FOREWORD INTRODUCTION

DIBUTYL ADIPATE

CAS N°:105-99-7

SIDS Initial Assessment Report

For

SIAM 4

Tokyo, Japan, 20-22 May 1996

1. Chemical Name: Dibutyl adipate

2. CAS Number: 105-99-7

3. Sponsor Country: Japan

National SIDS Contact Point in Sponsor Country:

Mr. Yasuhisa Kawamura, Ministry of Foreign Affairs, Japan

4. Shared Partnership with:

5. Roles/Responsibilities of the Partners:

- Name of industry sponsor /consortium
- Process used

6. Sponsorship History

- How was the chemical or category brought into the OECD HPV Chemicals Programme ?

As a high priority chemical for initial assessment, dibutyl adipate was selected in the framework of the OECD HPV Chemicals Programme. SIDS Dossier and Testing Plan were reviewed at a SIDS Review Meeting in 1994, where the following SIDS Testing Plan was agreed.

No testing ( )

Testing(X) Physical-Chemical Properties
- Vapour pressure
- Partition coefficient

Environmental fate/Biodegradation
- Biodegradation
- Photodegradation
- Stability in water

Ecotoxicity
- Acute toxicity to fish
- Acute toxicity to daphnids
- Toxicity to algae
- Chronic toxicity to daphnids

Toxicity
- Repeated dose toxicity
- Reproductive toxicity

Gene mutation
Chromosomal aberration in vitro

At SIAM-2, conclusions were approved with comments. Comments at SIAM-2: Rearrangement of the documents, especially, reproductive endpoint.

7. Review Process Prior to the SIAM:

8. Quality check process:

9. Date of Submission: Date of Circulation: April 30, 1996

10. Date of last Update:

11. Comments:

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	105-99-7
Chemical Name	Dibutyl adipate
Structural Formula	$C_4H_9OOC\text{-}CH_2CH_2CH_2CH_2\text{-}COOC_4H_9$

CONCLUSIONS AND RECOMMENDATIONS

The chemical does not reveal any remarkable toxicity or ecotoxicity.

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

Dibutyl adipate is volatile liquid and production volume is less than 100 tonnes/year in 1987 - 1992 in Japan. This chemical is used as for plasticizer for resins mainly. Dibutyl adipate is readily biodegradable. Dibutyl adipate is not hydrolyzed at pH 4, but hydrolysed at 7 and 9. The half-life is a week at pH 9. Direct photodegradation is not expected because dibutyl adipate does not absorb UV light.

The potential environmental distribution of dibutyl adipate obtained from a generic fugacity model (Mackay level III) showed the chemical will be distributed mainly to water and soil. The predicted environmental concentration (PEC_{local}) of this chemical was estimated to be 4×10^{-3} mg/l from Japanese exposure scenario.

For the environment, various NOEC and LC_{50} values were gained from test results; LC_{50} = 3.7 mg/l (acute fish); EC_{50} = 17 mg/l (acute daphnia); NOEC = 2.0 mg/l (algae); NOEC = 5.6 mg/l (long-term daphnia reproduction). Therefore, the chemical is considered to be moderately toxic to fish and daphnids and slightly toxic to algae. The lowest toxicity result for *Selenastrum capricornutum* (NOEC = 2.0 mg/l) was adopted for the calculation of a PNEC, applying an assessment factor of 100. Thus the PNEC of the chemical is 0.02 mg/l. Since the PEC is lower than the PNEC, environmental risk is presumably low.

As dibutyl adipate is produced in a closed system, exposure during synthesis may be excluded. This chemical is mainly used as a plasticizer for resins. There is a possibility of workplace exposure when the product is filled into barrels, with skin contact considered to be the main exposure route. Inhalation plays a minor role because the vapour pressure of this chemical is very low. Workers wear safety glasses and gloves during the filling process. Exposure levels calculated by the EU exposure model are 0.5 - 3.0 by inhalation and 0.1 - 1 mg/mg/m^2/day by dermal, respectively, at production site of this chemical. There are no actual measurement data of exposure. By wearing safety equipment during filling process, the exposure level can be very low.

The chemical is contained in consumer floor wax as a. Dermal exposure of this chemical is expected during housekeeping. The exposure level was estimated to be 3.6 mg/kg bw/day for one event.

For indirect exposure via the environment, the concentration in drinking water was estimated as to be less than 4×10^{-3} mg/l from the local exposure scenario.

Although the chemical showed positive result in chromosomal aberration test *in vitro* with metabolic activation, no genotoxic effects were observed in bacteria and no chromosomal aberration were observed *in vitro* without metabolic activation. In a combined repeat dose and reproductive/developmental toxicity screening test, salivation was observed in both sexes given 1,000 mg/kg/day. No test substance-related changes were noted in body weight gains, food consumption, findings obtained from haematology testing, blood chemical examination, urinalysis and pathological examination. For reproductive/developmental end-points, there were no adverse effects of this chemical on copulation, fertility, maintenance of pregnancy, parturition and lactation. In the 1,000 mg/kg group, pup weight on day 0 and 4 of lactation was slightly lower and viability on day 4 of lactation was decreased compared to those of

the control group. However, there were no malformations which were considered to be induced by this chemical. Therefore, the NOEL was 300 mg/kg/day for repeated dose toxicity as well as 300 mg/kg/day for reproductive toxicity.

For human health, margins of safety are considered to be sufficient. 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: 105-99-7		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point			- 38 °C
2.2	Boiling Point			183 °C (at 1013 hPa)
2.3	Density			No data available
2.4	Vapour Pressure		OECD TG 104	2.1 x 10^{-2} Pa at 25 °C
2.5	Partition Coefficient (Log Pow)		OECD TG 107	4.17 at 25 °C
2.6 A.	Water Solubility		OECD TG 105	35 mg/L at 25 °C
B.	pH			No data available.
	pKa			Not observed.
2.12	Oxidation: Reduction Potential			No data available.
ENVIRONMENTAL FATE AND PATHWAY				
3.1.1	Photodegradation			Half-life in water: Infinite
3.1.2	Stability in Water		OECD TG 111	Stable at pH 4.0 Half-life time: pH 7.0= 1850 day PH 9.0= 7.31 day
3.2	Monitoring Data			No data available.
3.3	Transport and Distribution		Calculated (Fugacity level III model)	If released 100% to water: In Air: 0.04% In Water: 34.60% In Soil: 34.97% In Sediment: 30.39%
3.5	Biodegradation		OECD TG 301C	Readily biodegradable: 86-95% (BOD) in 28 days, 100% (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} (96hr): 3.7 mg/L
4.2	Acute Toxicity to Aquatic Invertebrates (*Daphnia*)	*Daphnia magna*	OECD TG 202	EC_{50} (24hr): 17 mg/l
4.3	Toxicity to Aquatic Plants e.g. Algae	*Selenastrum capricornutum*	OECD TG 201	EC_{50} (72hr): 2.8 mg/l NOEC: 2.0 mg/l
4.5.2	Chronic Toxicity to Aquatic Invertebrates (*Daphnia*)	*Daphnia magna*	OECD TG 202	EC_{50} (21d, Immobility): 4.3 mg/l EC_{50} (21d, Reproduction): 8.9 mg/l NOEC (21d, Repro): 5.6 mg/l
4.6.1	Toxicity to Soil Dwelling Organisms			No data available.

CAS NO: 105-99-7		SPECIES	PROTOCOL	RESULTS
4.6.2	Toxicity to Terrestrial Plants			No data available.
(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}: 1,290 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	Japanese TG	NOAEL = 1,000 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	Negative (With metabolic activation) Negative (Without metabolic activation)
B.	Non-Bacterial In Vitro Test (Chromosomal aberrations)	CHL cells	OECD Guideline No.473 and Japanese Guidelines	Positive (With metabolic activation) Negative (Without metabolic activation)
5.6	Genetic Toxicity In Vivo			No data available.
5.8	Toxicity to Reproduction	Rat	OECD Preliminary Reproduction Test	NOAEL Parental = 1,000 mg/kg/day NOAEL F1 offspring = 300 mg/kg/day
5.9	Developmental Toxicity/ Teratogenicity			
5.11	Experience with Human Exposure			

SIDS Initial Assessment Report

1 DENTITY

1.1 Identification of the Substance

CAS Number: 105-99-7
IUPAC Name: Hexanedioic acid, dubutyl ester
Molecular Formula: $C_{14}H_{28}O_4$

Structural Formula: $C_4H_9OOC\text{-}CH_2CH_2CH_2CH_2\text{-}COOC_4H_9$

Synonyms: Dibutyl adipate

1.2 Purity/Impurities/Additives

Degree of Purity: > 99 %

Major Impurities: Unknown

Essential Additives: None

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

Property	Value
Melting point	-38 °C
Boiling point	183 °C
Vapour pressure	2.1×10^{-2} Pa at 25 °C
Water solubility	35 mg/l
Partition coefficient n-octanol/water (log value)	4.17

2 GENERAL INFORMATION ON EXPOSURE

Dibutyl adipate is a stable liquid, and the production volume was ca. 100 tonnes/year in 1987 – 1992 in Japan. Most of this amount was sold and handled in Japan. This chemical is used as a plasticizer. All disposal wastes are treated by incineration. Dibutyl adipate seems to be released into water and air from its production sites after biological treatment. No specific monitoring data of the chemical is available.

Dibutyl adipate is not hydrolyzed at pH 4, but hydrolysed at 7 and 9. The half-lives are 1850 days and 7.3 days at pH 7 and pH 9, respectively. Direct photodegradation is not expected because dibutyl adipate does not absorb UV light. The chemical is classified as "readily biodegradable" (OECD 301C: 86 - 95 % after 28d).

2.1 Environmental Exposure and Fate

2.1.1 Sources of Environmental Exposure

Global exposure

The potential environmental distribution of dibutyl adipate obtained from a generic level III fugacity model is shown in Table 2. The results show that if dibutyl adipate is released mainly to air and soil, it is likely to distribute into soil. But, if dibutyl adipate is released mainly to water, it is likely to be transported to water, soil and sediment. Due to the low vapour pressure of dibutyl adipate, it is unlikely to distribute into air (MITI & EA, Japan, 1994b).

Table 2: Environmental distribution dibutyl adipate using a generic level III fugacity model.

Compartment	Release: 100% to air	Release: 100% to water	Release: 100% to soil
Air	0.12%	0.04%	0.00%
Water	0.26%	34.60%	0.18%
Soil	99.40%	34.97%	99.66%
Sediment	0.22%	30.39%	0.16%

Local exposure

According to a Japanese manufacturer, 13 kg/year (estimated) of dibutyl adipate are released with 32,000 tonnes/year of effluent into a river (flow rate 63,000,000,000 tonnes/year). The local predicted environmental concentration (PEC_{local}) is 0.004 mg/l, employing the following calculation model. In this case, the dilution factor is estimated to be 1000.

$$\frac{\text{Amount of release } (1.3 \times 10^7 \text{ mg/y})}{\text{Volume of effluent } (3.2 \times 10^7 \text{ l/y}) \times \text{Dilution factor } (1000)}$$

2.1.2 Photodegradation

Direct photodegradation is not expected because dibutyl adipate does not absorb UV light.

2.1.3 Stability in Water

Dibutyl adipate is not hydrolyzed at pH 4, but hydrolysed at 7 and 9. The half-lives are 1850 days and 7.3 days at pH 7 and pH 9, respectively (OECD TG 111) (MITI, Japan, 1994b).

2.1.4 Biodegradation

If released into water, this substance is readily biodegraded (MITI (I), corresponding to the OECD 301C: 86 - 95 % during 28 days based on BOD and 100 % based on GC analysis) (MITI, Japan, 1994b).

2.1.5 Bioaccumulation

No data are available.

2.2 Human Exposure

2.2.1 Occupational Exposure

As dibutyl adipate is produced in a closed system, exposure during synthesis may be excluded. This chemical is mainly used as a plasticizer for resins. There is a possibility of a slight workplace exposure when the product is filled into barrels, with skin contact considered to be the main exposure route. Inhalation uptake plays a minor role because the vapour pressure of dibutyl adipate is very low.

The exposure level calculated by the EU Exposure Model, using the physical-chemical properties above, is as follows:

(1) at the production site:

A. Inhalation 0.5 - 3.0 ppm

B. Dermal 0.1 – 1 mg/cm^2/day

(2) at a use site:

A. Inhalation 200 - 500 ppm

B. Dermal 5 - 15 mg/cm^2/day

There are no actual exposure measurement results. Workers wear safety glasses and gloves during the filling process. Therefore, the exposure to worker is estimated to be low.

2.2.2 Consumer Exposure

Dibutyl adipate is contained in floor wax as a consumer product. Dermal exposure of dibutyl adipate is expected during housekeeping.

Density of product (floor wax)	1000 mg/cm3
Weight fraction of dibutyl adipate	10 %
Thickness of film layer on skin	0.01 cm (default value)
Surface area of exposed skin	250 cm^2

Frequency of use	l event x 1 hour per day for 1 day 6 times a year
Body weight	70 kg

Cder = 1,000 x 0.1 = 100 mg of substance per cm^3 of floor wax

Eder1 = 100 x 0.01 x 250 = 250 mg/event (i.e. 1 hour of use)

Eder2 = 250 x 1 x 70-1 = 3.6 mg/kg body weight/day

2.2.3 Exposure via the environment

The highest exposure to the general population via the environment would be expected through drinking water processed from surface water. Based on the physical chemical properties of dibutyl adipate, a significant removal of during processing is not expected. Although PEC_{global} cannot be estimated, the concentration in drinking water is assumed to be less than 0.004 mg/l.

3 HUMAN HEALTH HAZARDS

3.1 Effects on Human Health

3.1.1 Acute Toxicity

LD_{50} in acute oral toxicity studies in rats were reported to be 1,290 mg/kg. No data are available on inhalation or dermal acute toxicity data of dibutyl adipate.

3.1.2 Repeated Dose Toxicity

There is only one key study on repeated dose toxicity with dibutyl adipate. This chemical was studied for oral toxicity in rats according to the 28-day repeated dose toxicity test [Japanese TG]. As the study was well controlled and conducted under GLP, it is regarded as a key study. Male and female SD rats were orally administered (gavage) at doses of 0, 20, 140 and 1,000 mg/kg/day.

No test substance-related changes were noted in clinical observations, body weight gains, food consumption, and the findings obtained from hematology testing, blood chemical examination, urinalysis, and pathological examination. The NOAELs were considered to be 1,000 mg/kg/day in both sexes (MHW, 1996b).

3.1.3 Mutagenicity

In vitro Studies

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 the pre-incubation method. This study was well controlled and regarded as a key study.

Dibutyl adipate 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 a metabolic activation system (MHW, 1996b).

Non-bacterial test

A 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 within no apparent cytotoxic effect in continuous treatment. In short term treatment, it was set to 2.6 mg/ml because the concentration was equivalent to ca. 10 mM as required in the test guidelines. Structural chromosomal aberrations were observed with metabolic activation (MHW, 1996b).

In vivo Studies

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

3.1.4 Toxicity for Reproduction

Dibutyl adipate was studied for oral toxicity in rats according to the OECD Preliminary reproduction toxicity test [OECD TG] at doses of 0, 100, 300 and 1,000 mg/kg/day (MHW, Japan, 1996a).

Copulation, ovulation, fertility, maintenance of pregnancy, and parturition and lactation were not affected by the test compound. Reproductive parameters (i.e., duration of gestation, number of corpora lutea, implantations and resorptions, litter size, and sex ratio distribution) were comparable among all four groups including controls. In the 1,000 mg/kg group, pup weight on postnatal days 0 and 4 was slightly decreased along with viability on postnatal day 4. Thus the NOEL was considered to be 1,000 mg/kg/day for reproduction in male and female rats and 300 mg/kg/day for the F_1 generation. Concerning maternal and paternal general toxicity, no mortalities occurred in any group. There were no toxic effects of this chemical on the general condition of male and female animals. Slight suppression of body weight gain was observed in males in 1,000 mg/kg group, while body weight change in females and food consumption in male and female animals in all compound treated groups were comparable to those in the controls. Macroscopic findings at necropsy and histological findings for the internal genitalia showed no abnormalities. Kidney weights were increased in males and females of the 1,000 mg/kg groups compared to the control values. Thus the NOEL for general toxicity of this chemical in parent animals was considered to be 300 mg/kg/day.

3.2 Initial Assessment for Human Health

Although the chemical showed positive result in chromosomal aberration test in vitro with metabolic activation, no genotoxic effects in bacteria and chromosomal aberration in vitro without metabolic activation were observed. In a 28-day repeated dose toxicity test in rats at doses of 0, 20, 140 and 1,000 mg/kg/day, no test substance-related changes were noted in clinical observations, body weight gains, food consumption, and the findings obtained from hematology testing, blood chemical examination, urinalysis, and pathological examination. The NOAEL were considered to be 1,000 mg/kg/day in both sexes.

For reproductive/developmental end-points, there were no adverse effects of this chemical on copulation, fertility, maintenance of pregnancy, parturition and lactation. In the 1,000 mg/kg group, pup weight on day 0 and 4 of lactation was slightly lower and viability on day 4 of lactation was decreased compared to those of the control group. However, there were no malformations which were considered to be induced by this chemical. Therefore, NOEL was 300 mg/kg/day for repeated dose toxicity as well as 300 mg/kg/day for reproductive toxicity.

Based on the exposure levels estimated above, for human health, the margins of safety are considered to be sufficient. Therefore, the health risk is presumably low.

4 HAZARDS TO THE ENVIRONMENT

4.1 Aquatic Effects

Dibutyl adipate 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]. Acute and chronic toxicity data to test organisms for dibutyl adipate are summarized in Table 3. No other ecotoxicological data are available (EA, Japan, 1994).

Various NOEC and LC_{50} values were gained from above tests; 96h-LC_{50} = 3.7 mg/l (acute fish); 24h EC_{50} = 17 mg/l (acute daphnia); 72h EC_{50} = 2.8 mg/l (acute algae); 21d NOEC = 5.6 mg/l (long-term daphnia reproduction). Therefore, the chemical is considered to be moderately toxic to fish, daphnids and algae. As the lowest chronic toxicity result, the NOEC (biomass) of *Selenastrum capricornutum* (algae) of 2.0 mg/l was adopted. An assessment factor of 100 is applied. Thus the PNEC of dibutyl adipate is 0.02 mg/l.

Table 3. Acute and chronic toxicity data of dibutyl adipate to aquatic organisms.

Species	Endpoint[*1]	Conc. (mg/L)	Reference
Selenastrum capricornutum (algae)	Biomass: EC_{50} (72h) NOEC:	2.8 mg/L 2.0 mg/L	MOE, Japan. (1992)
Daphnia magna (water flea)	Mor: LC_{50}(24h) Imm: EC_{50}(21d) Rep: EC_{50}(21d) NOEC(21d)	17 mg/L 4.3 mg/L 8.9 mg/L 5.6 mg/L	
Oryzias latipes (fish, Medaka)	Mor: LC_{50}(24h) Mor: LC_{50}(72h) Mor:LC_{50}(96h)	5.1 mg/L 3.7 mg/L 3.7 mg/L	

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

4.2 Initial Assessment for the Environment

Dibutyl adipate is readily biodegradable (OECD 301C: 86-95 by BOD % after 28d). Dibutyl adipate is not hydrolyzed at pH 4, but hydrolysed at 7 and 9. The half-life is a week at pH 9. Direct photodegradation is not expected because dibutyl adipate does not absorb UV light.

The potential environmental distribution of dibutyl adipate 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 this chemical was estimated as 4 x 10^{-3} mg/l from a Japanese exposure scenario.

For the environment, various NOEC and LC_{50} values were gained from test results; 96h LC_{50} = 3.7 mg/l (acute fish); 24h EC_{50} = 17 mg/l (acute daphnia); 72h NOEC = 2.0 mg/l (acute algae); 21d NOEC = 5.6 mg/l (long-term daphnia reproduction). Therefore, the chemical is considered to be moderately toxic to fish and daphnids and slightly toxic to algae. As the lowest chronic toxicity result, the NOEC for *S. capricornutum* (2.0 mg/l) was adopted. As assessment factor of 100 is applied. Thus PNEC of the chemical is 0.02 mg/l. Since the PEC is lower than the PNEC, environmental risk is presumably low.

5 RECOMMENDATIONS

The chemical does not reveal any remarkable toxicity or ecotoxicity.

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

6 REFERENCES

EA, Japan (1994) "Investigation of 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 & MITI, Japan (1993) Unpublished Report on Exposure Estimation (HPV/SIDS Test conducted by EA and MITI, Japan)

MHW, Japan (1996a) Toxicity testing report, Vol. 4, 305-313.

MHW, Japan (1996b) Toxicity testing report, Vol. 3, 241-257.

MITI, Japan (1994a): Unpublished data

MITI, Japan (1994b) Unpublished Report (HPV/SIDS Test conducted by MITI, Japan. Test was performed in Chemicals Inspection and Testing Institute, Japan)

SIDS DOSSIER

Dibutyl adipate

CAS No. 105-99-7

Sponsor Country: Japan

S I D S P R O F I L E

1.01 A.	**CAS No.**	105-99-7
1.01 C.	**CHEMICAL NAME (OECD Name)**	Dibutyl adipate
1.01 D.	**CAS DESCRIPTOR**	Not applicable
1.01 G.	**STRUCTURAL FORMULA**	$C_4H_9OOC\text{-}CH_2CH_2CH_2CH_2\text{-}COOC_4H_9$
	OTHER CHEMICAL IDENTITY INFORMATION	
1.5	**QUANTITY**	In Japan, < 100 tonnes/year in 1987 - 1992.
1.7	**USE PATTERN**	Plastcizer in Japan Rodenticide in Europe
1.9	**SOURCES AND LEVELS OF EXPOSURE**	In Japan, 1. Amount released from production site to water is 13 kg/year
ISSUES FOR DISCUSSION (IDENTIFY, IF ANY)		

S I D S S U M M A R Y

CAS NO: 105-99-7		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	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
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	Y	N	N	Y	N	Y	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								

1.01 SUBSTANCE INFORMATION

A.	**CAS-Number**	105-99-7
B.	**Name (IUPAC name)**	Dibutyl adipate
C.	**Name** *(OECD name)*	Dibutyl adipate
D.	**CAS Descriptor**	Not applicable
E.	**EINECS-Number**	203-350-4
F.	**Molecular Formula**	$C_{14}H_{28}O_4$
G.	**Structural Formula**	

$$C_4H_9OOC\text{-}CH_2CH_2CH_2CH_2\text{-}COOC_4H_9$$

H.	**Substance Group**	Not applicable
I.	**Substance Remark**	None
J.	**Molecular Weight**	258.40

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**	
	Name:	Same as above contact person
	Address:	

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 99 %

1.2 SYNONYMS Dibutyl adipate

1.3 IMPURITIES Unknown

1.4 ADDITIVES Unknown

1.5 QUANTITY

Location	Production (tonnes)	Date
Japan	< 100/year	1987-1992

Reference: MITI, Japan (1994a)

1.6 LABELLING AND CLASSIFICATION

None

1.7 USE PATTERN

A. General

Type of Use:	**Category:**
(1) Industry use	Plasticizer
(2) Direct use	Rodenticide

Reference: (1) MITI, Japan (1994a)
(2) ECDIN Database (1994)

B. Uses in Consumer Products

Contained in printing ink and floor wax

Reference: MITI, Japan (1994a)

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUE

None

1.9 SOURCES OF EXPOSURE

Source: Media of release: Water from a production site
Quantities per media: 13 kg/year

Reference: MITI, Japan (1994a)

1.10 ADDITIONAL REMARKS

A. Options for disposal Incineration

Reference: MITI, Japan (1994a)

B. Other remarks None

2.1 MELTING POINT

Value:	- 38 °C
Decomposition:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Sublimation:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Method:	
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Reference:	Lange's Hamdbook of Chemistry, 11th Ed.

2.2 BOILING POINT

(a)

Value:	183 °C
Pressure:	
Decomposition:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Method:	
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Reference:	Lange's Handbook of Chemistry, 11th Ed.

(b)

Value:	145 °C
Pressure:	0.533 hPa
Decomposition:	Yes **[ ]** No **[X]** Ambiguous **[ ]**
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Reference:	Company data

2.3 DENSITY (Relative density)

No data available

2.4 VAPOUR PRESSURE

Value:	2.1×10^{-2} Pa
Temperature:	25°C
Method:	calculated **[ ]**; measured **[X]** OECD Test Guideline 104 Dynamic method
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Reference:	MITI, Japan (1994b)

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

Log Pow:	4.17
Temperature:	25 °C
Method:	calculated **[ ]**; measured **[X]** OECD Test Guideline 107
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Reference:	MITI (1994b)

2.6 WATER SOLUBILITY

A. Solubility

Value:	35 mg/l
Temperature:	25 °C

Description:	Miscible **[ ]**; Of very high solubility **[ ]**; Of high solubility **[ ]**; Soluble **[ ]**;Slightly soluble **[ ]**; Of low solubility **[X]**; Of very low solubility **[ ]**; Not soluble **[ ]**
Method:	OECD Test Guideline 105
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Reference:	MITI, Japan (1994b)

B. pH Value, pKa Value

No data available

2.7 FLASH POINT

Value:	161 °C
Type of test:	Closed cup [ ]; Open cup [X]; Other [ ]
Method:	Unknown
GLP:	Yes **[ ]** No **[X]** ? **[ ]**
Reference:	Company data

2.8 AUTO FLAMMABILITY

No data available

2.9 FLAMMABILITY

No data available

2.10 EXPLOSIVE PROPERTIES

No data available

2.11 OXIDIZING PROPERTIES

No data available

2.12 OXIDATION: REDUCTION POTENTIAL

No data available

2.13 ADDITIONAL DATA

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

No data available

B. Other data

None

3.1 STABILITY

3.1.1 PHOTODEGRADATION

Type:	Air **[ ]**; Water **[X]**; Soil; Other **[ ]**	
Light source:	Sunlight **[X];** Xenon lamp **[ ];** Other **[ ]**	
Spectrum of substance:	epsilon = 0.0 at 300 nm	
	Estimated parameter for calculation:	
	Quantum yeild	0.01
	Concentration	5×10^{-5} M
	Depth of water body	500 cm
	Conversion constant	6.023×10^{20}
Result:	Degradation rate	0.0 mol / l / s
	Half life	Infinite
Reference:	W. J. Lyman, W. F. Reehl and D. H. Rosenblatt, "Handbook of Chemical Property Estimation Method", McGraw Hill Book Co., 1981.	

3.1.2 STABILITY IN WATER

Type:	Abiotic (hydrolysis) **[X]**; biotic (sediment)**[ ]**
Result:	Stable at pH 4 Half life: 1850 days at pH 7 7.31 days at pH 9 at 25 °C
Method:	OECD Test guideline 111
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Dibutyl adipate
Reference:	MITI, Japan (1994b)

3.1.3 STABILITY IN SOIL

No data available

3.2 MONITORING DATA (ENVIRONMENT)

No data available

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

3.3.1 TRANSPORT

No data available

3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)

The potential environmental distribution of dibutyl adipate obtained from a generic level III fugacity model is shown in Table. The results show that if dibutyl adipate is released mainly to water, it is unlikely to distribute into soil compartment. But, if dibutyl adipate is released mainly to water, it is likely to be transported to water, soil and sediment. Due to the low vapour pressure of dibutyl adipate, it is unlikely to distribute into air.

Environmental distribution of dibutyl adipate using a generic level III fugacity model.

Compartment	Release: 100% to air	Release: 100% to water	Release: 100% to soil
Air	0.12%	0.04%	0.00%
Water	0.26%	34.60%	0.18%
Soil	99.40%	34.97%	99.66%
Sediment	0.22%	30.39%	0.16%

Reference: EA & MITI, Japan (1994)

3.4 IDENTIFICATION OF MAIN MODE OF DEGRADABILITY IN ACTUAL USE

No data available

3.5 BIODEGRADATION

Type:	aerobic **[X]**; anaerobic **[ ]**
Inoculum:	adapted **[ ]**; non-adapted **[X]**;
Concentration of the chemical:	100 mg/l related to Test Substance **[X]**
Medium:	water**[ ];**water-sediment**[ ];**soil **[ ];**sewage treatment **[ ]** other **[**Japanese standard activated sludge**]**
Degradation:	Degree of degradation after 28 days 89; 95; 86 % from BOD 100, 100 and 100 % from GC analysis
Results:	Readily biodeg. **[X];** Inherently biodeg. **[ ]**; under test condition no biodegradation observed **[ ]**
Method:	OECD Test Guideline 301 C
GLP:	Yes **[X]** No **[ ]** ? **[ ]**
Test substance:	Dibutyl adipate
Reference:	MITI (1994b)

3.6 BOD_5,COD OR RATIO BOD_5/COD

Not applicable

3.7 BIOACCUMULATION

No data available

3.8 ADDITIONAL REMARKS

A. Sewage treatment None

B. Other information None

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: $LC_{50\ (24h)}$ = 5.1 mg/l (95% confidence limits: 4.2-6.0 mg/l)
$LC_{50\ (48h)}$ = 4.1 mg/l(95% confidence limits:3.2-5.2 mg/l)
$LC_{50\ (72h)}$ = 3.7 mg/l (95% confidence limits: 2.9-4.8 mg/l)
$LC_{50\ (96h)}$ = 3.7 mg/l (95% confidence limits: 2.9-4.8 mg/l)
NOEC = mg/l
LOEC =
Analytical monitoring: Yes **[ ]** No **[X]** ? **[ ]**
Method: OECD Test Guideline 203 (1981)
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: Dibutyl adipate, purity = 99 %
Remarks: A group of 10 fishes were exposed to 5 nominal concentrations (1.0-10 mg/l). Stock solutions was prepared with DMSO:HC 40 = 9:1 (200 mg/l). Controls with and without this vehicle were taken for the test.
Reference: EA, Japan (1994)

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: $EC_{50\ (24h)}$ = 17 mg/l
Analytical monitoring: Yes **[ ]** No **[X]** ? **[ ]**
Method: OECD Test Guideline 202 (1984)
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: Dibutyl adipate, purity: = 99 %
Remarks: 20 daphnids (4 replicates; 5 organisms per replicate) were exposed to each of 5 nominal concentrations (5.6-56 mg/l). Stock solution was prepared with DMSO:HCO-40 = 9:1 (100 mg/l). Controls with and without this vehicle were taken for the test.
Reference: EA, Japan (1994)

B. Other aquatic organisms

No data available

4.3 TOXICITY TO AQUATIC PLANTS e.g. Algae

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

Exposure period: 72 hours
Results: Biomass: EC_{50} (24h) =
EC_{50} (72h) = 2.8 mg/l
NOEC = 2.0 mg/l
LOEC =
Analytical monitoring: Yes **[ ]** No **[X]** ? **[ ]**
Method: open-system **[**X**]**; closed-system **[ ]**
OECD Test Guideline 201 (1984)
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: Dibutyl adipate, purity = 99 %
Remarks: The EC_{50} values were calculated based on 5 nominal concentrations (1-5 mg/l). Stock solution was prepared with DMSO (100 mg/l). Controls with and without this vehicle were taken for the test.
Reference: EA, Japan (1994)

4.4 TOXICITY TO BACTERIA

No studies located

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1. CHRONIC TOXICITY TO FISH

No data available

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 **[ ]**; Reproduction rate **[X]**; Other **[X]**
Exposure period: 21 day
Results:
Immobility: LC_{50} (24 h) =
LC_{50} (48 h) = 9.3 mg/l
LC_{50} (96 h) =
LC_{50} (7 d) =
LC_{50} (14 d) =
LC_{50} (21 d) = 4.3 mg/l (95% confidence level: 3.4-5.4 mg/l)
NOEC =
LOEC =
Reproduction: EC_{50} (14 d)= l
EC_{50} (21 d) = 8.9 mg/l(95% confidence level:4.5-28 mg/l)
NOEC = 5.6 mg/l ($p < 0.05$)
LOEC = 18 mg/l ($p < 0.05$)
Analytical monitoring: Yes **[ ]** No **[X]** ? **[ ]**
Method: OECD Test Guideline 202 (1984)
GLP: Yes **[ ]** No **[X]** ? **[ ]**
Test substance: Dibutyl adipate, purity = 99 %
Remarks: 40 daphnids (4 replicates; 10 organisms per replicate) were exposed to each of 5 nominal concentrations (0.18-18 mg/l).

Stock solution was prepared with DMSO:HCO = 9:1 (100 mg/l).
Controls with and without this vehicle were taken for test.

Reference: EA, Japan (1994)

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

No data available

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

No data available

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

No data available

4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)

No studies available

4.8 BIOTRANSFORMATION AND KINETICS IN ENVIRONMENTAL SPECIES

No data available

4.9 ADDITIONAL REMARKS

None

5.1 ACUTE TOXICITY

5.1.1 ACUTE ORAL TOXICITY

Type :	LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[X]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain:	Rat
Value :	1,290 mg/kg
Method:	Unknown
GLP:	Yes **[ ]** No **[ ]** ? **[X]**
Test substance:	purity: Unknown
Remarks:	None
Reference:	Pesticide Index, Frear E.H. (1976)

5.1.2 ACUTE INHALATION TOXICITY

No data available

5.1.3 ACUTE DERMAL TOXICITY

No data available

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION

No data available

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

No data available

5.2.2 EYE IRRITATION/CORROSION

No data available

5.3 SKIN SENSITISATION

No data available

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:	28 days
Frequency of treatment:	7 days/week
Post exposure observation period:	14 days
Dose:	0, 20, 140 or 1000 mg/kg (6 animals /group)
Control group:	Yes **[X]**; No **[ ]**; No data **[ ]**; olive oil
	Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**

NOEL: 1,000 mg/kg/day
Results: No test substance-related changes were noted in clinical observations, body weight gains, food consumption, and the findings obtained from hematology testing, blood chemical examination, urinalysis, and pathological examination.
Method: Guidelines for 28-Day Repeat Dose Toxicity Test of Chemicals (Japan)
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: Commercial, purity: 99.8 %
Reference: MHW, Japan (1996b)

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, TA1537
E. coli WP2 uvrA
Concentration: 0, 312.5, 625, 1250, 2500, 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:

S. typhimurium TA 100, TA1535, TA98, TA1537

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

E. coli WP2 uvrA

	+	?	-
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: > 99 %
Remarks: Procedure: Plate incorporation 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 (1996b)

B. NON-BACTERIAL IN VITRO TEST

Type :	Cytogenetics Assay
System of testing:	
Species/strain:	Chinese hamster lung (CHL/IU) cells
Concentration:	-S9 (continuous treatment) 0, 0.7, 1.3, 2.6 mg/ml
	-S9 (short-term treatment) 0, 0.012, 0.023, 0.046 mg/ml
	+S9 (short-term treatment) 0, 0.7, 1.3, 2.6 mg/ml
Metabolic activation:	With **[ ]**; Without **[ ]**; With and Without **[X]**; No data **[ ]**
Results:	
Cytotoxicity conc:	With metabolic activation: 0.7 mg/ml
	Without metabolic activation: 0.7 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:	Commercial, purity 99.8 %
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
	Media: RPMI 1640 medium *plus* 10% foetal calf serum *plus* phytohaemagglutinin
	No. replicates: 1
Reference:	MHW, Japan (1996b)

5.6 GENETIC TOXICITY IN VIVO

No data available

5.7 CARCINOGENICITY

No data available

5.8 TOXICITY TO REPRODUCTION

(a)

Type:	Fertility **[ ]**; One generation study **[ ]**;
	Two generation study **[ ]**; Other **[X]**
Species/strain:	Rat/Crj: CD (Sprague-Dawley)
Sex:	Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration:	Oral gavage
Exposure period:	Males: 42 days
	Females: from 14 days before mating to day 3 of lactation.
Frequency of treatment:	7 day /week
Postexposure observation periodi:	
Premating exposure period:	male: 14 days; female: 14 days
Duration of the test;	

Doses: 0, 100, 300 or 1,000 mg/kg (13 /animals/sex/group)
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**; Historical **[ ]**
NOEL Parental: 1,000 mg/kg/day (reproductive effect)
300 mg/kg/day (general toxicity)
NOEL F1 Offspring: 300 mg/kg/day
NOEL F2 Offspring: N/A
Results: Copulation, ovulation, fertility, maintenance of pregnancy, and parturition and lactation were not affected by the test compound. Reproductive parameters (i.e., duration of gestation, number of corpora lutea, implantations and resorptions, litter size, and sex ratio distribution) were comparable among all four groups including controls. In the 1,000 mg/kg group, pup weight on postnatal days 0 and 4 was slightly decreased along with viability on postnatal day 4. Thus the NOEL was considered to be 1,000 mg/kg/day for reproduction in male and female rats and 300 mg/kg/day for the F_1 generation.
Concerning maternal and paternal general toxicity, no mortalities occurred in any group. There were no toxic effects of this chemical on the general condition of male and female animals. Slight suppression of body weight gain was observed in males in 1,000 mg/kg group, while body weight change in females and food consumption in male and female animals in all compound treated groups were comparable to those in the controls. Macroscopic findings at necropsy and histological findings for the internal genitalia showed no abnormalities,. Kidney weights were increased in males and females of the 1,000 mg/kg groups as compared to the control values. Thus the NOEL for general toxicity of this chemical in parent animals was considered to be 300 mg/kg/day.
Method: OECD Preliminary Reproduction Toxicity Screening Test
GLP: Yes **[X]** No **[ ]** ? **[ ]**
Test substance: Commercial, purity > 99 %
Remarks:
Reference: MHW, Japan (1996a)

(b)
Type: Fertility **[ ]**; One generation study **[ ]**; Two generation study **[ ]**; Other **[X]**
Species/strain: Rat (SD)
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[X]**; No data **[ ]**
Route of Administration: intraperitoneal
Exposure period: Males: injection on 5th, 10th, and 15th days of gestation
Frequency of treatment:
Postexposure observation period:
Premating exposure period: male: 14 days, female: 14 days
Duration of the test;
Doses: 0, 0.5244, 1.0488 and 1.748 ml/kg
Control group: Yes **[X]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[X]**;
Historical **[ ]**
NOEL Parental :
NOEL F1 Offspring: 0.5244 ml/kg
NOEL F2 Offspring: N/A
Results: Foetal data (live/dead): 1.0488 ml/kg
1.7480 ml/kg
(Skeletal defects): 1.7480 ml/kg

Method:	Other
GLP:	Yes **[ ]** No **[**X**]** ? **[ ]**
Test substance:	Purity: Unknown
Remarks:	
Reference:	Singh, A.R. et al, (1973)

5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

See 5.8

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

No data available

B. Toxicodynamics, toxicokinetics

No data available

5.11 EXPERIENCE WITH HUMAN EXPOSURE

None

EA, Japan (1994) "Investigation of 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)

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