,000 \text{ mg/l}$ (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.

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	
<i>Oryzias latipes</i> (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	

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

Notes: ^{*1} Mor; mortality, Rep; reproduction.

4. <u>ECOTOXICOLOGICAL DATA</u>

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:	$LC_{50} (24h) > 1,000 \text{ mg/l}$	
	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 Oryzias 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:	<pre>static [X]; semi-static []; flow-through []; other [];</pre>
	open-system [X]; closed-system []
Species:	Daphnia magna
Exposure period:	24 hr
Results:	$EC_{50} (24h) = > 1,000 \text{ mg/l}$
	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 []

72 hr	
Biomass:	$EC_{50}(24h) =$
	EC_{50} (72h) > 1,000 mg/l
	NOEC = $> 1000 \text{ mg/l} (p < 0.05)$
	LOEC =
: Yes [] No [X	[] ? []
OECD Test	Guideline 201 (1984)
open-system	[X]; closed-system []
Yes [] No [X] ? []
Tripropylene	glycol, purity = 97%
The EC ₅₀ val	ues were calculated based on 5 nominal
Concentratio	ns (95-1000 mg/l) and laboratory water control.
EA, Japan (1	992)
	72 hr Biomass: (; Yes [] No [X OECD Test open-system Yes [] No [Tripropylene The EC ₅₀ val Concentratio EA, Japan (1

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

static []; semi-	<pre>static [X]; flow-through []; other [];</pre>
open-system [X	X]; closed-system []
Daphnia magna	<i>a</i>
Mortality [X]; l	Reproduction rate [X]; Other []
21 day	•
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
1	EC_{50} (21 d) > 1,000 mg/l
	NOEC = $> 1,000 \text{ mg/l}$
	LOEC = > 1,000 mg/l
Yes [] No [X] ? []
OECD Test Gu	ideline 202 (1984)
Yes [] No [X] ? []
Tripropylene gl	ycol, purity = 97%
40 daphnids (4	replicates; 10 organisms per replicate) were exposed
• ·	
to 5 nominal co	oncentrations (10-1000 mg/l), control of DMSO:
to 5 nominal co HCO-40= 9:1 (oncentrations (10-1000 mg/l), control of DMSO: 320 mg/l) and laboratory water control.
	static []; semi- open-system [2 <i>Daphnia magna</i> Mortality [X]; 1 21 day Mortality: Reproduction: Yes [] No [X] OECD Test Gu Yes [] No [X] Tripropylene gl 40 daphnids (4

要 旨

試験委託者

環境庁

<u>表 題</u>

リン酸トリス(イソプロピルフェニル)の藻類(Selenastrum capricornutum)に対する 生長阻害試験

試験番号

NMMP/E09/1090

試験方法

本試験は、OECD 化学品テストガイドライン No. 201「藻類生長阻害試験」(1984 年)に準拠して実施した。

- 1) 被験物質 :リン酸トリス (イソプロピルフェニル)
- 2) 培養方式 :振とう培養(100rpm)
- 3)供試生物種 : Selenastrum capricornutum (ATCC-22662)
- 4) 温度 : 23±2 ℃
- 5) 暴露期間 : 72 時間
- 6) 試験液量 : 100 mL (OECD 培地)
- 7) 照明 :4000 ~ 5000 lux (連続照明)
- 8) 初期細胞濃度 :1×10⁴ cells/mL
- 9) 試験濃度(設定): 対照区、助剤対照区(100mg/L)、500.0mg/L(最高分散濃度)

追加試驗 : 対照区、助剤対照区(100mg/L)、62.5mg/L、125.0mg/L、250.0mg/L

10)試験液中の被験物質の分析

:HPLC法(暴露開始時、終了時)

結 果

生長曲線下の面積の比較による生長阻害濃度
EbC50 (0-72) = 106.7mg/L以上
無影響濃度 (NOEC(面積法 0-72)) = 12.8mg/L

2) 生長速度の比較による生長阻害濃度

ErC50 (24-48) = 106.7mg/L以上 無影響濃度 (NOEC(速度法 24-48) = 106.7mg/L以上 ErC50 (24-72) = 106.7mg/L以上 無影響濃度 (NOEC(速度法 24-72) = 106.7mg/L以上

(上記濃度は、全て実測濃度に基づく値)

リン酸トリス (p-クメニル)(CAS 26967-76-0)





毒性値

0-72hErC50(実測値に基づく)>110 mg/L 0-72hNOECr(実測値に基づく)=13 mg/L

要 旨

試験委託者

環境庁

表 題

リン酸トリス (イソプロピルフェニル)のオオミジンコ (Daphnia magna)に対する急性遊泳 阻害試験

試験番号

NMMP/E09/2090

試験方法

本試験は、OECD 化学品テストガイドライン No.202「ミジンコ類、急性遊泳阻害試験および 繁殖試験」(1984年)に準拠して実施した。

1)被験物質	:リン酸トリス (イソプロピルフェニル)
2)暴露方法	:止水式
3)供試生物	:オオミジンコ (Daphnia magna)
4)暴露期間	: 48 時間
5)連数	:1濃度区に付き4連
6)生物数	:20 頭/1濃度区(1連に付き5頭で1濃度区 20 頭)
7)試験濃度	: 対照区、助剤対照区、70.0mg/L
	試験液が白濁するため、試験可能最高濃度を 70.0mg/L とした。
8)試験水量	: 100 mL
9)照明	: 室内光、16 時間明/8 時間暗
10)試験水温	$: 20 \pm 1^{\circ}$ C

<u>結 果</u>

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1)24 時間暴露後の結果

24 時間半数遊泳阻害濃度(EiC50)=70.0mg/L以上

2)48時間暴露後の結果

48 時間半数遊泳阻害濃度(EiC50)=70.0mg/L以上

最大無作用濃度(NOECi)=70.0mg/L以上

100%阻害最低濃度=70.0mg/L以上

(上記濃度は、全て設定濃度に基づく値)



Mortality or Immobility in Daphnia magna

要 旨

試験委託者

環境庁

表 題

リン酸トリス (イソプロピルフェニル)のオオミジンコ (Daphnia magna)に対する繁殖阻害 試験

試験番号

NMMP/E09/3090

試験方法

本試験は、OECD 化学品テストガイドライン No. 202「ミジンコ類、急性遊泳阻害試験および 繁殖試験」(1984年4月採択)の改訂版であるガイドライン No. 211「オオミジンコ繁殖試験」 (1997年4月提案)に準拠して実施した。

- 1) 被験物質 : リン酸トリス (イソプロピルフェニル)
- 2) 暴露方法 : 半止水式(週に3回、試験液の全量を交換)
- 3)供試生物 : オオミジンコ (Daphnia magna)
- 4) 暴露期間 : 21 日間
- 5) 試験濃度 : 対照区、助剤対照区、40.0mg/L(設定濃度) (助剤濃度100mg/L、助剤 HCO-40)
- 6) 試験液量 : 1 容器(連) につき 80 mL
- 7) 連数 : 10 容器 (連) / 濃度区
- 8)供試生物数 : 10頭/濃度区(1連につき1頭)
- 9) 試験温度 : 20±1℃
- 10)照明 : 室内光、16 時間明/8 時間暗

11) 被験物質の分析 : HPLC 法

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結 果

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1) 試験液中の被験物質濃度

被験物質が水に難溶であり、助剤を用いて調製した試験液が白濁したため、ミジンコの産 出幼体が計数できる最高濃度40.0mg/Lで試験を実施した。

実測濃度が設定濃度の±20%以内であったので結果の算出には設定濃度を用いた。

- 2) 21 日間の親ミジンコの半数 致死濃度 (LC50) = 40.0mg/L以上
- 3) 21 日間の 50% 繁殖阻害濃度 (ErC50) = 40.0mg/L以上
- 4) 21 日間の最大無作用濃度(NOECr) = 40.0mg/L以上
- 5) 21 日間の最小作用濃度(LOECr) = 40.0mg/L以上

(上記濃度は、設定濃度に基づく値である)

Figure 1 Cumulative Numbers of Dead Parental Daphnia



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Figure 2 Mean Cumulative Numbers of Juveniles Produced per Adult ($\Sigma F1/P$) during 21 days

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