FOREWORD INTRODUCTION

P-TOLUENESULFONAMIDE

CAS N°: 70-55-3

Substance

End Point	:	**IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
Common Name	:	**p-Toluenesulfonamide**
CAS Number	:	**70-55-3**
RTECS Number	:	**XT5075000**

Synonyms

p-Methylbenzenesulfonamide
4-Methylbenzenesulfonamide
Toluene-4-sulfonamide
Toluene-p-sulfonamide
Tolylsulfonamide
p-Tolylsulfonamide
Tosylamide
p-Tosylamide
4-MBSA

Properties & Definitions

Molecular Formula	:	**C7H9NO2S**
Molecular Weight	:	**171.23**
Melting Point	:	**137.5C**
Boiling Point	:	**221C at 10 mmHg**
State	:	**Solid**
Flash Point	:	**202C (c-cup)**
Vapour Pressure	:	**0.1 kPa(0.75 mmHg) at 170C**
Octanol/Water Partition Coefficient	:	**log Pow = 0.84 at 25C**
Water Solubility	:	**3.2 g/L at 25C**
Impurities	:	**=<4%. o-Toluenesulfonamide, sodium chloride, ammonium chloride.**
General Comments	:	Non-volatile. Stable in neutral, acidic or alkaline solutions.

Overall Evaluation

SIDS INITIAL ASSESSMENT

PRESENTLY OF LOW CONCERN

4-Methylbenzenesulfonamide is non-volatile stable solid, and the production volume is ca. 1700 tonnes and 1000 tonnes for 1985 and 1991, respectively, in Japan. Canada and Sweden imported less than 100 kg in 1992. This chemical is used mainly as intermediate for pesticides and drugs in closed system, but is used as additive to outdoor paints in Sweden. This chemical is stable in neutral, acidic or alkaline solutions, and is classified as "not readily biodegradable".

The fact that the chemical is slightly toxic to algae, but non-toxic to fish and daphnids, implies the environmental risk presumably to be low. The PEC is lower than the MTC.

The chemical showed no genotoxic effects, and LOAEL for repeated dose toxicity was 120 mg/kg/day and NOAEL for reproductive toxicity was 300 mg/kg/day. Estimated dose of low concern (EDLC) was calculated as 0.024 mg/kg/day and 0.6 mg/kg/day for repeated dose toxicity and reproductive toxicity, respectively. Daily intake of the chemical was estimated as 4.36-E-5 mg/day from calculation using MNSEM 145I exposure model.

Therefore, health risks from general environment presumably to be low because estimated human exposure (EHE) level of this chemical is lower than the EDLC.

In conclusion, although 4-methylbenzenesulfonamide is persistent and toxicological tests showed moderate toxicity, no further testing is needed at present considerering its use pattern and exposure levels.

ENVIRONMENTAL EXPOSURE

Biodegradability: "not readily biodegradable"

ESTIMATION OF ENVIRONMENTAL FATE, PATHWAYS AND CONCENTRATIONS

Comparison of calculated environmental concentration using several models.

Model MNSEM:
Air: 1.88E-8 ug/L; Water: 0.0203 ug/L; Soil: 2.15E-3 ug/kg; Sediment: 0.104 ug/kg
Model CHEMCAN2:
Air: 1.38E-11 ug/L; Water: 0.0203 ug/L; Soil: 1.02E-6 ug/kg; Sediment: 0.0113 ug/kg
Model CHEMFRAN:
Air: 4.22E-13 ug/L; Water: 0.0203 ug/L; Soil: 5.93E-8 ug/kg; Sediment: 0.0113 ug/kg
Model UKMODEL:
Air: 5.88E-8 ug/L; Water: 0.0202 ug/L; Soil: 3.63E-2 ug/kg; Sediment: 0.0727 ug/kg

CONSUMER EXPOSURE

In Sweden, this chemical (< 100 kg) is used as a preservative of all types of outdoor paints (one or more formulation paints). From present information on uses, consumer exposure seems to be low because this chemical is used mainly as raw material for synthesis of pesticides, drugs and fluorescent colorants in closed system.

OCCUPATIONAL EXPOSURE

Processes are closed system except drying and packaging. Exposure will be considered in drying process (2.5 hour/tonne product) and packaging process (1.25 hour/tonne product). No data on work place monitoring have been reported. Occupational exposure seems to be low.

CONCLUSION

Based upon the available information , although 4-methylbenzenesulfonamide is persistent and toxicological tests showed moderate toxicity, no further testing is needed at present considering its exposure levels and use pattern.

RECOMMENDATION

Continuation of data collection on exposure will be recommended.
If this chemical is used largely in consumer products in the future, long-term repeated dose (e.g. 90 days) toxicity test may be needed, because histopathological changes of urinary bladder and thymus were observed in combined repeat/repro. toxicity test.
Also, monitoring of this chemical in the production site may be recommended for the prevention of occupational exposure.

Production-Trade

Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Geographic Area : **JPN**

Production

Quantity	*Year*
1000 t - P	**1991**
1700 t - P	**1985**

General Comments : These (1700 t) refer to the values for production and import levels in 1985.

References

!SIDSP*
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Production-Trade

Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**

Production

Quantity	*Year*
<100 kg - IM	**1992**

General Comments : Canada and Sweden imported less than 100 kg in 1992. There are no production and no products containing the substance in Denmark and Finland.

References

!SIDSP*
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Processes

Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**

Process

Process comments : The chemical is synthesized by reaction of p-toluenesulfonyl chloride with ammonia. Processes are closed system except drying and packaging.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Uses

Chemical Name : **Benzenesulfonamide, 4-methyl**
CAS Number : **70-55-3**

Use

Quantity	*Year*	*Comments*
		Unspecified amount used as raw material for the synthesis of pesticides, fluorescent colorant and drugs.
		Unspecified amount used as plasticizer for thermosetting resins below 1%.

References

Secondary References : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Uses

Chemical Name : **Benzenesulfide, 4-methyl-**
CAS Number : **70-55-3**
Geographic Area : **SWE**

Use

Quantity	*Year*	*Comments*
		Unspecified amount used in a preservative which is mainly used as an additive to all types of outdoor paints (one or more formulation paints).

References

Secondary References : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**CONCENTRATION**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**
Geographic Area	:	**JPN**

Test Subject

Organism	*Medium*	*Specification*	*Lifestage*	*Sex*
	AIR			
	WATER			
	SOIL			

Species/strain/system : Air, water, soil, sediment.

Test Method and Conditions

Test method description : Multi-Phase Non-Steady State Equilibrium Model for Evaluation of Fate of Chemicals in Environment consisting of Air, Water, Soil and Sediment Phases. Version 1.4.5I. also called MNSEM 145I. (Presented by Kikuo Yoshida).

Test Results

Matrix	*Concentrations*	*Spec.*	*Date*
	1.88E-12 mg/L		
In air. 2.69E-10 ppm also reported. Steady state mass = 3.77 g.			
	2.03E-5 mg/L		
In water. Steady state mass = 4.05E+5 g.			
	2.15E-6 mg/kg		
In soil. Steady state mass = 3.45E+3 g.			
	1.04E-4 mg/kg		
In sediment. Steady state mass = 1.04E+4 g.			

General Comments : Clearing time 25 days. (No specification given for media). All above values are calculated using MNSEM 145I method.

References

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

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**CONCENTRATION**
Chemical Name	:	**p-Toluenesulfonamide**
CAS Number	:	**70-55-3**
Geographic Area	:	**JPN**

Test Subject

Organism	*Medium*	*Specification*	*Lifestage*	*Sex*
	FOOD			
	FOOD			
	PLANT			

Species/strain/system : Meat, milk, vegetation

Test Results

Matrix	*Concentrations*	*Spec.*	*Date*
	3.39E-11 mg/L		
In meat			
	2.99E-11 mg/L		
In milk			
	6.24E-6 mg/L		
In vegetation			

General Comments : All above given values are calculated using MNSEM 145I method.

References

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

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**HUMAN INTAKE AND EXPOSURE**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**
Geographic Area	:	**JPN**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*
	AIR				
	AQ				
	FOOD				

Species/strain/system : Air, drinking water, fish, meat, milk and vegetables.

Test Method and Conditions

Test method description : Multi-Phase Non-Steady State Equilibrium Model for Evaluation of Fate of Chemicals in Environment consisting of Air, Water, Soil and Sediment Phases. Version 1.4.5I. Also called MNSEM 145I. (Presented by Kikuo Yoshida).

Test Results

Intake	*Spec.*	*Date*
3.77E-8 mg/d Through inhalation of air		
4.05E-5 mg/d Through drinking water		
7.78E-7 mg/d Through ingestion of fish		
2.51E-12 mg/d Through ingestion of meat		
3.65E-12 mg/d Through ingestion of milk		
2.33E-6 mg/d Through ingestion of vegetables		
4.36E-5 mg/d Total exposure dose		

References

Primary Reference : **#URMEA***

Unpublished Report on Exposure Estimation Test conducted by MITI and Environmental Agency, Japan

Secondary Reference : **!SIDSP***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**BIODEGRADATION**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**
Study type	:	**LAB**

Test Subject

Organism	*Medium*	*Specification*
	SLUDG	

Species/strain/system	:	Activated sludge, 30 mg/L as suspended solid

Test Substance

Purity Grade	:	**97.4%**

Test Method and Conditions

Test method description	:	OECD Guideline 301C. The sludge samples were mixed by stirring in a single container and cultured at 25C for 1 month. GLP: No
Temperature	:	**25 C**
(An)aerobic	:	**AEROB**

Exposure

Exposure Period	:	**28 d**
Dose / Concentration	:	**100 mg/L**

Test Results

Quantity		*Time*	*Comments on result*
1 %	AV		Degree of biodegradation from BOD7
4 %	AV		Degree of biodegradation from BOD14
3 %	AV		Degree of biodegradation from BOD28
0 %	AV		Degree of biodegradation from DOC
0 %	AV		Degree of biodegradation from HPLC

General Comments	:	These results indicate that the chemical should be classified as "not readily biodegradable".

References

Primary Reference	:	**#MCIBD*** Unpublished Report on Biodegradation Test of (specific chemical) conducted by MITI
Secondary Reference	:	**!SIDSP*** OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**PHOTODEGRADATION**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**

Test Substance

Purity Grade	:	**97.4%**

Test Method and Conditions

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

Exposure

Dose / Concentration	:	**8.6 mg/L**

Test Results

Quantity	*Time*	*Comments on result*
50 %	**132 d**	Estimated half-life.

General Comments	:	Photochemical degradation rate 3.05E-12 mo/L/s. Depth in water body 500 cm. Conversion constant 6.023E+20. Quantum yield for disappearance of chemical by photolysis under solar irradiation 0.01.

References

Primary Reference	:	**#MCITH*** Unpublished Report on Hydrolysis and Photodegradation Test of (specific chemical), HPV/SIDS test conducted by MITI
Secondary Reference	:	**!SIDSP*** OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**HYDROLYSIS**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**
Study type	:	**LAB**

Test Substance

Purity Grade	:	**97.4%**

Test Method and Conditions

Test method description	:	OECD Guideline 111. Hydrolysis as a function to pH. GLP: yes
Temperature	:	**25 C**

Test Results

Quantity	*Time*	*Comments on result*
50 %	**>1 y**	Measured half-life in pH 4.0, 7.0 and 9.0 at 25C.

References

Primary Reference :

#MCITH*

Unpublished Report on Hydrolysis and Photodegradation Test of (specific chemical), HPV/SIDS test conducted by MITI

Secondary Reference :

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

[redacted]

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**

Species/strain/system : Sprague Dawley Crj:CD(SD)

Test Method and Conditions

Test method description : OECD Test Guideline 401. GLP: Yes

Test Results

Organism	*Medium*	*Spec.*	*Route*	*Lifestage*	*Sex*	*Effect*	*Effect Comments*
RAT			**ORL**	**ADULT**		**LD50**	Oral LD50 for rats was established as >2000 mg/kg, under the test conditions.

References

Primary Reference : **#MHAAB***
Unpublished Report on Acute Toxicity Screening Test of (specific chemical)-HPV/SIDS, test conducted by MHW

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

[redacted]

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**

Species/strain/system : Mouse, strain not specified

Test Method and Conditions

Test method description : No information was provided. GLP: No

Test Results

Organism	*Medium*	*Spec.*	*Route*	*Lifestage*	*Sex*	*Effect*	*Effect Comments*
MOUSE			**ORL**	**ADULT**		**LD50**	Oral LD50 for mice was established as 400 mg/kg, under the test conditions.

References

Primary Reference : **DPIRDU**
Sax, N. I., and Lewis, R. J. Dangerous Properties of Industrial Materials - Report, 3

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MAMMALIAN TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
RAT			**ORL**	**ADULT**	**M**	**13/GROUP**	**13**
					F	**13/GROUP**	**13**

Species/strain/system : Rat, Crj:CD(SD)

Test Substance

Vehicle - Solvent : 5% gum arabic solution

Test Method and Conditions

Test method description : OECD Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test. GLP: yes

Exposure

Exposure Type : **SHORT**
Exposure Period : **42 d**
Dose / Concentration : **120-750 mg/kg**
Exposure comments : Doses of: 0, 120, 300, 750 mg/kg/day were administered by oral gavage for 42 days to male rats and from day 14 before mating through day 3 of lactation to female rats.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
URINE	**CHEM**				

4 animals from the high-dose groups displayed hematuria within the first 3 days of dosing.

BW	**DECR**		**M**

Body weights of the high-dose males were significantly lower than the controls throughout the dosing period.

BW	**DECR**		**F**

A reduction in body weight gain was observed in the mid- and high-dose females during the gestation and/or lactation period.

KIDNY	**SIZE**		
LIVER	**SIZE**		

Relative kidney and liver weights were slightly increased in the high-dose animals. In addition dark-colored livers were observed in the 6 high-dose males.

URS

In the histopathological examinations urinary bladder epithelium were seen in 6 low and 11 each in mid- and high- dose males and 1 low-, 12 mid- and 7 high-dose females.

BLOOD CHNG

Haematological examinations indicated a dose dependent increase in white blood cells counts in the mid- and high- dose males. There was also increased number of neutrophils in the high-dose males.

BLOOD BIOCH

Levels of BUN, GOT and chloride were significantly elevated in the mid- and high-dose males. GPT level was significantly increased and potassium decreased in the high-dose males

NOAEL
EDLC

No adverse effect level was established as 120 mg/kg/day. Estimated dose of low concern was calculated as 0.0240 mg/kg /day under the test conditions.

General Comments : A dose dependent increase in the frequency and incidence of hypersalivation was shown in all treated groups. Food consumption of the high-dose males was significantly suppressed in the first week of dosing and in the mid- and high-dose females during the gestation period. There was also observed an involution of the thymus in 8 high- and mid- dose females. Food consumption were recorded at scheduled times during the study. Hematological and blood chemistry measurements and histopathological examinations were done for the males at termination. Pertinent pregnancy and offspring parameters, e.g. (mating performance, duration of gestation, pup viability, body weight and sex distribution, gross anomalies were determined.

References

Primary Reference : **#MHRAB***

Unpublished Report on Combined Repeat Dose and Reproductive Developmental Toxicity Screening Test of (specific chemical)-HPV/SIDS test conducted by MHW

Secondary Reference : **!SIDSP***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MUTAGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
BACT			**VTR**				

Species/strain/system : Salmonella typhymurium TA98, TA100, TA1535, TA1537 and Escherichia coli WP2 uvrA

Test Substance

Vehicle - Solvent : DMSO

Test Method and Conditions

Test method description : Japanese Guideline for Screening Mutagenicity Testing of Chemicals - Plate method. GLP: yes

Exposure

Dose / Concentration : **3125-5000 ug**
Exposure comments : Postive control: -S9: AF-2 (TA98, TA100), sodium azide (TA1535), 9-aminoacridine (TA1537). +S9: 2-aminoanthracene (all strains). Doses of: 0, 312.5, 625, 1250, 2500, 5000 ug/plate were utilised. 3 plates/test, in 2 replicates.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
	CELL				

Minimum concentration at which toxicity to bacteria was observed was 5000 ug/plate with and without metabolic activation.

NEF

Mutagenic effect was not observed under the test conditions.

General Comments : The test substance was classified as "negative" for mutagenic effects under the test conditions.

References

Primary Reference : **#URMMT***
Unpublished Report on Mutagenicity Test conducted by the Ministry of Health and Welfare (MHW), Japan

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MUTAGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
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 : **99.9%**
Vehicle - Solvent : DMSO

Test Method and Conditions

Test method description : Japanese Guideline for Screening Mutagenicity Testing of Chemicals. GLP: yes

Exposure

Dose / Concentration : **0.33-1.70 mg/mL**
Exposure comments : Positive control: -S9: mitomycin C, +S9: cyclophosphamide. Doses for -S9: 0, 0.33, 0.65, 1.30 mg/mL. Doses for +S9: 0, 0.43, 0.85, 1.70 mg/mL. 2 plates/test.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
	CELL				

The lowest concentration producing cell toxicity was >2.0 mg /mL with metabolic activation and 2.0 mg/mL without metabolic activation.

NEF

Mutagenic effect was not observed under the test conditions.

General Comments : The test material was classified as "negative" for chromosomal aberrations, under the test conditions.

References

Primary Reference : **#URMMT***
Unpublished Report on Mutagenicity Test conducted by the Ministry of Health and Welfare (MHW), Japan

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MUTAGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
INSEC				**ADULT**			

Species/strain/system : Fruit fly (Drosophila melanogaster)

Test Method and Conditions

Test method description : Sex-linked Recessive Lethal Test

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
	MUT				

Positive mutagenic effects of the test substance were observed under the test conditions.

References

Primary Reference : **TOLED5**
Eckhardt, K. et al. Toxicology Letters, 7, 51, (1980)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MUTAGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
INSEC				**ADULT**			

Species/strain/system : Fruit fly (Drosophila melanogaster)

Test Method and Conditions

Test method description : Sex-linked Recessive Lethal Test

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
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	NEF				

Mutagenic effects were not observed under the test conditions.

References

Primary Reference : **MUREAV**
Kramers, P. G. N. Mutation Research, 56, 163, (1977)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **MUTAGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
MOUSE				**ADULT**	**M**		
					F		

Species/strain/system : Mice, NMRI

Test Method and Conditions

Test method description : Micronucleus test

Exposure

Exposure Type : **SHORT**
Exposure comments : Doses utilized in this micronucleus test were not specified.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
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	NEF				

There were no effects observed under the test conditions.

References

Primary Reference : **TOLED5**
Eckhardt, K. et al. Toxicology Letters, 7, 51, (1980)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **REPRODUCTION**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
RAT			**ORL**	**ADULT**	**M**	**13/GROUP**	**13**
					F	**13/GROUP**	**13**

Species/strain/system : Rat, Crj:CD(SD)

Test Substance

Purity Grade : **99.9%**
Vehicle - Solvent : 5% gum arabic solution

Test Method and Conditions

Test method description : OECD Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test. GLP: yes

Exposure

Exposure Type : **SHORT**
Exposure Period : **42 d**
Dose / Concentration : **120-750 mg/kg/ day**
Exposure comments : Doses of: 0, 120, 300, 750 mg/kg/day were given in oral gavage for 42 days to the male rats and from 14 day before mating through day 3 of lactation to the female rats.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
	NEF			**M**	

Mating performance and fertility were not affected by the test compound.

NEF

Reproduction parameters were comparable among all four groups including the control. No remarkable histopathological changes in the ovaries was observed in any of the non-pregnant females.

NOAEL

No adverse effect level for P generation was 300 mg/kg/day under the test conditions.

REPRO EDLC

Estimated dose of low concern for reproduction was calculated as 0.6 mg/kg/day

General Comments : A difficult labor was observed in two of the high-dose females. A decrease of lactation index in the high-dose female group was observed. A decrease of litter weight at birth in the high-dose group was observed.

References

Primary Reference : **#MHAAB***
Unpublished Report on Acute Toxicity Screening Test of (specific chemical)-HPV/SIDS, test conducted by MHW

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **TERATOGENICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
RAT				**FETUS**			

Species/strain/system : Rat, Crj:CD(SD)

Test Substance

Purity Grade : **99.9%**

Test Method and Conditions

Test method description : OECD Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test. GLP: yes

Exposure

Dose / Concentration : **120-750 mg/kg**
Exposure comments : Doses of maternal exposure: 0, 120, 300, 750 mg/kg/day were tested for teratogenic effects.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
BW	**DECR**				

The newborns to the high-dose dams showed significant decrease in body weight on day of lactation.

LIFE	**DECR**

A significant decrease in survival rate was observed in the newborns in the high-dose group.

NOAEL

No adverse effect level for F-1 generation was 300 mg/kg under the test conditions.

General Comments : Two of the high-dose female rats showed the signs of difficult labor and all of their offspring died by day 3 of lactation. Morphological observation for offspring revealed no teratogenic effect of the test substance.

References

Primary Reference : **#MHRAB***
Unpublished Report on Combined Repeat Dose and Reproductive Developmental Toxicity Screening Test of (specific chemical)-HPV/SIDS test conducted by MHW

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point	:	**AQUATIC TOXICITY**
Chemical Name	:	**Benzenesulfonamide, 4-methyl-**
CAS Number	:	**70-55-3**
Study type	:	**LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
ALGAE	**AQ**	**FRESH**					

Species/strain/system : Algae (Selenastrum capricornutum)

Test Substance

Purity Grade : **>99%**

Test Method and Conditions

Test method description : OECD Guideline. GLP: no

Exposure

Exposure Type	:	**ACUTE**
Exposure Period	:	**72 h**

EC50

EC50 for 72 hours = 23 mg/L (w/v). (Reported as EbC50 ppm (w/v)). Activity rises very sharply.

References

Primary Reference : **#EAATU***

Unpublished Report on Toxicity of (specific chemical) to Algae- HPV/SIDS test conducted by EA

Secondary Reference : **!SIDSP***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
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 : **>98%**

Test Method and Conditions

Test method description : OECD Guideline; Probit method. GLP: no

Exposure

Exposure Type : **ACUTE**
Exposure Period : **24-48 h**
Exposure comments : Doses of 150 mg/L were also tested.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
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EC0

EC0 for 24 hours = 32 mg/L (w/v). (Reported as ppm (w/v)).

EC50

EC50 for 24 hours = 150 mg/L (w/v). (Reported as ppm (w/v)).

EC100

EC100 for 24 hours = 320 mg/L (w/v). (Reported as ppm (w/v)).

References

Primary Reference : **#EADGP***
Unpublished Report on Toxicity of (specific chemical) to Daphnids-HPV/SIDS test conducted by EA

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
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 : **>98%**

Test Method and Conditions

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

Exposure

Exposure Period : **21 d**

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
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NOEL

No observed effect concentration (maximum) for 21 days = 47 mg/L (w/v). (Reported as ppm (w/v)).

LOEL

Lowest (first) observed effect concentration (minimum) for 21 days = 150 mg/L (w/v). (Reported as ppm (w/v)).

References

Primary Reference : **#EADGP***
Unpublished Report on Toxicity of (specific chemical) to Daphnids-HPV/SIDS test conducted by EA

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**
Study type : **LAB**

Test Subject

Organism	*Medium*	*Specification*	*Route*	*Lifestage*	*Sex*	*Number exposed*	*Number controls*
FISH	**AQ**	**FRESH**					

Species/strain/system : Orange-red Killifish (Oryzias latipes)

Test Substance

Purity Grade : **>98%**

Test Method and Conditions

Test method description : OECD Guideline, semi-static test. GLP: no

Exposure

Exposure Type : **ACUTE**
Exposure Period : **24-96 h**
Exposure comments : Doses more also tested for 48 and 72 hours.

Test Results

Organ	*Effect*	*Rev.*	*OnSet*	*Sex*	*Affected in Exposed - Controls*
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LC0

LC0 for 24, 48, 72 and 96 hours = 324 mg/L (w/v). (Reported as ppm (w/v)).

LC50

LC50 for 24, 48, 72 and 96 hours = 435 mg/L.

LC100

LC100 for 24, 48, 72 and 96 hours = 583 mg/L (w/v). (Reported as ppm (w/v)).

References

Primary Reference : **#EAFGP***
Unpublished Report on Toxicity to Fish-HPV/SIDS test conducted by the EA

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Study

End Point : **TERRESTRIAL ACUTE TOXICITY**

Chemical Name : **Benzenesulfonamide, 4-methyl-**
CAS Number : **70-55-3**

Species/strain/system : Wild bird species
Dose / Concentration : **75 mg/kg**

Test Method and Conditions

Test method description : No information was provided. GLP: no

Test Results

Organism	*Medium*	*Spec.*	*Route*	*Lifestage*	*Sex*	*Effect*	*Effect Comments*
BIRD			**ORL**	**ADULT**		**LD50**	Oral LD50 for the wild bird species was established as 75 mg/kg, under the test conditions.

References

Primary Reference : **TXAPA9**
Schafer, E. W. Toxicology and Applied Pharmacology, 21, 315, (1972)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1994)

Substance

Chemical Name :
Reported Name : **p-toluene sulfonamide**
CAS Number : **70-55-3**

Area	*Type*	*Subject*	*Spec.*	*Description*	*Level / Summary Information :*
USA	**REG**	**FOOD**	**ADDIT**	**RSTR**	; Summary - THIS SUBSTANCE IS INCLUDED ON A L IST OF SUBSTANCES USED TO PREPARE ADHESIVES W HICH MAY BE SAFELY USED AS COMPONENTS OF ARTI CLES INTENDED FOR USE IN PACKAGING, TRANSPORT ATION, OR HOLDING FOOD IN ACCORDANCE WITH THE FOLLOWING PRESCRIBED CONDITIONS: SUBSTA NCE MUST BE SEPARATED FROM THE FOOD BY A FUNCTION AL BARRIER, MUST NOT EXCEED LIMITS OF GOOD MA NUFACTURING PRACTICE USED WITH DRY FOODS, OR NOT EXCEED TRACE AMOUNTS AT SEAMS AND EDGE EX POSURES WHEN USED WITH FATTY AND AQUEOUS FOOD S. ALSO REGULATED BY SEA M INTEGRITY, LABELIN G STANDARDS, AND ANY PROVISION UNDER 21 CFR 1 75
		TRANS		**RSTR**	
		STORE		**RSTR**	
		PACK		**RSTR**	

Title : SUBSTANCES FOR USE ONLY AS COMPONENTS OF ADHE SIVES

Reference :	**FEREAC, 42, 14534, 1977** **Federal Register**	***Effective Date :***	1977
Last Amendment :	**CFRUS*, 21, 175, 105, 1988** **Code of Federal Regulations**	***Entry / Update :***	NOV1991