

Exposure period: 33 day(s)
 Unit: mg/l Analytical monitoring: yes
 NOEC: 1.02 -
 LOEC: 2.04 -

Method: other: comp. to OECD 210 (Fish, Early-life Stage Toxicity Test, 1992)
 Year: 1992
 GLP: no data
 Test substance: other TS: 99 %

Remark: In a first step 50 embryos were tested on hatchability and development after 4 - 5 days of incubation. In a second step 15 randomly selected fryes from the initial egg cups were observed on their further development for 33 days. The 33 d-NOEC was determined by the authors Call & Geiger (1992) to be 0.264 mg/l based on the endpoint 'normal larvae' related to the hatched larvae. The review of the raw data of the study shows, that at the next higher test concentration of 0.530 mg/l a statistically significant effect compared to the control could be observed, however, there is no dose-effect relation for this endpoint at higher test concentrations. The highest test concentration of 3.9 mg/l shows less normal larvae after hatch with a deviation of 7 % compared to the control. Apart from that regarding the endpoint 'normal larvae related to initial embryos' no effect at any concentration can be seen. Regarding 'weight' and 'length' of the fry, at both endpoints a deviation to the control of > 5 % can be seen at a concentration of 2.04 mg/l. Also for this endpoint there is no dose-effect relationship seen at the next higher concentration. As statistically significant effects for the endpoint "normal larvae" were seen at concentrations above 0.264 mg/l, the NOEC derived by the authors is used for the hazard assessment for reasons of precaution.

Test condition: Flow through system
 Photoperiod: 16 h light / 8 h dark
 Temperature, mean: 24.81 degree C
 O2, mean: 6.32 mg/l
 pH, mean: 7.42
 Total hardness: 54.35 mg/l CaCO3
 Total alkalinity, mean: 45.09 mg/l CaCO3

Reliability: (2) valid with restrictions
 Well-documented study, comparable to guideline

Flag: Critical study for SIDS endpoint
 07-SEP-2001 (17)

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
 Endpoint: reproduction rate
 Exposure period: 21 day(s)
 Unit: mg/l Analytical monitoring: yes
 NOEC: = 3 -

Method: other: UBA-Verfahrensvorschlag (vorlaeufiger) "Verlaengerter Toxizitaetstest bei Daphnia magna" (Bestimmung der NOEC fuer Reproduktionsrate, Mortalitaet und den Zeitpunkt des ersten Auftretens von Nachkommen; 21d) (1984)
 Year: 1987
 GLP: no data
 Test substance: other TS: no purity given

Remark: semistatic test system
Reliability: (1) valid without restriction
Test procedure according to national standards
Flag: Critical study for SIDS endpoint
27-JUL-2001 (57)

Species: Daphnia magna (Crustacea)
Endpoint: reproduction rate
Exposure period: 21 day(s)
Unit: mg/l Analytical monitoring: no data
LOEC: 9.9 -

Method: other: According to the Protocol of the Dutch Standards
Organisation, NEN 6502 (1980)
Year: 1988
GLP: no data
Test substance: other TS: no purity given

Remark: semi static test system
Reliability: (2) valid with restrictions
Basic data given
27-JUL-2001 (23)

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

Species: other terrestrial plant: *Lactuca sativa* Ravel R2
Endpoint: growth
Expos. period: 14 day(s)
Unit: mg/kg soil dw
EC50: = 3.2 - 10

Method: other: OECD Guide-line 208 (1984)
Year: 1991
GLP: no data
Test substance: other TS: purity \geq 95 % (summarized information for all test substances)

Remark: Two different natural soils at different testing facilities were used. Both soil characteristics corr. to OECD advice of an Entisol soil (organic matter content 1.4 % and 1.8 % resp., and clay content 12 % and 24 % resp., pH 7.5). Nominal concentrations given

Test condition: 10 seeds per tray, trays covered with glass plates, temperature 21 °C, photoperiod 16 h light / 8 h dark; light intensity 6,500 Lux; humidity 40-80 %

Reliability: (2) valid with restrictions
Guideline study with acceptable restrictions; only one type of soil tested

Flag: Critical study for SIDS endpoint
10-AUG-2001 (46)

Species: other terrestrial plant: *Cucumis sativus* var. National Pickling
Endpoint: growth
Expos. period: 6 day(s)
Unit: mg/l

Method: other: germination and growth of seedlings in sand
Year: 1961
GLP: no
Test substance: other TS: recrystallized

Remark: A definite amount of test solution was added to sand. Three concentrations were tested (20, 50, and 100 ppm) by weight in to water.

Result: A 6 d-ED 50 of 18.1 mg/l was determined for sand.

Reliability: (3) invalid
Unsuitable test system (no soil tested)

11-JUL-2001 (27)

Species: *Phaseolus aureus* (Dicotyledon)
Endpoint: growth
Expos. period: 6 day(s)
Unit: mg/l

Method: other: germination and growth of seedlings in sand
Year: 1961
GLP: no
Test substance: other TS: recrystallized

Remark: A definite amount of test solution was added to sand. Three concentrations were tested (20, 50, and 100 ppm) by weight in to water.

Result: A 6 d-ED 50 of 29.9 mg/l was determined for sand.

Reliability: (3) invalid
Unsuitable test system (no soil tested)

11-JUL-2001

(27)

4.6.3 Toxicity to Soil Dwelling Organisms

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

5.0 Toxicokinetics, Metabolism and Distribution

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex: male
No. of Animals: 15
Vehicle: other: polyethylene glycol 400
Value: = 219 mg/kg bw

Method: other: 15 rats/dose group, 7 doses dissolved in polyethylenglycol 400, given by gavage, observation time: 14 d
Year: 1976
GLP: no
Test substance: as prescribed by 1.1 - 1.4

Remark:	dosis mg/kg	conc. %	result m /s /n	signs of intoxication		time of death
				start	end	
	50	1	0/ 0/15	-	-	-
	100	2	0/15/15	49 min.	5 d	-
	150	3	2/15/15	20 min	7 d	2 d
	200	4	4/15/15	16 min	7 d	24 h
	250	5	10/15/15	36 min	11 d	1-2 d
	300	6	14/15/15	13 min	9 d	24 h
	500	10	15/15/15	18 min	-	24 h

m: number of rats which died;
n: number of animals put in test
s: number of animals with signs of intoxication:
reduced general condition, cyanotic appearance

Reliability: (2) valid with restrictions
no histopathological examination performed, individual animal data and information on GLP is missing

21-MAR-2003

(6)

Type: LD50
Species: rat
Sex: female
No. of Animals: 15
Vehicle: other: polyethylene glycol 400
Value: = 457 mg/kg bw

Method: other: 15 rats/dose group, 8 doses dissolved in polyethylenglycol 400, given by gavage, observation time: 14 d
Year: 1976
GLP: no
Test substance: as prescribed by 1.1 - 1.4

Remark:	dosis	conc.	result	signs of intoxication		time of death
	mg/kg	%	m /s /n	start	end	
	25	0.5	0/ 0/15	-	-	-
	50	1	0/15/15	24 h	3 d	-
	100	2	0/15/15	24 h	7 d	-
	250	5	1/15/15	90 min	7 d	8 d
	350	7	2/15/15	11 min	7 d	1-2 d
	500	10	10/15/15	2 h	13 d	1-2 d
	650	13	12/15/15	8 min	12 d	1-2 d
	850	17	15/15/15	2 h	-	1-2 d

m: number of rats which died;
n: number of animals put in test
s: number of animals with signs of intoxication:
reduced general condition, cyanotic appearance
Reliability: (2) valid with restrictions
no histopathological examination performed, individual
animal data and information on GLP is missing

21-MAR-2003

(6)

Type: LD50
Species: rat
Strain: Wistar
Sex: male
No. of Animals: 10
Vehicle: other: Lutrol
Value: = 251 mg/kg bw

Method: other: 10 rats/dose, 5 doses, test subst. dissolved in lutrol,
gavage: application volume: 20 ml/kg bw., observation time: 14
d, some of the rats, that died, and some of the survivors were
dissected

Year: 1982
GLP: no

Test substance: as prescribed by 1.1 - 1.4

Remark:	dosis	result	signs of intoxication	time of death
	mg/kg	m /s /n	start	
	100	0/ 0/10	-	-
	200	2/10/10	1 h	8 - 24 h
	250	5/10/10	1 h	4 - 24 h
	300	7/10/10	1 h	8 h - 3 d
	400	10/10/10	1 h	4 h - 2 d

m: number of rats which died;
n: number of animals in test
s: number of animals with signs of intoxication:
reduced general condition, cyanotic appearance, rough fur,
sedation, narcosis, no macroscopic effects in dissected
animals

Reliability: (2) valid with restrictions
study meets criteria of today, but information on GLP is
missing

Flag: Critical study for SIDS endpoint

21-MAR-2003

(7)

Type: LD50
Species: rat
Strain: Wistar

Sex: female
 No. of Animals: 10
 Vehicle: other: Lutrol
 Value: = 263 mg/kg bw

Method: other: 10 rats/dose, 5 doses, test subst. dissolved in lutrol, gavage: application volume: 20 ml/kg bw., observation time: 14 d, some of the animals, that died, and some of the survivors were dissected

Year: 1982
 GLP: no

Test substance: as prescribed by 1.1 - 1.4

Remark:	dosis mg/kg	result m /s /n	signs of intoxication start	time of death
	100	0/ 0/10	-	-
	200	3/10/10	2 h	8 h - 3 d
	300	5/10/10	2 h	24 h - 3 d
	400	9/10/10	1 h	24 h - 3 d
	500	10/10/10	1 h	4 h - 3 d

m: number of rats which died;
 n: number of animals in test
 s: number of animals with signs of intoxication:
 reduced general condition, cyanotic appearance, rough fur, sedation, narcosis, paralysis of the hind limb

Reliability: no macroscopic effects in dissected animals
 (2) valid with restrictions
 study meets criteria of today, but information on GLP is missing

Flag: Critical study for SIDS endpoint
 21-MAR-2003

(8)

Type: LD50
 Species: rat
 Strain: Wistar
 Sex: male
 No. of Animals: 10
 Vehicle: other:sesame oil
 Value: = 144 mg/kg bw

Method: other: 10 rats/dose, males were more sensitive in a pre-test, starved 16 hrs prior appl. and 2 hrs post appl., 4 doses, dissolved in sesame oil, single application by gavage, observation time: 14 d

Year: 1975
 GLP: no

Test substance: other TS: no data on purity

Remark: doses and mortality rate (death occurred within 3 days):
 63 mg/kg: 0/10; 100 mg/kg: 2/10;
 160 mg/kg: 5/10; 250 mg/kg: 10/10
 signs of intoxication: imbalance, rough fur, diarrhea, slight tremor
 section of survivors: no findings
 section of rats, that had died, was not possible because of autolytic changes.

Reliability: (2) valid with restrictions
 individual animal data of signs of intoxication and information on GLP is missing

Flag: Critical study for SIDS endpoint (40)
25-MAR-2003

Type: LD50
Species: rat
Sex: no data
Vehicle: no data
Value: = 350 mg/kg bw

Method: other: no information
Year: 1967
GLP: no data
Test substance: other TS: no data on purity

Reliability: (4) not assignable
lack of information
16-JUN-2003 (22)

Type: LD50
Species: rat
Sex: no data
Vehicle: no data
Value: = 339 mg/kg bw

Method: other: no information given
Year: 1982
GLP: no data
Test substance: other TS: no data on purity

Remark: clinical signs: central nervous system affected,
methaemoglobin former (no further information)

Reliability: (4) not assignable
lack of information
16-JUN-2003 (50)

Type: LD50
Species: rat
Strain: Sprague-Dawley
Sex: male/female
Vehicle: other: corn oil
Value: = 560 mg/kg bw

Method: other: 2 or 3 rats/dose, single oral dose as 10 % warm
solution, observation time: 7 d
Year: 1983
GLP: no data
Test substance: other TS: purity: 99.71 %

Remark: doses and mortality:
398 mg/kg: males 1/2 females 0/3
501 mg/kg: males 1/3 females 1/2
631 mg/kg: males 2/2 females 2/3
794 mg/kg: males 3/3 females 2/2
signs of intoxication: reduced appetite and activity(2-3
days in survivors), increasing weakness, ocular discharge,
collapse and death
time to death: 1-4 days with most deaths within 2 days
gross autopsy:
decadents: hemorrhagic lungs, jaundiced liver, darkened
kidneys and spleen, and gastrointestinal inflammation
survivors: lung congestion and darkened kidneys and spleen

Reliability:	(2) valid with restrictions individual animal data and information on GLP is missing	
Flag:	Critical study for SIDS endpoint	
21-MAR-2003		(68) (113)
Type:	LD50	
Species:	rat	
Sex:	no data	
Vehicle:	no data	
Value:	= 288 mg/kg bw	
Method:	other: observation time: 14 d (no further information)	
Year:	1972	
GLP:	no	
Test substance:	other TS: no data on purity	
Reliability:	(4) not assignable lack of information	
16-JUN-2003		(2)
Type:	LD50	
Species:	rat	
Value:	= 510 mg/kg bw	
Method:	other: no details given	
Reliability:	(4) not assignable lack of information	
16-JUN-2003		(106)
Type:	LD50	
Species:	rat	
Sex:	male	
Value:	= 270 mg/kg bw	
Method:	other: according to Smyth, Am. Ind. Hyg. Ass. J. 30, 470 (1962)	
Year:	1977	
GLP:	no	
Test substance:	other TS: no data on purity	
Reliability:	(4) not assignable lack of information	
16-JUN-2003		(107)
Type:	LD50	
Species:	rat	
Sex:	male	
Value:	= 300 mg/kg bw	
Method:	other: no further information given	
Year:	1988	
GLP:	no data	
Test substance:	other TS: no data on purity	
Reliability:	(4) not assignable lack of information	
16-JUN-2003		(65)
Type:	LD50	
Species:	rat	
Sex:	male	

No. of Animals: 5
Vehicle: other: none
Value: ca. 630 mg/kg bw

Method: other: 3 rats/dose, single oral application of undiluted
substance, observation time: 14 d
Year: 1975
GLP: no
Test substance: other TS: o-nitrochlorobenzene residue

Remark: dose / mortality / time of death:
50 mg/kg / 0/5 / -;
500 mg/kg / 2/5 / one day;
5000 mg/kg / 5/5 / one day
signs of intoxication: reduced appetite and activity (2-4
days in survivors, increasing weakness, collapse, and death
gross autopsy:
decedents: haemorrhagic areas of the lungs, slight liver
discoloration, acute gastrointestinal inflammation
survivors: viscera appeared normal

Reliability: (4) not assignable
o-nitrochlorobenzene residue used, no information for
o-nitrochlorobenzene itself

21-MAR-2003 (111)

Type: LD50
Species: mouse
Sex: no data
Vehicle: no data
Value: = 440 mg/kg bw

Method: other: no information given
Year: 1982
GLP: no data
Test substance: other TS: no data on purity

Remark: clinical signs: central nervous system affected,
methaemoglobin former (no further information)

Reliability: (4) not assignable
lack of information

16-JUN-2003 (50)

Type: LD50
Species: mouse
Sex: no data
Vehicle: no data
Value: = 135 mg/kg bw

Method: other: observation time: 14 d (no further information)
Year: 1972
GLP: no
Test substance: other TS: no data on purity

Reliability: (4) not assignable
lack of information

16-JUN-2003 (2)

Type: LD50
Species: mouse
Value: = 340 mg/kg bw

Method: other: no details given

Reliability: (4) not assignable
lack of information
16-JUN-2003 (106)

Type: LD50
Species: mouse
Value: = 140 mg/kg bw

Method: other: according to Smyth, Am. Ind. Hyg. Ass. J. 30, 470
(1962)

Year: 1977

GLP: no

Test substance: other TS: no data on purity

Reliability: (4) not assignable
lack of information
16-JUN-2003 (107)

Type: LD50
Species: rabbit
Sex: no data
Vehicle: no data
Value: = 280 mg/kg bw
Method: other: no information given
Year: 1982
GLP: no data

Test substance: other TS: no data on purity
Remark: clinical signs: central nervous system affected,
methaemoglobin former (no further information)

Reliability: (4) not assignable
lack of information
16-JUN-2003 (50)

5.1.2 Acute Inhalation Toxicity

Type: LC50
Species: rat
Strain: other: CD
Sex: male
No. of Animals: 10
Exposure time: 4 hour(s)
Value: ca. 3200 mg/m³
Method: other: 10 male rats/conc., head-only exposure, 6 conc., heated
vapour was diluted with humidified and O₂-enriched air and
thus converted to a mixture of vapour and liquid aerosol, post
exposure observation time: 14 d
Year: 1981
GLP: no data

Test substance: other TS: purity: 99.8 %
Remark: Concentration Mortality Time to death
(mg/l) 0, 1, 2, 3, 5, 7 (d)

1.56	1/10				1
1.83	3/10		2	1	
2.46	2/10		1	1	
2.64	10/10	1	1	7	1
3.23	1/10			1	
3.33	6/10	1	2	2	1

signs of intoxication during exposure: slight to moderate cyanosis, semi-prostration, lethargy and reddish brown nasal discharge to 24 hours, slight to moderate corneal opacity, tachypnea, some rats with partial hind-leg paralysis, abnormal arched-back posture
signs of intoxication post exposure: weight loss of 8 to 16 % from 1 to 3 days with normal gains thereafter, pallor, stained perineal area, lethargy; some rats with salivation, lacrimation and corneal opacity, chromodacryorrhea
gross autopsy not reported
LD50: 495 ppm
Mortalities were not strictly dose-dependant, stat. analysis showed a non significant regression
value: LD50: 495 ppm
Reliability: (2) valid with restrictions
gross autopsy not reported, no information about GLP
Flag: Critical study for SIDS endpoint
21-MAR-2003 (31)

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rat
Strain: Wistar
Sex: male
No. of Animals: 10
Vehicle: other: polyethylene glycol 400
Value: = 655 mg/kg bw
Method: other: 10 rats/dose, 6 doses, subst. (solved in polyethylene glycol 400) appl. on the shaved back for 24 hours, covered by alu and a plaster, then rinsed with water and soap, post exposure observ.-time: 14 d
Year: 1976
GLP: no
Test substance: as prescribed by 1.1 - 1.4

Remark:	dosis mg/kg	conc. %	result m/s	signs of intoxication n	time of death start	time of death end
	250	25	1/10/10		18 h	14 d
	350	25	1/10/10		18 h	7 d
	500	50	3/10/10		18 h	9 d
	750	50	7/10/10		24 h	13 d
	1000	50	7/10/10		18 h	4 d
	1500	75	9/10/10		18 h	14 d

m: number of rats which died;
n: number of animals put in test
s: number of animals with signs of intoxication:
reduced general condition, difficulties in breathing, cyanotic appearance, some animals showed lacrimation
(2) valid with restrictions

Reliability: no pathologic examination performed, individual animal data and information on GLP are missing
Flag: Critical study for SIDS endpoint
21-MAR-2003 (6)

Type: LD50
Species: rat