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1,2-BUTANEDIOL
CAS N°: 584-03-2

Substance

End Point : IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES
Chemical Name : 1,2-Butanediol
Common Name : 1,2-Butanediol
CAS Number : 584-03-2
RTECS Number : EK0380000

Synonyms

1,2-Butylene glycol

1,2-Dihydroxybutane

Properties & Definitions

Molecular Formula : C₄H₁₀O₂
Molecular Weight : 90.14
Melting Point : -50C*
Boiling Point : 193C
State : Liquid
Vapour Pressure : 2.13kPa(16mmHg) at 100C
Octanol/Water Partition Coefficient : log Pow = -0.34 at 25C
Water Solubility : > 100g/l
Impurities : Water, 1,4-butanediol, 1-acetoxy-2-hydroxybutane
General Comments : 1,2-Butanediol is stable in neutral, acidic or alkaline solutions. *MP:(DCP) the value -40 to -30 is also reported.

Overall Evaluation

SHORT SUMMARY OF THE REASONS WHICH SUPPORT THE RECOMMENDATION

1,2-Butanediol is stable liquid, and the production volume was 882 tonnes for 1991 in Japan. This chemical is stable in acidic or alkaline solutions, and is classified as "readily biodegradable" by the results of the biodegradation test conducted as SIDS testing.

The chemical is non-toxic to fish, daphnids and algae.

The chemical showed no genotoxic effects, and NOAEL for repeated dose toxicity was 200 mg/kg/day and NOAEL for reproductive toxicity was 1,000 mg/kg/day. Estimated Dose of Low Concern (EDCL) was calculated as 0.2 mg/kg/day and 10 mg/kg/day for repeated dose toxicity and reproductive toxicity, respectively.

Daily intake of the chemical was estimated as 3.13E-4 mg/day from calculation using MNSEM 145J exposure model.

In conclusion, although 1,2-butanediol showed weak toxicity in toxicological tests, no further testing are needed at present.

Production-Trade

Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Production

Quantity Year

26000 T - P

1985

882 T - P

1991

General Comments : Data for 1985 is approximated and includes imported amounts.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Processes

Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Process

Process comments : Production is done through a continuous reaction and distillation operation.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Uses

Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
		Industrial use in closed systems where the chemical is fully changed to other substances by esterification.

References

Secondary References : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **Pathway into the Environment and Environmental Fate.**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Quantity Transported

General Comments : 1,2-Butanediol is used and transformed in closed systems so there is no emission and no exposure to the environment.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **CONCENTRATION**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Test Method and Conditions

Test method description : Multiphase, non-steady state equilibrium model for the evaluation of chemicals in the environment consisting of air , water, soil and sediment. Version 1.4.5J (presented by: Kikuo Yoshida) MNSEM 145J. Values are calculated.

Test Results

<u>Matrix</u>	<u>Concentrations</u>	<u>Spec.</u>	<u>Date</u>
AIR	2.42E-08 ppm		
In air, steady state mass = 1.78E-02g			
AQ	1.43E-04 mg/l		
In water, steady state mass = 2.68E+06g			
SOIL	7.11E-06 mg/l		
In soil, steady state mass = 1.14E+04g			
SED	3.31E-04 mg/l		
In sediment, steady state mass = 3.31E+04g			
FOOD	2.21E-11 mg/l		
In meat.			
FOOD	2.18E-11 mg/l		
In milk.			
PLANT	6.74E-05 mg/l		
In vegetation.			

References

Primary Reference : **#URMEA***
 Unpublished Report on Exposure Estimation Test conducted by MITI and Environmental Agency, Japan, (1993)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6-7, (1993)

Study

End Point : **HUMAN INTAKE AND EXPOSURE**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>
	AIR		IHL		
	AQ		ORL		
	FOOD		ORL		

Test Method and Conditions

Test method description : Multiphase, non-steady state equilibrium model for the evaluation of fate of chemicals in the environment consisting of air, water, soil and sediment. Version 1.4.5.J (presented by: Kikuo Yoshida) MNSEM 145J values are calculated.

Test Results

<u>Intake</u>	<u>Spec.</u>	<u>Date</u>
1.78E-06 mg/d Inhalation of air (from MNSEM 145J)		
2.86E-04 mg/d Drinking water (from MNSEM 145J)		
8.24E-07 mg/d Ingestion of fish (from MNSEM 145J)		
1.64E-12 mg/d Ingestion of meat (from MNSEM 145J)		
2.66E-12 mg/d Ingestion of milk (from MNSEM 145J)		
2.52E-05 mg/d Ingestion of vegetable (from MNSEM 145J)		
3.13E-04 mg/d Total estimated exposure dose (from MNSEM 145J)		

References

Primary Reference : **#URMEA***
 Unpublished Report on Exposure Estimation Test conducted by MITI and Environmental Agency, Japan, (1993)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6, (1993)

Study

End Point : **BIODEGRADATION**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Geographic Area : **JPN**

Species/strain/system : Activated sludge

Test Substance

Purity Grade : **99%**

Test Method and Conditions

Test method description : OECD Guideline 301C. GLP:YES. Aerobic test. The sludge samples were mixed by stirring in a single container, and then cultured at 25C for one month.

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
32 %	AV	Degree of biodegradation from BOD7
81 %	AV	Degree of biodegradation from BOD14
96 %	AV	Degree of biodegradation from BOD28
92 %	AV	Degree of biodegradation from DOC
100 %	AV	Degree of biodegradation from HPLC
<i>General Comments</i>	:	These results indicate that 1,2-butylene glycol should be classified as "readily biodegradable".

References

Primary Reference : **#MITIR***
 Chemical Report submitted by the Ministry of International Trade and Industry, Japan, (1993)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

Study

End Point : **PHOTODEGRADATION**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Test Substance

Purity Grade : **99%**

Test Method and Conditions

Test method description : W. J. Lyman et al., Handbook of Chemical Properties Estimation Method, McGraw Hill Book Co., 1981. GLP: No.

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
		Half-life for photolysis: Infinitude 0.00D+00 mol/l/s (estimation)

References

Primary Reference : **#MITIR***
Chemical Report submitted by the Ministry of International Trade and Industry, Japan, (1993)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **HYDROLYSIS**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**
Medium : **AQ**
Specifications : **FRESH**

Test Substance

Purity Grade : **99%**

Test Method and Conditions

Test method description : OECD Guideline 111. GLP: YES. Hydrolysis measured as a function of pH.
Temperature : **25 C**
pH : **4-9**

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
T/2	>1 y	Half lives of 1,2-butanediol at 25C and at pH 4.0, 7.0 and 9.0 equal or higher than 1 year.

References

Primary Reference : **#MITIR***
Chemical Report submitted by the Ministry of International Trade and Industry, Japan, (1993)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Species/strain/system : Swiss albino/ICR
Dose / Concentration : **>4192 mg/kg BW**
Exposure comments : Acute oral dosing for LD50 limit testing. The range of the doses was not provided.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
MOUSE			ORL		F	LD50	

References

Primary Reference : **TXAPA9**
 Holman, N. W. et al. Toxicology and Applied Pharmacology, 49, 385, (1979)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Species/strain/system : No information provided neither on strain nor on sex of the test rats.
Dose / Concentration : **>16000 mg/kg BW**

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			ORL	ADULT		LD50	

References

Primary Reference : **RTECS***
 Registry of Toxic Effects of Chemical Substances

Secondary Reference : **!SIDSP***
 Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **MAMMALIAN TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
RAT			ORL	ADULT	M	10/DOSE	10
					F	10/DOSE	10

Species/strain/system : Crj-CD(SD) strain

Test Substance

Purity Grade : **>99%**
Vehicle - Solvent : Distilled water

Test Method and Conditions

Test method description : OECD Combined Repeated Dose and Reproductive/Developmental Toxicity Screening Test. GLP:YES

Exposure

Exposure Period : **42 d**
Dose / Concentration : **40-1000 mg/kg BW**
Exposure comments : Daily oral gavage of 0 (negative control), 40, 200, or 1000mg/kg body weight/day for 42 days for males. Females were exposed from day 14 before mating to day 3 of lactation.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	NOAEL			M	

200mg/kg body weight/day was the dose at which no toxic effects were observed.

EDLC

0.2mg/kg/day was calculated as estimated dose of low concern for repeated dose toxicity.

NEF

There were no death throughout the observation period of 42 days. Body weight, food consumption, hematology parameters, clinical chemistry parameters, organ weight, or pathological examination between the treated and control animals did not show any visible differences.

SON	FUNCT	F
RESPI	ACTIV	

Transient hypolocomotion and hypopnea at the 1000mg/kg in females.

References

- Primary Reference* : **#MOMHW***
Chemical Report submitted by the Ministry of Health and Welfare, Japan
- Secondary Reference* : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 11-12, (1993)
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Study

End Point : **MUTAGENICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT**VTR**

Species/strain/system : Salmonella typhimurium: TA100, TA1535, TA98, TA1537

Test Substance

Purity Grade : **99%**
Vehicle - Solvent : **DMSO**

Test Method and Conditions

Test method description : Japanese Guideline for Screening mutagenicity testing of chemicals. 3 plates used per test. GLP:YES

Exposure

Dose / Concentration : **312.5-5000 ug/ PLATE**
Exposure comments : Doses of: 0, 312.5, 625, 1250, 2500 or 5000 micrograms of 1,2-butanediol were applied per plate in 3 plates. Positive control: A) S9 negative received AF-2 sodium azide or 9-aminoacridine, B) S9 positive received 2-aminoanthracene. S9 activated by phenobarbital and 5,6-benzoflavone.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
CHNG					

Minimum concentration of test substance at which toxicity to bacteria was observed is > 5000ug/plate with metabolic activation and 5000ug/plate without metabolic activation.

DNA **NEF**

In all strains at all concentrations tested, with or without metabolic activation, the test substance did not induce any changes within the chromosomal chromatin.

General Comments : 1,2-Butanediol was considered as "negative" in gene mutation tests under the experimental conditions used.

References

Primary Reference : **#MOMHW***
Chemical Report submitted by the Ministry of Health and Welfare, Japan

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 12-13, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

HAMST

VTR

Species/strain/system : Chinese hamster CHL cells

Test Substance

Purity Grade : **>99%**
Vehicle - Solvent : **DMSO**

Test Method and Conditions

Test method description : Japanese Guideline for Screening mutagenicity testing of chemicals. Positive controls without S9 activation received mytomycin C and those with S9 activation received cyclophosphamide.

Exposure

Dose / Concentration : **0.23-0.90 mg/ml**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
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	CELL				

The lowest concentration producing toxicity to cells with and without metabolic activation was > 1mg/ml.

DNA **NEF**

At all concentrations tested there were no chromosomal changes observed in the cells with or without metabolic activation as compared with negative controls.

General Comments : The test material (1,2-butanediol) was considered as negative in chromosomal aberration tests in vitro under the experimental conditions used.

References

Primary Reference : **#MOMHW***
Chemical Report submitted by the Ministry of Health and Welfare, Japan

Secondary Reference : **!SIDSP***
OECD/SIDS/MHW JAPAN. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 13-14, (1993)

Study

End Point : **REPRODUCTION**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
RAT			ORL	ADULT	F	10/DOSE	10
					M	10/DOSE	10

Species/strain/system : Crj-CD(SD) strain

Test Substance

Purity Grade : >99%

Test Method and Conditions

Test method description : OECD Combined Repeated Dose and Reproductive/Developmental Toxicity Screening Test. GLP:YES

Exposure

Dose / Concentration : **40-1000 mg/kg BW**
Exposure comments : 1,2-Butanediol was given orally (gavage) at doses of 0, 40, 200, or 1000mg/kg body weight/day to female rats for 14 days before mating and continued through pregnancy up to 3 days of lactation. On day 4 of lactation all animals were sacrificed.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
REPRO	NEF			F	

No reproductive toxicity observed in parental animals or offsprings. There were no visible differences in body weight, food consumption, hematology parameters, clinical chemistry parameters, organ weight, or pathological examination between the treated and control animals.

NOAEL

1000mg/kg for parental and F1 generation.

REPRO ELDC

Estimated dose of low concern = 10 mg/kg/day

General Comments : There were no death throughout the entire observation period. There were no visible differences in body weight, food consumption, hematology parameters, clinical chemistry parameters, organ weight, or pathological examination between the treated and control animals. No effect on reproduction and developmental toxicities were observed.

References

Primary Reference : **#MOMHW***
Chemical Report submitted by the Ministry of Health and Welfare, Japan

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 11-12, (1993)

Study

End Point : **AQUATIC ACUTE TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Species/strain/system : Red Killifish (*Oryzias latipes*)
Exposure Period : **24-96 h**
Exposure comments : Same doses were also tested for 48h and 72h.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
FISH	AQ	ESTUA				LC0 LC50	LC0 = 1000mg/l for 24h, 48h, 72h and 96h. LC50 > 1000mg/l for 24h, 48h, 72h, and 96h. (Both values reported as 1000ppm).

References

Primary Reference : **#URTEA***
 Unpublished Toxicity Test conducted by the Environmental Agency, (EA), Japan

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **AQUATIC ACUTE TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**

Species/strain/system : Water flea (*Daphnia magna*)
Exposure Period : **24 h**
Dose / Concentration : **100->1000 mg/l**

Test Method and Conditions

Test method description : Probit method

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
CRUS	AQ	FRESH				LC0 LC50	Both values reported as 1000ppm.

References

- Primary Reference* : **#URTEA***
Unpublished Toxicity Test conducted by the Environmental Agency, (EA),
Japan, (1993)
- Secondary Reference* : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, (1993)
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Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

ALGAE **AQ** **FRESH**

Species/strain/system : Green algae (Selenastrum capricornutum)

Test Substance

Purity Grade : **99%**

Test Method and Conditions

Test method description : OECD Guideline. GLP:NO

Exposure

Exposure Period : **72 h**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	EC50				

Effective concentration (reported as EBC50) = 10,000ppm

References

Primary Reference : **#URTEA***
Unpublished Toxicity Test conducted by the Environmental Agency, (EA), Japan, (1993)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1991)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **1,2-Butanediol**
CAS Number : **584-03-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

CRUS AQ FRESH

Species/strain/system : Water flea (Daphnia magna)

Test Substance

Purity Grade : **99%**

Test Method and Conditions

Test method description : OECD Test Guideline. GLP: NO. Static test.

Exposure

Exposure Period : **21 d**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
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	NOEC				

Maximum concentration at which no effect was observed for 21 days > 1000mg/l. (Reported as 1000ppm).

References

Primary Reference : **#URTEA***
Unpublished Toxicity Test conducted by the Environmental Agency, (EA), Japan, (1993)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

