201-15009

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Existing Chemical	:	ID: 3622-84-2
CAS No.	:	3622-84-2
EINECS Name	:	N-butylbenzenesulphonamide
EC No.	:	222-823-6
TSCA Name	:	Benzenesulfonamide, N-butyl-
Molecular Formula	:	C10H15NO2S

Producer related part

Company	:	Proviron Fine Chemicals N.V.
Creation date	:	13.08.2003

Substance related part

Company	:	Proviron Fine Chemicals N.V.
Creation date	:	13.08.2003
Status	:	
Memo	:	HPV Challenge Program
Printing date	:	29.12.2003
Revision date	:	
Date of last update	:	29.12.2003
Number of pages	:	20
Chapter (profile)	:	Chapter: 1.0.1, 1.0.2, 1.0.3, 1.0.4, 1.1.0, 1.1.1, 1.2, 1.6.1, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6.1, 2.7, 3.5, 4.1, 4.2, 4.3, 5.0, 5.1.1, 5.1.2, 5.1.3, 5.4, 5.5, 5.9
Reliability (profile)	:	
Flags (profile)	:	

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	manufacturer
Name	:	Proviron Fine Chemicals N.V.
Contact person	:	Vincent Acou
Date	:	
Street	:	Stationsstraat 123 bus 2
Town	:	8400 Oostende
Country	:	Belgium
Phone	:	+32 59 56 21 00
Telefax	:	+32 59 56 21 30
Telex	:	
Cedex	:	
Email	:	vincent.acou@proviron.com
Homepage	:	

21.06.2001

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

Type	:	manufacturer
Name of plant	:	Proviron Fine Chemicals N.V.
Street	:	Stationsstraat 123 bus 2
Town	:	8400 Oostende
Country	:	Belgium
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

21.06.2001

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	
Smiles Code	:	
Molecular formula	:	C10H15NO2S
Molecular weight	:	213.3
Petrol class	:	

21.06.2001

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :

Substance type : organic
Physical status : liquid
Purity : >= 99 % w/w
Colour :
Odour :

10.12.2003

1.2 SYNONYMS AND TRADENAMES

BBSA; n-Butylamide of benzenesulphonic acid

14.05.1998

1.6.1 LABELLING

Labelling : provisionally by manufacturer/importer
Specific limits :

10.12.2003

2.1 MELTING POINT

Value	:	< -30 °C
Sublimation	:	
Method	:	other: ISO 1392
Year	:	1991
GLP	:	no
Test substance	:	

14.05.1998

2.2 BOILING POINT

Value	:	> 250 °C at 1013 hPa
Source	:	Proviron Fine Chemicals N.V. Oostende

10.12.2003

2.3 DENSITY

Type	:	relative density
Value	:	ca. 1.147 g/cm³ at 20 °C
Method	:	other: ISO 758
Year	:	1991
GLP	:	no
Test substance	:	

14.05.1998

2.4 VAPOUR PRESSURE

Value	:	.56 hPa at 184 °C
Decomposition	:	
Method	:	
Year	:	1954
GLP	:	no
Test substance	:	

Source	:	Proviron Fine Chemicals N.V. Oostende

14.05.1998

2.5 PARTITION COEFFICIENT

Partition coefficient	:	octanol-water
Log pow	:	= 2.1 at °C
pH value	:	
Method	:	other (calculated)
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Method	:	Rekker calculation method
Source	:	Proviron Fine Chemicals

21.11.2003

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	ca. 1.02 at 20 °C
pH value	:	ca. 6.7
concentration	:	1.02 g/l at 20 °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	

21.11.2003

2.7 FLASH POINT

Value	:	>= 200 °C
Type	:	open cup
Method	:	other: ISO 2719
Year	:	1991
GLP	:	no
Test substance	:	

14.05.1998 (3)

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	21.5 mg/l related to Test substance related to
Contact time	:	
Degradation	:	ca. 18 (±) % after 28 day(s)
Result	:	
Control substance	:	other
Kinetic	:	% %
Deg. product	:	
Method	:	OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	In the toxicity control more than 25% degradation occured within 14 days (based on ThCOé). Therefore, the test substance was assumed to be not inhibitory.
Result	:	The substance was not readily biodegradable under the conditions of the performed modified Sturm test.
Source	:	Proviron Fine Chemicals
Reliability	:	(1) valid without restriction
Flag	:	confidential

21.11.2003

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC50	:	= 56 measured/nominal
Method	:	OECD Guide-line 202
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Proviron Fine Chemicals
Reliability	:	(1) valid without restriction
Flag	:	confidential

21.11.2003

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Selenastrum capricornutum (Algae)
Endpoint	:	growth rate
Exposure period	:	72 hour(s)
Unit	:	mg/l
NOEC	:	= 10
EC50	:	= 83 measured/nominal
Method	:	OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	The EC50 for cell growth inhibition was 49 mg/l, the NOEC was determined to be 22 mg/l.
Source	:	Proviron Fine Chemicals
Reliability	:	(1) valid without restriction
Flag	:	confidential

21.11.2003

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	= 2070 mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	
Method	:	Directive 92/69/EEC, B.1
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction
Flag	:	confidential

10.12.2003 (4)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	LC50
Value	:	> 4.066 mg/l
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	4 hour(s)
Method	:	OECD Guide-line 403 "Acute Inhalation Toxicity"
Year	:	1991
GLP	:	yes
Test substance	:	other TS: BBSA 99.8% grade
Remark	:	BBSA concentration at saturation (in air) : 0.06 ug/l at 20°C
Flag	:	confidential

14.05.1998 (1)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD50
Value	:	> 2000 mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	
Method	:	Directive 92/69/EEC, B.3
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction

Flag : confidential
10.12.2003 (5)

5.4 REPEATED DOSE TOXICITY

Type : Sub-acute
Species : rat
Sex : male/female
Strain : Wistar
Route of admin. : gavage
Exposure period : 28 Days
Frequency of treatm. : Daily
Post exposure period :
Doses : 0-50-150-1000 mg/kg/day
Control group : yes
NOAEL : = 50 mg/kg
Method : OECD Guide-line 407 "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-d Study"
Year : 2003
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Result : The high dose of 1000 mg/kg/day resulted in the deth or moribund state of all rats. Clinical signs shown by these animals prioe to death/sacrifice included lethargy, hunched posture, uncoordinated movements, abnormal gait, salivation, emaciation, laboured respiration, swelling of hte abdomen or head and piloerection.
Examination revealed liver enlargement and hepatocyte hypertrophy, liver necrosis, hyaline droplets formation in the renal papillary collecting ducts, adrenal gland enlargement with fatty change or cortical hypertrophy and reduced size and/or arophy of the thymus, spleen and male reproductive organs.
At 150 mg/kg/day, post-mortem findings were confined to liver enlargement and hepatocyte hypertrophy, thymic atrophy and lymphocytolysis.
Cortical hyaline were noted in the kidneys of most male rats dosed at 50 mg/kg/day and above. This is a specific male rat response and is not observed in female rats or higher species of either sex.
Degenerating nerve fibres were observed at low incidence and severity in the spinal cord and sciatic nerves at 150 and 1000 mg/kg/day.
At 50 and 150 mg/kg/day, there were no changes at performance of functional observations, body weight and food consumption measurements.
At 50 mg/kg/day there sere no treatment related macro- or microscopic findings.
Source : Proviron Fine Chemicals
Conclusion : A No Observed Adverse Effect Level (NOAEL) of 50 mg/kg/day was established (excluding the presence of hyaline droplets in male kidneys).
Reliability : (1) valid without restriction
Flag : confidential
21.11.2003

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : salmonella typhimurium
Test concentration : 5, 50, 500 and 5000 ug/plate. Strains : TA1535, TA1537, TA1538, TA98 & TA100
Cycotoxic concentr. :

Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 471
Year	:	1983
GLP	:	no
Test substance	:	other TS: UCB 99.5% grade
Flag	:	confidential

14.05.1998 (2)

9. References

(1) BAYER AG, Fachbereich Toxikologie; unpublished study T9037171/T 8039718; 04.01.1991 (joint property BAYER/UCB)

(2) HRC UCB 180/83524 (1983)

(3) Proviron Fine Chemicals N.V. Oostende

(4) UCB 565/952011/AC

(5) UCB 566/951936/AC