

4. ECOTOXICITY

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|-------------------------|---|---------------------------------------|
| Remark: | static test 24h-EC50: 75 mg/l | |
| 10-MAY-1994 | | (21) |
| Species: | Daphnia magna (Crustacea) | |
| Exposure period: | 21 day(s) | |
| Unit: | mg/l | Analytical monitoring: |
| NOEC: | 1 - | |
| Method: | OECD Guide-line 202 | |
| Remark: | EC50: > 3.2 - < 10 (Immobilization of parental organisms); a NOEC for the inhibition of the reproduction rate could not be determined | |
| 26-APR-1995 | | (18) |
| Species: | Daphnia magna (Crustacea) | |
| Exposure period: | 24 hour(s) | |
| Unit: | mg/l | Analytical monitoring: no |
| EC0: | 22 - | |
| EC50: | 92,4 - | |
| EC100: | 354 - | |
| Method: | other: Daphnien-Schwimmunfaehigkeits-Test, UBA-Verfahrensvorschlag Mai 1984, Bestimmung der Schwimmunfaehigkeit beim Wasserfloh Daphnia magna, EC0, EC50, EC100 24h, statisches System | |
| Year: | 1989 | |
| GLP: | yes | |
| Remark: | Distillate of technical product | |
| | | (18) |
| Species: | Daphnia magna (Crustacea) | |
| Exposure period: | 48 hour(s) | |
| Unit: | mg/l | Analytical monitoring: no data |
| EC50: | 33,9 - | |
| Method: | other: EEC, 1989, Methods for the determination of ecotoxicity. C.2 Acute toxicitty for Daphnia (Updated Version 11/89). EEC Directive 79(831, Annex V, Part C. Brussels, Belgium (static) | |
| Year: | 1994 | |
| GLP: | no data | |
| Test substance: | other TS: purity > 99 % | |
| Remark: | Arithmetic mean of 3 test results (standard deviation was 5.3 mg/l). | |
| 26-APR-1995 | | (22) |
| Species: | Daphnia magna (Crustacea) | |
| Exposure period: | 48 hour(s) | |
| Unit: | mg/l | Analytical monitoring: |
| LC50 : | 12 - | |
| Remark: | validation not possible | |
| Source: | DOW Europe S.A., Switzerland | |
| 26-APR-1995 | | (20) |

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4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Chlorella pyrenoidosa (Algae)
Endpoint: growth rate
Exposure period: 5 day(s)
Unit: mg/l **Analytical monitoring:**
EC100 : >= 146 -
Remark: Validity uncertain. Slow growth of the control culture.
Test condition: 25 degree C, pH 7

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC10: ,67 -
EC50: 2,5 -
Method: other: Scenedesmus-Zellvermehrungs-Hemmtest, DIN 38412 Teil 9, Bestimmung der Hemmwirkung von Wasserinhaltsstoffen auf Gruenalgen
Year: 1989
GLP: yes
Test substance: other TS: purity 98.04 %
Remark: Due to the high growth rate, the pH rose to 10.2 - 10.3 after 72 hours in the control and for concentrations of TETA up to 1 mg/l
(18)

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC10: ,95 -
EC50: >= 100 -
Method: other: Scenedesmus-Zellvermehrungs-Hemmtest, DIN 38412 Teil 9, Bestimmung der Hemmwirkung von Wasserinhaltsstoffen auf Gruenalgen
Year: 1989
GLP: yes
Test substance: other TS: purity 98.04 %
Remark: Due to the high growth rate, the pH rose to 10.2 - 10.3 after 72 hours in the control and for concentrations of TETA up to 1 mg/l
(18)

Species: Selenastrum capricornutum (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no
NOEC: < 2,5 -
EC50: 20 -
Method: Directive 87/302/EEC, part C, p. 89 "Algal inhibition test"
Year: 1990
GLP: yes

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Test substance: other TS: Triethylenetetramine, purity 97.5%

Remark: For the endpoint {growth rate}, the same results were obtained
 10-MAY-1994 (24)

Species: Selenastrum capricornutum (Algae)
Endpoint: growth rate
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
EC50: 3,7 -

Method: other: EEC, 1988, Methods for the determination of ecotoxicity. Algal inhibition test. Off J. Eur. Comm. L 133 1988-0530
Year: 1994
GLP: no data
Test substance: other TS: purity > 99 %

Remark: Arithmetic mean of 5 test results (standard deviation: 1.5 mg/l). The culture medium was modified by increasing the KH₂PO₄ conc. from 1.6 to 160 mg/l and the NaHCO₃ conc. from 50 to 100 mg/l, to improve the growth of algae and the buffer capacity of the medium.
 26-APR-1995 (22)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: Pseudomonas fluorescens (Bacteria)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
EC0: 500 -

Method: other: Bestimmung der biologischen Schadwirkung toxischer Abwaesser gegen Bakterien. DEV, L 8 (1968) modifiziert

Remark: technical product;
 no further information on test conditions (18)

4.5 Chronic Toxicity to Aquatic Organisms4.5.1 Chronic Toxicity to Fish4.5.2 Chronic Toxicity to Aquatic Invertebrates

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TERRESTRIAL ORGANISMS4.6.1 Toxicity to Sediment Dwelling Organisms4.6.2 Toxicity to Terrestrial Plants

Remark: no validated information

4.6.3 Toxicity to Soil Dwelling Organisms4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

Species: other avian: Agelaius Phoenicus (redwinged blackbird)
Endpoint: mortality
Unit: mg/kg bw
LD50 : > 101 -

Method: other: no data
GLP: no data
Test substance: other TS: TETA (no information about purity)

Remark: Estimated LD50 based on food consumption data over a 18 h period

29-NOV-1994

(25)

4.7 Biological Effects Monitoring4.8 Biotransformation and Kinetics4.9 Additional Remarks

Remark: Sea-urchin: Inhibition of development
Eggs of the species Paracentrotus lividus were incubated in sea-water 30 min after impregnation (concentration TETA: 293 - 7313 mg/l). No teratogenic effects observed.
Depending on the developmental stage there was an effect on larvae (293 mg/l), gastrula (731 mg/l), blastula (2925 mg/l), cleavage stage (7313 mg/l).

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Remark: Application of 1460 mg/l TETA (alcoholic solution) to 1-2 days old larval stages and 2 days old egg-stages of the species Dysdercus koenigii F. had no acute toxic effects and no effects on the eggs as well as no sterilizing effects.

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5.0 Toxicokinetics, Metabolism and Distribution5.1 Acute Toxicity5.1.1 Acute Oral Toxicity

Type: LD50
 Species: rat
 Value: = 2780 mg/kg bw

Method: other: male rats, undiluted testsubstance (no further information)
 GLP: no data
 Test substance: no data

29-JUL-1996

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Type: LD50
 Species: rat
 Value: ca. 3750 mg/kg bw

Method: other: 3 animals per group; doses: 1000, 2500, 3750, 5000 mg/kg; test substance diluted in water
 GLP: no data
 Test substance: no data

17-OCT-1994

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Type: LD50
 Species: rat
 Value: = 4340 mg/kg bw

Method: other: 5 animals per group, test substance diluted in water
 GLP: no data
 Test substance: no data

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Type: LD50
 Species: rat
 Value: = 2500 mg/kg bw

GLP: no data
 Test substance: no data

Remark: method: no data

(13)

Type: LD50
 Species: rat
 Value: = 4300 mg/kg bw

GLP: no data
 Test substance: no data

Remark: method: no data

17-OCT-1994

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5. TOXICITY

Type: LD50
Species: mouse
Value: = 1600 mg/kg bw

GLP: no data
Test substance: no data

Remark: method: no data
17-OCT-1994

(31)

Type: LD50
Species: rabbit
Value: = 5500 mg/kg bw

GLP: no data
Test substance: no data

Remark: method: no data
17-OCT-1994

(31)

5.1.2 Acute Inhalation Toxicity

Type: other: see method
Species: rat

Method: other: saturated vapor at 21 degree C, 8 h exposure, 6 animals
GLP: no data
Test substance: no data

Remark: no symptoms
17-OCT-1994

(28)

Type: other: see method
Species: rat

Method: other: saturated vapor inhalation up to 8 h
GLP: no data
Test substance: no data

Remark: maximal time for no deaths 4 h

(30)

Type: other: see method
Species: other: see method

Method: other: 2 rats, 1 rabbit, 1 guinea pig, and 4 mice were exposed together to aerosol (10 ml of 40 % (v/v) ethanol solution, 400 l chamber) for 1 h

GLP: no data
Test substance: no data

Remark: effects: slight irritation of the mucous membranes and impeded respiration, effects reversible

17-OCT-1994

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5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Value: = 550 mg/kg bw

Method: other: 4 animals per dose, undiluted test substance
GLP: no data
Test substance: no data

Remark: no further information available
17-OCT-1994 (28)

Type: LD50
Species: rabbit
Value: = 805 mg/kg bw

Method: other: occlusive application of undiluted test substance
GLP: no data
Test substance: no data

Remark: no further information available (30)

5.1.4 Acute Toxicity, other Routes

Type: LD50
Species: rat
Route of admin.: i.p.
Value: = 200 mg/kg bw

Method: 3-5 animals per group, test substance as aqueous solution
GLP: no data
Test substance: no data

Remark: impeded respiration
17-OCT-1994 (29)

Type: LD50
Species: rat
Route of admin.: i.p.
Value: = 78,4 mg/kg bw

Method: no data
GLP: no data
Test substance: no data

Remark: symptoms like hyperemia, extravasations; regressive changes in liver and kidneys; abstract (32)

Type: LD50
Species: mouse
Route of admin.: i.p.
Value: = 604 mg/kg bw

Method: test substance neutralized with HCl, 10 mice per group
GLP: no data
Test substance: no data

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Remark: convulsions for max. 20 min, hyperemia of inner organs in the dead animals (33)

5.2 Corrosiveness and Irritation5.2.1 Skin Irritation

Species: rabbit

Method: other: non occlusive appl.;
a) 0.01 ml undiluted
b) 10% in water

GLP: no data

Test substance: no data

Remark: effects: a) 2 out of 2 animals with necrosis
b) no effects
no further information available

17-OCT-1994 (28)

Species: rabbit

Method: other: 20 mg applied to skin

GLP: no data

Test substance: no data

Remark: effects: necrotic foci and extravasations
no further information available, abstract (32)

Species: rabbit

Method: other: undiluted drug applied to the skin of 5 animals; no further information available

GLP: no data

Test substance: no data

Remark: effects: erythema, edema, necrosis (30)

Species: guinea pig

Method: other: intracutaneous injection of 0.1 ml 0.5-1% solution in water (non neutralized) or 2-3% solution in neutralized form

GLP: no data

Test substance: no data

Remark: effects: slight necrosis
no further information available (34)

Species: rat

Method: other: a) 1000 mg/kg undiluted; b) 50 mg/kg (25% in water); application on the shaved ventral skin; exposure time: 2 h

GLP: no data

Test substance: no data

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Remark: effects: strong irritations in both cases
17-OCT-1994 (29)

5.2.2 Eye Irritation

Species: rabbit
Method: other: instillation of a) 0.005 ml undiluted or b) 0.5 ml of a 40% watery solution
GLP: no data
Test substance: no data

Remark: effects: a) severe damage of the cornea b) 15% of the cornea damaged
17-OCT-1994 (28)

Species: rabbit
Method: other: 20 mg applied to the conjunctival sac
GLP: no data
Test substance: no data

Remark: effects: inflammation and lymphatic exudation
no further information available, abstract (32)

5.3 Sensitization

Type: Guinea pig maximization test
Species: guinea pig
Result: sensitizing

Method: other: 10 animals tested; induction concentration 0.5% intradermal and topical, challenge 2%
GLP: no data
Test substance: other TS: purity 99.5 %

Remark: 90% positive (35)

Type: Guinea pig maximization test
Species: guinea pig
Result: sensitizing

Method: other: 15 animals tested; induction concentration 0.5% intradermal and topical, challenge 2% (in water)
GLP: no data
Test substance: other TS: technical grade (no specification)

Remark: 80% of guinea pigs with positive reaction (36)

Type: Mouse ear swelling test
Species: mouse
Result: sensitizing

GLP: no data
Test substance: other TS: purity 99.5 %

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- Remark:** 4/10 positive (significant), induction conc. 10%, challenge 2.5%. (35)
- Type:** Open epicutaneous test
Species: human
- Remark:** 10 out of 22 workers exposed to araldite D and hardener TETA showed slight dermatosis, one worker serious allergic eczema. One of the 11 (the one with serious allergic eczema) showed allergic hypersensitivity in epicutaneous testing to TETA. (37)
- Type:** Patch-Test
Species: guinea pig
Result: not sensitizing
- Method:** other: no data
GLP: no data
Test substance: no data
- Remark:** no further information available, abstract (32)
- Type:** Patch-Test
Species: human
- Test substance:** no data
- Remark:** 4 out of 10 patients with dermatitis due to oil-based, amine containing drilling mud, showed allergic response to a 0.5% solution in the patch test. (38)
- Type:** Patch-Test
Species: human
- Remark:** In 23 out of 135 (18%) workers exposed to epoxy resins, a work-related dermatosis on the hands and/or forearms had been presented during the past 3 years. In all workers patch tests were performed and in 2 positive reactions to TETA were observed (2 out of 112 without dermatosis). (39)
- Type:** Patch-Test
Species: human
- Remark:** 422 employees of 8 factories had contact to epoxy resins and hardener TETA. In the course of 7 years there were 126 cases of dermatitis, 99 of whom were patch tested. 55.1% were positive to 1% TETA in water. The mean period between starting work and occurrence of dermatitis was 18.5 months. (40)
- Type:** Patch-Test
Species: human
- Remark:** 1544 patients(dermatitis) without exposure to epoxy resin systems and 137 patients in occupational contact with epoxy resins were patch tested. 28 out of the 1544 patients were

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positive to ethylenediamine; 12 of these were tested with TETA, 2 were positive. 400 out of the 1544 patients were also tested with TETA and results were negative. Tests with 137 patients in occupational contact to resins resulted in coexistence of positive reactions to TETA and ethylenediamine and TETA and diethylenetriamine.

(41)

Type: Patch-Test
Species: human

Remark: A 58 years old woman with dermatitis due to exposure with epoxy resins showed positive reaction in the patch test to epoxy resin and TETA as well as to ethylenediamine.

(42)

Type: Patch-Test
Species: human

Remark: 12 out of 32 ethylenediamine-sensitive patients showed cross-sensitivity reaction to TETA in the patch test.

(43)

Type: Patch-Test
Species: human

Remark: 19 out of 71 patients with allergic epoxy resin dermatitis were also allergic to different hardeners. 3 of them showed positive reactions to TETA in epicutaneous testing.

(44)

Type: Patch-Test
Species: human

Remark: A shipwright's yard worker complained a chronic dermatitis of the fingertips and palms. Beside other material he used epoxy resin SP 106. In the patch test a positive reaction to TETA was demonstrated after 48 and 96 h.

(45)

Type: Patch-Test
Species: human

Test substance: no data

Remark: 31 students and instructors at the same dental school were patch tested to contactants in dental components including TETA. None had any history of allergy. No positive allergic reactions were found.

(46)

Type: Patch-Test
Species: human

Test substance: no data

Remark: 2 out of 7 patients with airborne contact dermatitis of hands and face due to epoxy resins showed positive reactions in the patch test to TETA.

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- Type:** Patch-Test
Species: human
- Remark:** 14 young female patients (12 of them were seborrhean) in occupational contact with araldite D and hardener 951 (mainly TETA) suffering from eczema were patch tested. 1 of the 14 women was positive to 3% of the hardener in ethanol (48 h). (48)
- Type:** other
Species: human
- Remark:** 20 workers (6 without, 8 with slight and 6 with severe dermatosis) were patch tested with technical TETA (1% in water). 5 of the 6 workers with severe dermatosis showed a positive reaction. (34)
- Type:** other: see remarks
Species: human
- Remark:** 164 out of 328 workers from 11 factories producing electrical equipment showed slight dermatosis (21%, erythematous itching patches) or severe eczemas (22%) caused by direct contact to araldite resin D or hardener TETA. TETA concentration in air was below analytic limits of 0.00015 mg/l. (49) (50)
- Type:** other: see remarks
Species: human
- Remark:** 6 workers with diagnoses of occupational asthma were examined for sensitivity to epoxy resin systems and their components. In one worker asthma followed exposure to TETA fume in inhalation challenge testing. Skin sensitivity test was negative. (51)
- Type:** other: see remarks
Species: human
- Remark:** 447 patients suffering from eczema, occupationally exposed to epoxy resins, have been tested with Epidian 5 (resin) and five concentrations of the hardener TETA. In Poland these health damages were characterized by a considerable percentage of those sensitized to TETA. The calculation of eczema incubation period and testing the allergen by several allergen concentrations demonstrated that the sensitivity to TETA was sometimes very enhanced. (52)