FOREWORD INTRODUCTION

FSD-NA

FORMALDEHYDE REACTION PRODUCTS WITH SULFONATED 1,1'-OXYBIS[METHYL-BENZENE] SODIUM SALTS

CAS N°: 90387-57-8

SIDS Initial Assessment Report for 15th SIAM

(Boston, USA, 22-25 October 2002)

Chemical Name : Formaldehyde, reaction products with sulfonated 1,1'-oxybis[methyl-benzene], sodium salts (FSD-Na)

CAS No : 90387-57-8

Sponsor Country : Germany

National SIDS Contact Point in Sponsor Country Lead Organization:

Name of lead organization:
BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit)

Contact person:

Prof. Dr. Ulrich Schlottmann

Address:

Postfach 12 06 29
D- 53048 Bonn- Bad Godesberg

History: see next page

Testing: No new SIDS testing (X)
New SIDS testing ( )

Comments:

last literature search:

Toxicology: 23.12.01; Ecotoxicology: 07.01.02

OECD/ICCA - The BUA* Peer Review Process

Qualified BUA personnel (toxicologists, ecotoxicologists) perform a quality control on the full SIDS dossier submitted by industry. This quality control process follows internal BUA guidelines/instructions for the OECD/ICCA peer review process and includes:

- a full (or update) literature search to verify completeness of data provided by industry in the IUCLID/HEDSET

- Review of data and assessment of the quality of data

- Review of data evaluation

- Check of adequacy of selection process for key studies for OECD endpoints, and, where relevant, for non-OECD endpoints by checking original reports/publications

- Review of key study description according robust summaries requirements; completeness and correctness is checked against original reports/publications
  (if original reports are missing: reliability (4) = not assignable)

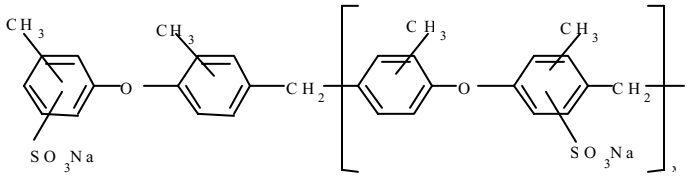
- Review o f validity of structure-activity relationships

- Review of full SIDS dossier (including SIAR, SIAP and proposal for conclusion and recommendation for further work)

- In case of data gaps, review of testing plan or rationale for not testing.

* BUA (GDCh-Beratergremium für Altstoffe): Advisory Committee on Existing Chemicals of the Association of German Chemists (GDCh)

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	90387-57-8
Chemical Name	Formaldehyde, reaction products with sulfonated 1, 1'-oxybis[methylbenzene], sodium salts (= FSD-Na)
Structural Formula	 $X \geq 1$

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

The acute toxicity of formaldehyde, reaction products with sulfonated 1,1'-oxybis (methylbenzene), sodium salts, (FSD-Na) is very low. The LD_{50} is above 5000 mg/kg after oral exposure in rats (clinical signs: apathy and reduced activity at 5000 mg/kg bw). FSD-Na is well tolerated after single application to the skin of rats. The dermal LD_{50} is above 500 mg/kg.

FSD-Na was not irritating to the skin of rabbits in a test performed according to OECD Guideline 404, but induced slight effects when a 23-25 % aqueous preparation was applied for 24 hours under occlusive conditions. There was no evidence for irritation from limited and not well-documented human volunteer studies. FSD-Na was slightly irritating to the eyes of rabbits in two studies performed in accordance with OECD Guideline 405.

FSD-Na is well tolerated by rats and dogs after repeated oral exposure. The NOAEL for rats is ca. 500 mg/kg bw/day (3 months) and for dogs ca. 620 mg/kg bw/day (6 months). Effects on the kidneys were seen at higher doses in rats (1500 mg/kg bw/day: increased kidney weights, dilated tubuli, changes in the tubular epithelial cells, tubular cell necrosis).

There is no evidence indicating a potential of FSD-Na to induce gene mutations or chromosome aberrations *in vitro*.

There is no study on the effects of FSD-Na on fertility. In a three months rat and a six months dog oral repeat dose study, histological examination of the testes, epididymides, prostate glands and seminal vesicles (rat only) did not reveal any treatment related effects. In females, no treatment related effects on the uterus and ovaries were observed. No developmental or maternal effects were observed in a teratogenicity study performed in accordance with OECD Guideline 414 at the maximum recommended dose of 1000 mg/kg bw/day (NOEL for maternal and developmental effects: 1000 mg/kg bw/day).

Environment

The substance is soluble in water with 79 g/l. A log Kow of 2.79 and a vapor pressure of $5.39 \cdot 10^{-22}$ Pa was calculated with a simplified molecular structure. As the substance is ionized under environmental conditions, the calculation of a Mackay model is not appropriate. On the basis of the physico-chemical properties of FSD-Na, at equilibrium, one can expect water to be the main target compartment. The substance is neither readily nor inherently biodegradable. In an OECD confirmatory test performed with adapted activated sludge, no biodegradation was observed. However monitoring data showed the substance to be removed > 85 % at the industrial biological sewage treatment plant of the production site. Based on the EU TGD (Simpletreat model) it can be estimated that this removal cannot be transferred to other sewage treatment plants due to possibly different waste water composition and adaptation mechanisms. Based on the chemical structure, hydrolysis is not expected under environmental conditions. Calculation of the indirect photodegradation in air according to Atkinson with a simplified molecule

structure, lead to a rough estimation of the half-life $t_{1/2}$ = 3.5 hours for reaction with OH radicals. Measured data on bioaccumulation show the substance not to be bioaccumulative. The BCF on fish was determined to be about 6.5 (mean value; highest single value = 13).

The acute toxicity has been determined for *Brachydanio rerio* with a 96 h-LC_0 of >=100 mg/l, for *Leuciscus idus* with a 48 h-LC50 between 200 and 500 mg/l and for *Daphnia magna* with a 48 h-EC_0 of >= 100 mg/l. For the growth rate of algae (*Scenedesmus subspicatus*) a 72 h-EC_{50} = 29 mg/l and a 72 h-NOEC of 6.3 mg/l has been determined. For the inhibition of the respiration of activated domestic sludge a 3 h-EC_{50} has been determined with > 100 mg/l. A PNECaqua of 0.029 mg/l is derived from the test on the alga, using an assessment factor of 1000.

Exposure

FSD-Na currently is produced in the range of 1,000 to 5,000 t/a worldwide by one company. The substance is used worldwide as an emulsifying agent in the dyestuff producing industry (30 %) and as a syntan (synthetic tanning agent) in the leather industry (30 %). In several countries the substance is licensed as a dispersion agent in plant protection agents (40 %). Releases into the environment may occur during production, during use in the textile and leather industry, during formulation and use of plant protection agents and in minor amounts from products containing the substance (washing out from textiles and leather during cleaning processes). Releases into the atmosphere may not occur as the substance is a salt. Due to the use in plant protection agents, releases into terrestrial compartments may occur.

RECOMMENDATION

The chemical is a candidate for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health: No recommendation for further work within the context of the OECD SIDS program since adequate information is available on all SIDS endpoints and because no particular hazard to human health could be identified.

Environment: High releases are to be expected from the use of the substance in the textile and leather industry. As no elimination can be expected in non-industrial sewage treatment plants according to the EU TGD (Simpletreat model), high local concentrations in surface waters may occur. However, no information about emissions is currently available. In addition, no information is available about releases into the terrestrial compartment from the use of plant protection agents that contain FSD-Na as dispersing agent. Therefore, an exposure assessment is recommended. If then indicated, further tests with aquatic and/or terrestrial organisms may be considered.

FULL SIDS SUMMARY

CAS NO: 90387-57-8		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point			> 200 °C, decomposition at > 300 °C
2.2	Boiling Point			not assignable, salt
2.3	Density			
2.4	Vapor Pressure		Calculated (MPBPWIN, v. 1.90)	5.39 * 10-22 Pa
2.5	log Kow		Calculated (KOWWIN, v. 1.66)	2.79
	BCF	Carassius sp.	National Japanese Guideline	BCF = 4.79 (mean value) with 149 µg/l BCF = 8.29 (mean value) with 14.8 µg/l BCF = 13 (highest single value)
2.6 A	Water Solubility			79 ± 5 g/l at 20 °C 203 ± 4 g/l at 30 °C
B	pH pKa			
2.12	Oxidation: Red. Potential			
ENVIRONMENTAL FATE AND PATHWAY				
3.1.1	Photodegradation		Calculated acc. to Atkinson	in air t ½ = 3.5 h (12 hr- sunlight day; 1.5 * 10^6 OH/cm³)
3.1.2	Stability in Water			Based on the chemical structure hydrolysis is not expected under environmental conditions
3.2	Monitoring Data			in air = mg/m³ in surface water = µg/l in soil/sediment = mg/kg dw in biota = mg/kg dw
3.3	Transport and Distribution		Henry's Law Constant Mackay Level I	not assignable, substance is ionized under environmental conditions target compartment: water
3.5	Biodegradation	activated sludge, aerobic	OECD 301 D "Closed Bottle", 1981	0 % after 28 d
		activated sludge, aerobic, adapted	OECD 302 B "Mod. Zahn-Wellens", 1989	21 % after 28 d
		activated sludge, adapted	OECD confirmatory test	no biodegradation observed
		industrial activated sludge, aerobic	wwtp -monitoring	removal > 85 %
ECOTOXICOLOGY				
4.1	Acute/Prolonged Toxicity to Fish	Brachydanio rerio Leuciscus idus	German UBA proposal 1984	LC_0 (96 h) ≥ 100 mg/l LC_0 (48 h) = 200 mg/l LC_{100} (48 h) = 500 mg/l
4.2	Acute Toxicity to Aquatic Invertebrates	Daphnia magna	Dir. EEC 92/69, C.2; 1992	EC_0 (48 h) ≥ 100 mg/l
4.3	Toxicity to Aquatic Plants e.g. Algae	Scenedesmus subspicatus	Dir. EEC 92/69, C.3; 1992	EC_{50} (72 h) = 29 mg/l (growth rate) NOEC (72h) = 6.3 mg/l (growth rate)
4.5.1	Chronic Toxicity to Fish			
4.5.2	Chronic Toxicity to Aquatic Invertebrates			

CAS NO: 90387-57-8		SPECIES	PROTOCOL	RESULTS
4.6.1	Toxicity to Soil Dwelling Organisms			
4.6.2	Toxicity to Terrestrial Plants			
4.6.3.	Toxicity to other Non-Mammalian Terrestrial Species (incl. Birds)			
TOXICOLOGY				
5.1.1	Acute Oral Toxicity	Rat	84/449/EC	LD_{50} > 5000 mg/kg
5.1.2	Acute Inhalation Toxicity			
5.1.3	Acute Dermal Toxicity	Rat (male)	25% solution, Open application for 7 days	LD50 > 500 mg/kg
5.2	Corrosiveness and Irritation			
5.2.1	Skin Irritation	Rabbit	OECD 404	not irritating
		Human	10 males	not irritating
5.2.2	Eye Irritation	Rabbit	OECD 405	slightly irritating
5.3	Sensitisation	Guinea pig	intracutaneous; 10+1 exposures (0.1% solution)	not sensitising
		Human	6 volunteers; 9+1 exposures	not sensitising
5.4	Repeated Dose Toxicity	Rat	13 W; gavage	NOEL = 500 mg/kg bw/day LOAEL: 1500 mg/kg bw/day(body weight gain reduced, increased water consumption, histopathological changes in the kidney)
		Dog	6 months; diet	NOAEL = 620 mg/kg bw/day (= 15000 ppm)
5.5	Genetic Toxicity in Vitro			
A	Bacterial Test (Gene Mutation)	Salmonella typhimurium TA1535, TA1537, TA100, TA98	Ames test, with and without metabolic activation	without: negative with: negative
B	Non-Bacterial in Vitro Test	V79 cells	CA, with and w ithout metabolic activation OECD 473	without: negative; with: negative
5.8	Toxicity to Reproduction	Rat	13 w; gavage;	No effects on reproductive organs at 1500 mg/kg bw/day
		Dog	6 months; diet;	No effects on reproductive organs at 620 mg/kg bw/day (= 15000 ppm)
5.9	Developmental Toxicity/ Teratogenicity	Rat	gavage, day 0-19 of gestation OECD 414	NOEL (maternal toxicity): 1000 mg/kg bw/day NOEL (developmental toxicity): 1000 mg/kg bw/day
5.10	Carcinogenicity			
5.11	Experience with Human Exposure			

SIDS INITIAL ASSESSMENT REPORT

1. IDENTITY

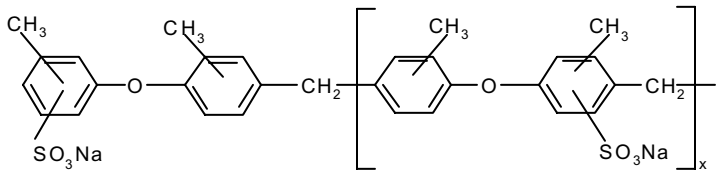
CAS Number 90387-57-8

Name Formaldehyde, reaction products with sulfonated 1,1'-oxybis[methylbenzene], sodium salts

Synonyms Formaldehyde, reaction products with sulfonated 1,1'-ditolylether, sodium salts

Abbreviation: **FSD-Na**

Structural formula



X ≥ 1

Physico-Chemical Properties:

FSD-Na is a salt with a melting point of > 200 °C. Decomposition starts at > 300 °C. The substance is soluble in water with 79 ± 5 g/l at 20 °C and 203 ± 4 g/l at 30 °C. With a simplified molecular structure a vapor pressure of $5.39 \cdot 10^{-22}$ Pa and a log Kow of 2.79 was calculated. The purity of the substance is given with about 70 to 80 % FSD-Na salt. The product contains about 20 to 30 % sodium sulfate, about 5 % water, and ≤ 0.6 % ditolylether as impurities [Bayer AG 2001, Bayer AG 2001a,b,c,d].

2. GENERAL INFORMATION ON EXPOSURE

FSD-Na currently is produced in the range of 1,000 to 5,000 t/a worldwide by one company (year 2000). The substance is used worldwide as an emulsifying agent in the dyestuff producing industry (30 %) and as a syntan (synthetic tanning agent) in the leather industry (30 %). In several countries the substance is licensed as a dispersion agent in plant protection agents (40 %) [Bayer AG 2001]. There is no information available about the number of processing sites.

FSD-Na is produced in a closed system by sulfonation of ditolylether followed by condensation with formaldehyde. After neutralization the substance is dried [Bayer AG 2001].

In the Danish product register (2002) the substance is listed as colouring agent for the industry groups manufacture of textiles, finishing of textiles, manufacture of sugar and manufacture of other household furniture. In the Swiss product register (June 2002) the substance is named in 80 products containing FSD-Na in amounts up to 100 %. Main product types are paints, lacquers and varnishes for industrial use. Three product types for public use contain FSD-Na up to 10 %, especially for herbicidal and fungicidal use. In the Swedish product register (February 2002) FSD-Na is not listed.

2.1 Environmental Exposure and Fate

2.1.1 Environmental Exposure

Releases into the environment may occur during production, during use in the textile and leather industry, during formulation and use of plant protection agents and from products containing the substance.

Releases during production

Emission into the hydrosphere is observed within a daily monitoring program at the production site of the producer. The 90 percentile of the measured FSD-Na concentrations at the outlet of the industrial sewage treatment plant into the receiving water is 670 µg/l. As worst case for the receiving water a PEC of 0.96 µg/l is calculated taking the 10 percentile of the river low flow and the 90 percentile concentration of the outlet into account. The sludge of the sewage treatment plant is burned off in a special waste incineration plant. Thus there is no emission to the geosphere by sludge application at the production site [Bayer AG 2001].

There is no emission of FSD-Na into the atmosphere from production as the substance is a salt and produced as a solution. When the substance is gained as a solid, air washers are used for the exhaust air of the fully automatic drying and bagging machine. [Bayer AG 2001]

Releases during use in textile and leather industry and during formulation of plant protection agents

Releases into the aquatic environment from application of FSD-Na while processing leather or textiles are to be expected. According to the EU Technical Guidance Documents, high releases have to be assumed from these life-cycle steps. In addition, during formulation of plant protection agents, in which the substance is used as dispersing agent, environmental releases are to be expected. Data about these releases are not readily available.

Releases from products

Environmental releases from products containing FSD-Na may occur (washing out from textiles and leather during cleaning processes). However, no significant environmental concentrations are expected from this life-cycle step due to the diffuse emissions.

Releases from use of plant protection agents

Releases into the terrestrial compartment may occur from the use of plant protection agents that contain FSD-Na as dispersing agent. However, a quantification is presently not possible.

2.1.2 Environmental Distribution and Fate

The calculation of a Henry's law constant or of the Mackay fugacity model does not seem appropriate for this substance, as the substance is ionized under environmental conditions. Based on the physico-chemical properties, for the emission from production, water seems to be the main target compartment for FSD-Na.

FSD-Na is not readily biodegradable. In a Closed Bottle test (OECD 301 D) biodegradation was 0 % after 28 days [Bayer AG 1985a]. In addition, a Zahn-Wellens test has been conducted according to OECD guideline 302 B. The inoculum was adapted to the test substance for 4 weeks. The elimination was 21 % after 28 days [Bayer AG 1994]. This result shows that FDS-Na is not inherently biodegradable even by adapted inoculum. These findings are confirmed by an OECD confirmatory test performed with adapted activated sludge.

Under test conditions, no biodegradation was observed [Bayer AG 1992]. However comparison of influent and effluent concentrations of the industrial sewage treatment plant of the production site showed the substance to be removed to > 85 % [Bayer AG 2001]. Based on the EU TGD (Simpletreat model) it can be estimated, that this removal cannot be transferred to other sewage treatment plants due to possible different waste water composition and adaptation mechanisms.

The calculation of the indirect photolysis by SRC-AOPWIN v1.90 showed a half-life $t_{½}$ of 3.5 hours for a simplified structure of the substance: only two sulfonated ditolylether sodium salts connected by a methylene bond. This approach has been chosen for a rough estimation of the indirect photodegradation by OH radicals of the reaction products of formaldehyde with sulfonated ditolylethers sodium salts [? ayer AG 2001e].

Based on the chemical structure, hydrolysis is not expected under environmental conditions.

Measured data on bioaccumulation showed no bioaccumulation potential of FSD-Na. A 56 day test on Carassius sp. acc. to a national Japanese Guideline showed mean BCF values of 4.79 and 8.29 for test substance concentrations of 149 µg/l and 14.8 µg/l respectively. The test was conducted in a flow through system with ^{14}C-labelled test substance [Bayer AG 1979].

2.2 Human Exposure

FSD-Na is not listed as a dangerous substance in the sponsor country and the EU. Thus there is no workplace limit concentration laid down for FSD-Na. However, when contact with the substance is expected (i.e. at maintenance or repair work), wearing of personal protective equipment like gloves, protecting glasses, and masks if necessary, are demanded precautionary at the production site as well as with the help of the safety data sheet during use. Since FSD-Na is not listed as a dangerous substance, there is no monitoring of the substance itself at the production facility. However, this facility is monitored due to the handling of other feed-stock substances [Bayer AG 2001].
Data on workers exposure during professional use are not available.
Because textiles and leather goods may contain small amounts of FSD-Na a consumer exposure may be possible but is assumed to be minimal.

3. HUMAN HEALTH HAZARDS

Effects on Human Health

3.1 Toxikokinetics

No data available

3.2 Acute oral toxicity

The acute oral toxicity of FSD-Na was assessed in rats, rabbits and cats.
In male and female rats the LD_{50} was above the maximum tested dose of 2500 or 5000 mg/kg bw in all studies (Ramm 1986; Heimann 1981,1982; Bomhard 1978; Solmecke 1969). Unspecific signs of toxicity (apathy, reduced motor activity) were observed only in 2 studies at 5000 mg/kg bw (Heimann 1981and 1982).

Conclusion:

The acute oral toxicity of FSD-Na is very low. The LD_{50} is above 5000 mg/kg bw after oral exposure in rats. The only clinical signs noted were apathy and reduced motor activity (at 5000 mg/kg bw).

3.3 Acute dermal toxicity

There is only one, poorly documented study, in which the acute dermal toxicity of FSD-Na was examined in 5 male rats. A dose of 500 mg/kg, applied openly as a 25% aqueous solution to the clipped back of the animals was tolerated without any systemic or local effects during the 7 day exposure period (Solmecke 1969).
Conclusion:
FSD-Na is well tolerated after single application to the skin of rats. The LD_{50} is above 500 mg/kg.

3.4 Acute inhalation toxicity

No data available

3.5 Skin irritation

The irritating potential of FSD-Na on the skin was determined in rabbits and humans.
In a skin irritation study performed under semi-occlusive conditions according to OECD guideline 404, the moistened test substance (500 mg solid material covered with saturated solution) was not irritating to the skin of rabbits (Draize scores of "0" each for erythema and edema) (Pauluhn 1985). No erythema, but slight to well-defined edema was still present in intact and scarified skin after 8 days in 5 of 6 rabbits treated with 500 µl of liquid test substance (~24% solution in water) for 24 hours under occlusive conditions (Schreiber 1979), whereas in a further, but not well-documented study, no significant irritation was found in 6 rabbits after semi-occlusive treatment with 500 mg of the test substance for 24 hours (Thyssen, 1980).

Human experience:

Two studies were carried out in 10 human volunteers each and found no irritating potential after 24 hours of exposure of the forearm to 50 mg of the solid test substance (Solmecke 1969; Kimmerle 1969).

Conclusion:

FSD-Na was not irritating to the skin of rabbits in a test performed according to OECD guideline 404, but induced slight effects when the liquid test substance (~24% solution in water) was applied for 24 hours under occlusive conditions. There was no evidence for irritation from limited and not well-documented human volunteer studies.

3.6 Eye irritation

The irritation potential of FSD-Na on the eye was examined in 5 studies in rabbits.
In an eye irritation study performed according to OECD guideline 405, the undiluted test substance was slightly irritating to the eyes of rabbits (Draize scores: cornea 0, iris 0, conjunctiva redness 1, chemosis 0.7). All effects were completely reversible within 7 days (Pauluhn 1985). This confirmed the results of a previous study, also performed according to OECD guideline 405 with scores of 0 for cornea, 0 for iris, 1 for conjunctiva redness and 0 for chemosis (Krötlinger, 1983).
Slight, transient corneal opacity was recorded after instillation of 100µl/animal of a 24%aqueous solution. Recovery was achieved in 2 days (Schreiber 1979).

Conclusion:

FSD-Na was slightly irritating to the eyes of rabbits in two studies performed in accordance with OECD guideline 405.

3.7 Skin sensitisation

No studies are available according to current guidelines. In a study treating 15 guinea pigs ten times intracutaneously (0,1% solution) and challenging 14 days later by re-injection of a 0.1 % solution as before in a previously untreated area of the back, no positive reaction was observed in any of the animals. The test did not include a positive control group. (Solmecke 1969).
Human experience:
No irritating or sensitizing effects were noted in a study with 6 volunteers, treated 9 times for 24 hours each with the solid test substance and challenged after 10 days (Solmecke 1969).

Conclusion:

The available data are not sufficient to evaluate the sensitizing potential of FSD-Na.

3.8 Repeated Dose Toxicity

Toxicity after repeated oral administration for 3 months to rats (gavage, 20 animals per sex/group) was reported in 1983 by Mihail and Nash. At doses of 150 and 500 mg/kg bw/day no effect at all was recorded.

At 1500 mg/kg bw/day, the consumption of water was increased by 38 and 33% in males and females, respectively, and body weight gain was decreased by 7.5 and 5 % in males and females, respectively. At necropsy the absolute and relative kidney and spleen weights were significantly increased in these rats, but no changes in the haematological, enzymatic and urinary parameters were found during and at the end of the study. Histopathology revealed changes in the kidneys of animals of both sexes in the high-dose group (dilated tubuli, changes in the tubular epithelial cells, tubular cell necrosis). Changes in other organs, including the sex organs were not observed. The NOAEL was 500 mg/kg bw/day (Mihail and Nash, 1983).
Groups of 6 male and 6 female Beagle dogs were fed diets containing 0, 3000, 7000 or 15,000 ppm FSD-Na for 6 months (corresponding to doses of approximately 0, 126, 340 and 620 mg/kg bw). No clinical symptoms and no changes in food consumption, body weight gain and blood chemistry were found as compared to the controls. One male each from the low and mid dose groups had to be killed in moribund state from treatment unrelated causes (enteritis). The only substance-related effect was an increase of the phagocytic activity in the mesenteric lymph nodes in some high-dose animals. This was concluded from the presence of increased numbers of macrophages in lymph node sinuses and from the incorporation of PAS-positive material into these cells. This effect was regarded by the author not as a toxic lesion but as the morphological correlate of a hyperfunctional state. Gross and microscopic examinations did not reveal any other substance-related effects. The NOAEL was 15000 ppm (~620 mg/kg bw/day) after 6 months of treatment (Bathe , 1984).

Conclusion:

FSD-Na is well tolerated by rats and dogs after repeated oral exposure. The NOAEL for rats is ca. 500 mg/kg bw/day (3 months) and for dogs ca. 620 mg/kg bw/day (6 months). Effects on the kidneys were seen at higher doses in rats.

3.9 Genotoxicity

The potential of FSD-Na to induce gene mutations was assessed in an Ames test in Salmonella typhimurium strains TA98, TA100, TA1535 and TA1537 in concentrations up to 5000 µg/plate. No increase in the number of revertants was recorded with and without metabolic activation by rat S9-mix. Cytotoxic effects were noted at 5000 µg/plate. The study was performed under GLP conditions and included an independent repeat experiment. The concurrent positive and solvent controls were functional (Gahlmann 1992).
In a GLP study performed according to OECD guideline 473, the test substance (purity 72%) did not induce chromosome aberrations in Chinese hamster V79 cells, neither in the absence nor in the presence of a metabolic activation system (rat liver S-9 mix). Concentrations that were evaluated varied from 100 to 1000 µg/mL without S9-mix and between 400 and 1400 µg/mL with S9-mix. Metaphase chromosomes prepared from cells at two sampling times (18 and 30 hrs) and two treatment periods (4 and 18 hrs) were evaluated. Without S-9 mix, cytotoxicity was observed at 1000 mg/mL in the cultures treated for 4 hours and at 200 mg/mL in the cultures treated for 18 hours. In the presence of metabolic activation, cytotoxicity was seen at 1400 mg/mL. The concurrent positive and solvent controls were functional (Herbold 2001)
No data are available on in vivo genotoxicity studies.

Conclusion:

There is no evidence indicating a potential of FSD-Na to induce gene mutations or chromosome aberrations in vitro.

3.10 Carcinogenicity

No data available.

3.11 Reproduction Toxicity (Fertility and Developmental Toxicity)

No fertility studies are available with FSD-Na. No indication of any effect on the reproductive organs was found in rats and dogs in three and six month-studies, respectively (Bathe 1984, Mihail and Nash, 1983). In male rats and dogs, testes, epididymides, seminal vesicles (rats only) and prostate glands were examined histologically. In female animals uteri and ovaries were examined microscopically. No treatment related findings were recorded. Hence, an adverse effect on fertility is not assumed.

In a teratogenicity study performed in accordance with OECD guideline 414 and under GLP conditions, 30 pregnant rats/group were treated from day 0 to 19 of gestation wth the maximum recommended dose of 1000 mg/kg bw/day by gavage (purity 76%). No clinical signs of toxicity and no effects on food consumption or body weight gain were observed in the dams. There were no effects observed on the gestation index, or any embryologic endpoints, including pre/post-implantation loss and resorption. There were no effects on litter size, the number of fetuses per implantation site, fetal weight, or placental weight. There were no fetal external, visceral or skeletal malformations or variations. Hence, the NOEL for both maternal and developmental toxicity was 1000 mg/kg bw/day (Astroff 1998).

Conclusion:

There is no evidence indicating a potential of FSD-Na to interfere with reproduction. In a three months rat and a six months dog oral repeat dose study, histological examination of the testes, epididymides, seminal vesicles (rats only) and prostate glands did not reveal any treatment related effects. In females, no treatment related effects on the uterus and ovaries were observed. No developmental or maternal effects were observed in a teratogenicity study performed in accordance with OECD guideline 414 at the maximum recommended dose of 1000 mg/kg bw. (NOEL for maternal and developmental toxicity: 1000 mg/kg bw/day).

4. HAZARDS TO THE ENVIRONMENT

4.1 Aquatic Effects

According to the available results from laboratory studies FSD-Na exhibits only a low toxicity on aquatic organisms, with the exception of algae. All tests have been performed using the technical product.
Acute toxicity to *Brachydanio rerio* was tested over 96 hours according to the German UBA draft guideline "Lethal effects towards zebrafish *Brachydanio rerio*" (LC0, LC50, LC100; 48-96 h - May 1984) in 1984. The 96 h-LC_0 was determined with >= 100 mg/l. Since at that time GLP was not common practice, no GLP protocol is available. Analytical monitoring had not been considered necessary due to the stability of the substance and its very good solubility in water [Bayer AG 1985b].
In a further acute toxicity test with *Leuciscus idus*, a 48h-LC0 of 200 mg/l and a 48h-LC100 of 500 mg/l was found. Therefore, the LC50 is between these two values. The effect values are related to nominal concentrations [Bayer AG, 1978].
With *Daphnia magna* an acute toxicity test was performed according to directive EEC 92/69 part C.2 with GLP and analytical monitoring. There were no adverse effects to *Daphnia magna* observed at a concentration of 100 mg/l after 48 hours [Bayer AG 2001f].
In an algal growth inhibition test with the alga *Scenedesmus subspicatus* a 72 h-EC_{50} of 29 mg/l and a NOEC of 6.3 mg/l was determined considering growth rate. The test was conducted according to directive EEC 92/69 part C.3 with GLP and analytical monitoring [Bayer AG 2001g].
The effect of FSD-Na on the respiration of activated domestic sludge has been tested according to the method described in ISO DP 8192 . The 3 h-EC50 has been determined with > 100 mg/l [Bayer AG 1985c].

Derivation of PNECaqua:
As basic value for the derivation of the PNECaqua the lowest available effect value of 29 mg/l found in the cell multiplication test with *Scenedesmus subspicatus* is used. As acute tests with species from 3 trophic levels are available an assessment factor of 1000 has to be used.
Therefore: PNECaqua = 29 mg/l / 1000 = 0.029 mg/l

4.2 Terrestrial Effects

There are no data on terrestrial effects.

4.3 Other Environmental Effects

There are no data on other environmental effects.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

Production and processing:

The current world production of FSD-Na amounts to the range of 1,000 to 5,000 t/a (year 2000) by one company. The substance is used worldwide as an emulsifying agent in the dyestuff producing industry and as a syntan (synthetic tanning agent) in the leather industry. In several countries the substance is licensed as a dispersion agent in plant protection agents. Releases into the environment may occur during production, during use in the textile and leather industry, during formulation and use of plant protection agents and from products containing the substance.
For the production of FSD-Na, monitoring data at the outlet of the industrial sewage treatment plant lead to a worst case PEC value of 0.96 µg/l in the receiving water. There is no emission into the atmosphere from production. Due to the use of the substance in plant protection agents, releases into terrestrial compartments may occur. No information is readily available on the amount of FSD-Na released by application.

Environmental behavior:

On the basis of the physico-chemical properties of the substance, at equilibrium, one can expect the compartment water to be the main target compartment for FSD-Na. The substance is neither readily nor inherently biodegradable. In a OECD confirmatory test performed with adapted activated sludge, no biodegradation was observed. However monitoring data showed the substance to be removed > 85 % at the industrial biological sewage treatment plant of the production site. Based on the EU TGD it can be estimated that this removal cannot be transferred to other sewage treatment plants due to possible different waste water composition and adaptation mechanisms.
Calculation of the indirect photodegradation in air acc. to Atkinson with a simplified molecule structure, lead to a rough estimation of the half-life $t_{1/2}$ = 3.5 hours for reaction with OH radicals.
Based on the chemical structure, hydrolysis is not expected under environmental conditions.
Measured data on bioaccumulation show the substance not to be bioaccumulative. The BCF on fish was determined to be about 6.5 (mean value; highest single value = 13).
The acute toxicity has been determined for *Brachydanio rerio* with a 96 h-LC_0 of >=100 mg/l, for *Leuciscus idus* with a 48 h-LC50 between 200 and 500 mg/l and for *Daphnia magna* with a 48 h-EC_0 of >= 100 mg/l. For the growth rate of algae (*Scenedesmus subspicatus*) a 72 h-EC_{50} = 29 mg/l and a 72 h-NOEC of 6.3 mg/l has been determined. For the inhibition of the respiration of activated domestic sludge a 3 h-EC50 has been determined with > 100 mg/l. A PNECaqua of 0.029 mg/l is derived from the test on the alga, using an assessment factor of 1000.

Human Health:

The acute toxicity of FSD-Na is very low. The LD_{50} is above 5000 mg/kg bw after oral exposure in rats (clinical signs: apathy and reduced activity at 5000 mg/kg bw). FSD-Na is well tolerated after single application to the skin of rats. The LD_{50} is above 500 mg/kg bw.
FSD-Na was not irritating to the skin of rabbits in a test performed according to OECD guideline 404, but induced slight effects when a 23-25% aqueous preparation was applied for 24 hours under occlusive conditions. There was no evidence for irritation from limited and not well-documented

human volunteer studies.

FSD-Na was slightly irritating to the eyes of rabbits in two studies performed in accordance with OECD guideline 405.
FSD-Na is well tolerated by rats and dogs after repeated oral exposure. The NOAEL for rats is ca. 500 mg/kg bw/day (3 months) and for dogs ca. 620 mg/kg bw/day (6 months). Effects on the kidneys were seen at higher doses in rats (1500 mg/kg bw-d: increased kidney weights, dilated tubuli, changes in the tubular epithelial cells, tubular cell necrosis).
There is no evidence indicating a potential of FSD-Na to induce gene mutations or chromosome aberrations in vitro.

There is no study on the effects of FDS-Na on fertility. In a three months rat and a six months dog oral repeat dose study, histological examination of the testes, epididymides, prostate glands and seminal vesicles (rat only) did not reveal any treatment related effects. In females, no treatment related effects on the uterus and ovaries were observed. No developmental or maternal effects were observed in a teratogenicity study performed in accordance with OECD guideline 414 at the maximum recommended dose of 1000 mg/kg bw/day. (NOEL for maternal and developmental toxicity: 1000 mg/kg bw/day).

5.2 Recommendations

Environment: The substance is a candidate for further work. High releases are to be expected from the use of the substance in the textile and leather industry. As no elimination can be expected in non-industrial sewage treatment plants according to the EU TGD (Simpletreat model), high local concentrations in surface waters may occur. However, no information about emissions is currently available. In addition, no information is available about releases into the terrestrial compartment from the use of plant protection agents that contain FSD-Na as dispersing agent. Therefore, an exposure assessment is recommended. If then indicated, further tests with aquatic and/or terrestrial organisms may be considered.
Human Health: No recommendation for further work within the context of the OECD SIDS program since adequate information is available on all SIDS endpoints and because no particular hazard to human health could be identified.

6. REFERENCES

Astroff, A.B. A developmental toxicity study in the Wistar rat, Report 108607, Study No. 98-612-PL, 9.Nov.1998, Bayer Corp., USA

Bathe R., 6-Month oral (feeding) toxicity study in Beagle dogs, Research and Consulting Company, Report No.R 2730, Jan/10/1984 (at the request of Bayer AG)

Bayer AG 1978; Internal Study, Acute toxicity to Leuciscus idus (August 1978)

Bayer AG 1979, Internal Study, Bioaccumulation Study to Carp (05.04.1979)

Bayer AG 1985a, Internal Study, Closed Bottle Test according to OECD Guideline 301 D (24.10.1985)

Bayer AG 1985b, Internal Study, Acute toxicity to Brachydanio rerio (30.09.1985)

Bayer AG 1985c, Internal Study, Toxicity to waste water bacteria (10.09.1985)

Bayer AG 1992; Internal Study, Degradation in the OECD Confirmatory Test (22.6.1992)

Bayer AG 1994, Internal Study, Zahn-Wellens-Test (24.10.1994)

Bayer AG 2001, Personal Communication December 2001

Bayer AG 2001a, Internal Study, Determination of the Melting Point, 25.01.2001

Bayer AG 2001b, Internal Study, Solubility in Water, 29.05.2001

Bayer AG 2001c, Calculation of Vapour Pressure by SRC-MPBPWIN, v1.40 (2000)

Bayer AG 2001d, Calculation of log Octanol-Water Partition Coefficient by SRC-KOWWIN, v1.66 (2000)

Bayer AG 2001e, Calculation of Indirect Photodegradation by SRC-AOPWIN v1.90 (2000)

Bayer AG 2001f, Internal Study, Acute toxicity to Daphnia magna (Study-No.: 1088 A/01 D)

Bayer AG 2001g, Internal Study, Acute toxicity to Scenedesmus subspicatus (Study-No.: 1088 A/01 A1)

Blau, S.: Report of Test-Kit Testing Laboratories, New York, 28. Mar. 1973, (number of report not known)

Bomhard, E., Bayer AG data, short report, oct/11/1978

Gahlmann R., Salmonella/Microsome Test, Report No.: 21408, may/21/1992, Bayer AG

Heimann, K-G., Bayer AG data, short report, july/10/1981

Heimann, K-G., Bayer AG data, short report, oct/06/1982

Herbold B., In vitro chromosome aberration test with chinese hamster V79 cells; Study No: T3070169; Bayer AG; Sep 27, 2001

Kimmerle, G., Bayer AG data, short report, april/17/1969

Krötlinger F., Prüfung auf primär reizende/ätzende Wirkung am Kaninchenauge, Bayer AG data, internal report, study number T 1016356, sep/08/1983

Mihail, F.; Nash G., Subchronische Toxikologische Untersuchungen an Ratten (3 months; gavage) Report No.: 11852, Bayer AG, june/01/1983

Pauluhn, J; Untersuchungen zum Reiz-/Ätzpotential an Haut und Auge (Kaninchen) Report No. 14140, dec/12/1985, Bayer AG

Ramm, W., , Untersuchung zur akuten oralen Toxizitaet an maennlichen und weiblichen Wistar-Ratten, jan/23/1986 Bayer AG

Schreiber, G., Bericht über die Prüfung auf primäre Hautreizwirkung Data of FHG (Schmallenberg), 30. Jan 1979 (at the request of Bayer AG)

Schreiber, G., Bericht über die Prüfung auf primäre Schleimhautreizwirkung, Data of FHG (Schmallenberg), 30. Jan 1979 (at the request of Bayer AG)

Solmecke, B; Kimmerle, G., Toxikologische Untersuchungen, Report No. 1635, nov/03/1969, Bayer AG

Thyssen, J., Bayer AG data, short report, jan/17/1980

I U C L I D Data Set

Existing Chemical	:	ID: 90387-57-8
CAS No.	:	90387-57-8
EINECS Name	:	Formaldehyde, reaction products with sulfonated 1,1'-oxybis[methylbenzene], sodium salts
EC No.	:	291-331-1
Molecular Formula	:	<no data>

Producer related part

Company	:	Bayer AG
Creation date	:	06.04.1992

Substance related part

Company	:	Bayer AG
Creation date	:	06.04.1992
Status	:	
Memo	:	Complete IUCLID data set
Printing date	:	27.06.2002
Revision date	:	11.02.1997
Date of last update	:	27.06.2002
Number of pages	:	1
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	
Substance type	:	organic
Physical status	:	solid
Purity	:	70 - 80 % w/w
Colour	:	
Odour	:	
Flag	:	Critical study for SIDS endpoint
07.12.2001		

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Formaldehyde, reaction products with sulfonated 1,1'-ditolylether, sodium salts

Flag	:	Critical study for SIDS endpoint
07.12.2001		
FSD-Na		
Flag	:	Critical study for SIDS endpoint
07.12.2001		

1.3 IMPURITIES

Purity	:	
CAS-No	:	
EC-No	:	
EINECS-Name	:	Sodium sulfate
Molecular formula	:	
Value	:	ca. 20 - 30 % w/w
Flag	:	Critical study for SIDS endpoint
14.01.2002		
Purity	:	
CAS-No	:	7732-18-5
EC-No	:	231-791-2
EINECS-Name	:	water
Molecular formula	:	
Value	:	ca. 5 % w/w
Flag	:	Critical study for SIDS endpoint
14.01.2002		

Purity	:	
CAS-No	:	
EC-No	:	
EINECS-Name	:	ditolyl ether
Molecular formula	:	
Value	:	<= .6 % w/w
Flag	:	Critical study for SIDS endpoint
12.12.2001		

1.4 ADDITIVES

1.5 TOTAL QUANTITY

Remark	:	Worldwide production volume in year 2000 in the range of 1000 to 5000 t/a
Flag	:	Critical study for SIDS endpoint
12.12.2001		

1.6.1 LABELLING

1.6.2 CLASSIFICATION

Classified	:	provisionally by manufacturer/importer
Class of danger	:	
R-Phrases	:	(52/53) Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Specific limits	:	
Flag	:	Critical study for SIDS endpoint
11.12.2001		

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use	:	industrial
Category	:	Agricultural industry
Flag	:	Critical study for SIDS endpoint
Type of use	:	industrial
Category	:	Leather processing industry
Flag	:	Critical study for SIDS endpoint
Type of use	:	industrial
Category	:	Textile processing industry
Flag	:	Critical study for SIDS endpoint
Type of use	:	use
Category	:	Colouring agents
Flag	:	Critical study for SIDS endpoint
Type of use	:	use
Category	:	other: disperse additives
Flag	:	Critical study for SIDS endpoint
14.01.2002		

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

Classified by	:	other: Bayer AG
Labelled by	:	
Class of danger	:	1 (weakly water polluting)
11.12.2001		

1.8.4 MAJOR ACCIDENT HAZARDS

Legislation	:	Stoerfallve rordnung (DE)
Substance listed	:	no
No. in Seveso directive	:	

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

Type of search	:	Internal and External
Chapters covered	:	
Date of search	:	
Remark	:	Physico-chemical properties / Environment / Ecotoxicology : last literature search January 2002: CAS number search in external and internal databases, e.g. HSDB, Aquire. Human Health: last literature search September 2001: CAS number search in external and internal databases, e.g. Biosis, Embase, Toxline, Scisearch.
Flag	:	Critical study for SIDS endpoint
27.06.2002		

1.13 REVIEWS

2.1 MELTING POINT

Value	:	> 200 °C
Decomposition	:	yes, at > 300 °C
Flag	:	Critical study for SIDS endpoint
11.12.2001		(1)

2.2 BOILING POINT

Remark	:	not assignable, salt
Flag	:	Critical study for SIDS endpoint

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Remark	:	Calculated vapour pressure: 5,39 x 10-22 Pa (25 °C) The calculation is based on a simplyfied structure of the substance with the Smiles Code: O=S(=O)(c2c(ccc(c2)C)Oc3ccc(c(c3)C)Cc4ccc(cc4C)Oc1cc(c(cc1)S(=O)(=O)O[Na])C)O[Na]
Flag	:	Critical study for SIDS endpoint
25.06.2002		(2)

2.5 PARTITION COEFFICIENT

Partition coefficient	:	
Log pow	:	2.79 at °C
pH value	:	
Remark	:	The calculation is based on a simplyfied structure of the subs tance with the Smiles Code: O=S(=O)(c2c(ccc(c2)C)Oc3ccc(c(c3)C)Cc4ccc(cc4C)Oc1cc(c(cc1)S(=O)(=O)O[Na])C)O[Na]
Flag	:	Critical study for SIDS endpoint
25.06.2002		(3)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	at °C
pH value	:	
concentration	:	79 g/l at 20 °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C

Description	:		
Stable	:		
Flag	:	Critical study for SIDS endpoint	
11.12.2001			(4)
Solubility in	:	Water	
Value	:	at °C	
pH value	:		
concentration	:	203 g/l at 30 °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	at 25 °C	
Description	:		
Stable	:		
Flag	:	Critical study for SIDS endpoint	
11.12.2001			(4)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Remark	:	not assignable, salt
Flag	:	Critical study for SIDS endpoint

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

Result	:	other: may cause dust explosion
Remark	:	may cause dust explosion
11.12.2001		

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	1500000 molecule/cm³
Rate constant	:	.00000000003681 cm³/(molecule*sec)
Degradation	:	50 % after 3.5 hour(s)
Deg. product	:	
Method	:	other (calculated): with SRC-AOPWIN v.1.90 (2000)
Year	:	
GLP	:	
Test substance	:	
Remark	:	The calculated half-life is based on a mean OH radical concentration of 1.5x10E6 OH radicals/cm3, and 12 sunlight hours per day as suggested by U.S.EPA at AOPWIN. The calculation is based on a simplyfied structure of the substance with the Smiles Code: O=S(=O)(c2c(ccc(c2)C)Oc3ccc(c(c3)C)Cc4ccc(cc4C)Oc1cc(c(cc1)S(=O)(=O)O[Na])C)O[Na]
Reliability	:	(2) valid with restrictions accepted calculation method
Flag	:	Critical study for SIDS endpoint
25.06.2002		(5)

3.1.2 STABILITY IN WATER

Remark	:	Based on the chemical structure of the substance, hydrolysis is not expected under temperature and pH values occuring in the environment.
Flag	:	Critical study for SIDS endpoint
07.12.2001		

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Remark	:	The calculation of a Mackay fugacity model does not seem appropriate as the substance is ionized under environmental conditions. With the high water solubility, water seems to be the main target compartment.
Flag	:	Critical study for SIDS endpoint
27.06.2002		

3.3.2 DISTRIBUTION

Media	:	water - air
Method	:	other (calculation): Calculation of the Henry's law constant

Year	:	
Remark	:	The calculation of Henry's law constant does not seem appropriate as the substance is ionized under environmental conditions.
Flag	:	Critical study for SIDS endpoint
25.06.2002		

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	other: secondary effluent from a laboratory scale unit receiving predominantly domestic sewage
Contact time	:	
Degradation	:	0 (±) % after 28 day(s)
Result	:	
Deg. product	:	
Method	:	other: OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test" (1981)
Year	:	1985
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	aniline as reference compound;
Test condition	:	20 +/-1 °C; 9.4 mg O2/l at start of test
Reliability	:	(2) valid with restrictions guideline study; basic data given
Flag	:	Critical study for SIDS endpoint
13.12.2001		(6)
Type	:	aerobic
Inoculum	:	activated sludge, adapted
Concentration	:	100 mg/l related to DOC (Dissolved Organic Carbon) related to
Contact time	:	
Degradation	:	21 (±) % after 28 day(s)
Result	:	
Deg. product	:	
Method	:	other: OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test" (1989)
Year	:	1994
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	100 mg/l DOC correspond to about 666.7 mg/l FSD-Na; adaptation to 100 mg/l DOC for 4 weeks. Aniline used as reference substance
Test condition	:	Concentration of inoculum: 400 mg dry matter/l
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint
14.12.2001		(7)
Type	:	aerobic
Inoculum	:	activated sludge, adapted
Contact time	:	
Degradation	:	(±) % after
Result	:	under test conditions no biodegradation observed
Deg. product	:	
Method	:	other: OECD Confirmatory Test for the Evaluation of Biodegradation of Ionic and Non-ionic Tensides (EG DEV L 24, DIN 38412, Part 24, April 1981)

Year	:	1992
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	After an adaptation period of 40 days a mean MBAS removal of 7.8 % was reached during the following 20 days
Test condition	:	Lab scale sewage treatment unit with an average retention time of 12 h, approx. 25°C, pH 7 (adjusted). Test substance concentration adjusted to 20 mg/l Methylene Blue Active Substance (MBAS) prior to incubation.
Reliability	:	(2) valid with restrictions guideline study, reported in sufficient detail
Flag	:	Critical study for SIDS endpoint
14.12.2001		(8)

3.6 BOD5, COD OR BOD5/COD RATIO

COD		
Method	:	other
Year	:	1985
COD	:	= 1270 mg/g substance
GLP	:	no
14.12.2001		

3.7 BIOACCUMULATION

Species	:	Carassius sp. (Fish, fresh water)
Exposure period	:	56 day(s) at 25 °C
Concentration	:	
BCF	:	4.79 - 8.29
Elimination	:	
Method	:	other: as prescribed for new chemical substances in Japan by "Law Concerning Screening of Chemical Substances and their Manufacture, etc. "
Year	:	1979
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Accumulation factors determined by recovered radioactivity in the fish body:

Test duration (days)	7	14	28	42	56	Mean
Accumulation factor low-concentration test	3.64	9.34	12.96	10.07	5.46	8.29
Accumulation factor high-concentration test	2.77	4.08	5.77	4.87	6.46	4.79

Test condition	:	Flow through system with 14 C-labelled test substance. 20 - 30 mg feed/carp and day. 20 carp in 100 l glas tanks.

Low conc. High Conc.

	Conc. of test subst.(ppb)	15	150
	Carp's body length (cm)	8.2	8.3
	Carp's body weigth (g)	14.00	14.86
	No. of carp	20	20
	Water temperature (°C)	25 +/- 1	25 +/- 1
	Test period (day)	7,14,28,42,56	7,14,28,42,56

Reliability : (1) valid without restriction
guideline study; report in Japanese, summary available in English; study well documented, meets generally accepted scientific principles

Flag : Critical study for SIDS endpoint

13.12.2001 (9)

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Brachydanio rerio (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC0	:	>= 100
Limit test	:	
Analytical monitoring	:	no
Method	:	other: German UBA Draft Guideline "Lethal effects towards zebrafish Brachydanio rerio" (LC0, LC50, LC100; 48-96 h - May 1984)
Year	:	1985
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	10 fish tested per concentration
Reliability	:	(2) valid with restrictions guideline study with acceptable restrictions; basic data given, GLP was not common practice that time; no analytical monitoring
Flag	:	Critical study for SIDS endpoint
14.12.2001		(10)
Type	:	static
Species	:	Leuciscus idus (Fish, fresh water)
Exposure period	:	48 hour(s)
Unit	:	mg/l
LC0	:	200
LC100	:	500
Limit test	:	
Analytical monitoring	:	no
Method	:	other: Bestimmung der akuten Wirkung von Stoffen auf Fische. Arbeitskreis "Fischtest" im Hauptausschuss "Detergentien" (15.10.73)
Year	:	1978
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	10 fish tested per concentration
Reliability	:	(2) valid with restrictions Guideline study with acceptable restrictions: basic data given, GLP was not common practice that time; no analytical monitoring
Flag	:	Critical study for SIDS endpoint
13.12.2001		(11)
Type	:	
Species	:	other: killifish
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC50	:	260
Limit test	:	
Analytical monitoring	:	no data
Method	:	other: National Japanese Guideline: JIS K01022/55
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Screening test on toxicity of the substance to fish in advance to the bioaccumulation study (see chapt. 3.7)
Test condition	:	20 fish per concentration tested; 6 concentrations tested; water temperature: 22 +/-1 °C
Reliability	:	(4) not assignable Only short abstract available
14.12.2001		(9)
Type	:	static
Species	:	Oryzias latipes (Fish, fresh water)

Exposure period	:	96 hour(s)
Unit	:	mg/l
LC0	:	180
LC100	:	1000
Limit test	:	
Analytical monitoring	:	no
Method	:	other: Bestimmung der akuten Wirkung von Stoffen auf Fische. Arbeitskreis "Fischtest" im Hauptausschuss "Detergentien" (15.10.73)
Year	:	1977
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(4) not assignable original reference not available

12.12.2001 (12)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC0	:	>= 100
Analytical monitoring	:	yes
Method	:	other: Directive 92/69/EEC, C.2 (1992)
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	No loss of TS during exposure. TS monitored by TOC analysis after 0 and 48 h. Mobility behaviour recorded daily.
Test condition	:	10 neonates per vessel, 2 replicates per concentration/control; reconstituted water (M4 medium); 20+/-0.1°C; pH 7.7+/-0.1; hardness: 273.1 mg CaCO3/l; oxygen content: 8.0+/-0.1 mg/l (Oxygen saturation >90 %)
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint

13.12.2001 (13)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	growth rate
Exposure period	:	72 hour(s)
Unit	:	mg/l
NOEC	:	= 6.3
LOEC	:	= 13
EC50	:	= 29
Limit test	:	
Analytical monitoring	:	yes
Method	:	other: Directive 92/69/EEC, part C, method 3 (1992)
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	No loss of TS concentrations during exposure. Samples taken after 0 and 72 h and analysed in terms of TOC removal.

Cell densities measured at 24 h intervals.

Result	:	Effect levels determined for the endpoint biomass: 72 h-NOEC(b): 6.3 mg/l 72 h-LOEC(b): 13 mg/l 72 h-EC50(b): 17 mg/l
Test condition	:	Exponentially growing cultures exposed to TS concentrations in the range of 3.1 - 50 mg/l; 3 replicates per concentration, 6 replicates per control; initial cell density: 10E4 cells/ml; mineral medium; 21-25°C; pH 7.7-10.4; light intensity: 60-120 uE x mE-2 x s
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint
13.12.2001		(14)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type	:	aquatic
Species	:	activated sludge
Exposure period	:	3 hour(s)
Unit	:	mg/l
EC50	:	> 100
Analytical monitoring	:	no
Method	:	other: ETAD 103: A Screening Test for the Assessment of the Possible Inhibitory Effect of a Chemical Substance on Aerobic Waste Water Bacteria (26.07.1979) the later ISO DP 8192
Year	:	1985
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(2) valid with restrictions guideline study with acceptable restrictions; basic data given, GLP was not common practice that time
Flag	:	Critical study for SIDS endpoint
14.12.2001		(15)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	male/female
Number of animals	:	10
Vehicle	:	water
Doses	:	5,0 g/kg
Method	:	Directive 84/449/EEC, B.1 "Acute toxicity (oral)"
Year	:	1986
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Limit Test: 1 dose NUMBER OF ANIMALS:5 male and 5 female rats, fasted VEHICLE: water; 20 ml/kg OBSERVATION: 14 days; PARAMETERS: observation; body weight; necropsy;
Result	:	MORTALITY: 0/10, SIGNS OF TOXICITY: no NECROPSY: no changes detected BODY WEIGHTS: no effect NO FURTHER DATA
Reliability	:	(1) valid without restriction
Flag	:	Critical study for SIDS endpoint
27.06.2002		(16)
Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	male
Number of animals	:	10
Vehicle	:	water
Doses	:	
Method	:	
Year	:	1982
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	LIMIT TEST: single dose by gavage NUMBER OF ANIMALS: 10 male animals (fasted); 1 dose group OBSERVATION: 7 d VEHICLE: water, suspension NO FURTHER DATA
Remark	:	MORTALITY: 3/10 SIGNS OF TOXICITY: 10/10, signs of toxicity not specified NO FURTHER DATA
Reliability	:	(2) valid with restrictions essential test conditions available; short observation period incomplete documentation
27.06.2002		(17)
Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	

Sex	:	male
Number of animals	:	10
Vehicle	:	water
Doses	:	
Method	:	other: limit test: 1 dose
Year	:	1981
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 10 per study PARAMETERS: signs of toxicity, body weights, mortality VEHICLE: water suspension OBSERVATION: 7d NO FURTHER DATA
Remark	:	several studies reported together
Result	:	fasted and non-fasted rats: MORTALITY: 0/10 ; SIGNS OF TOXICITY: 10/10 (apathy, hypokinesia, strained respiration, soft feces) NO FURTHER DATA
Reliability	:	(2) valid with restrictions essential test conditions available; short observation period limited documentation

27.06.2002 (18)

Type	:	LD50
Value	:	> 5 ml/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	female
Number of animals	:	10
Vehicle	:	other: none
Doses	:	
Method	:	other: limit test: 1 dose, 10 female animals, single dose by gavage, observation period: 14 d
Year	:	1978
GLP	:	no
Test substance	:	other TS:23-25% FSD-Na, 4-6% Na2SO4, 69-71% water
Method	:	NUMBER OF ANIMALS: 10 PARAMETERS: mortality VEHICLE: liquid product undiluted OBSERVATION: 14d NO FURTHER DATA
Result	:	MORTALITY: 0/10 SIGNS OF TOXICITY: none OBSERVATION: 14 d NECROPSY: no data NO FURTHER DATA
Reliability	:	(2) valid with restrictions essential test conditions available; dose given as ml/kg limited documentation, no GLP

27.06.2002 (19)

Type	:	LD50
Value	:	> 2500 mg/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	male
Number of animals	:	15
Vehicle	:	water
Doses	:	
Method	:	
Year	:	1969

GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 15 males/dose; 2 dose groups TREATMENT: 2 doses tested, 1000 mg/kg, 2500 mg/kg,single dose by gavage, PARAMETERS: signs of toxicity, body weights, mortality VEHICLE: water suspension OBSERVATION: 14d NO FURTHER DATA
Result	:	MORTALITY: 0/15; SIGNS OF TOXICITY: none BODY WEIGHTS: no effect NO FURTHER DATA
Reliability	:	(2) valid with restrictions
27.06.2002		(20)
Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	male
Number of animals	:	10
Vehicle	:	water
Doses	:	
Method	:	
Year	:	1982
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 10 male animals (non-fasted), 1 dose group TREATMENT: limit test; single dose by gavage VEHICLE: no data PARAMETERS: signs of toxicity, mortality OBSERVATION: 7d NO FURTHER DATA
Remark	:	essential test conditions available MORTALITY: 0/10 SIGNS OF TOXICITY: no signs of toxicity NO FURTHER DATA
Reliability	:	(2) valid with restrictions
27.06.2002		(17)
Type	:	LD50
Value	:	> 1000 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	male
Number of animals	:	3
Vehicle	:	water
Doses	:	500 - 1000 mg/kg
Method	:	
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSD-Na at least 75% purity
Method	:	NUMBER OF ANIMALS: 3 male animals/dose group; 2 dose groups TREATMENT: single dose by gavage, 2 doses tested, 500 mg/kg, 1000 mg/kg, VEHICLE: no data PARAMETERS: signs of toxicity, mortality OBSERVATION: 14 d NO FURTHER DATA
Remark	:	MORTALITY: 0/3;

SIGNS OF TOXICITY: no signs of toxicity
NO FURTHER DATA

Reliability : (2) valid with restrictions
essential test conditions available,
LIMITED DOCUMENTATION

27.06.2002 (20)

Type : LD50
Value : > 500 mg/kg bw
Species : cat
Strain :
Sex : male
Number of animals : 2
Vehicle : water
Doses :
Method : other: 1 dose tested, 2 male animals, single dose by gavage, observation period: 14 d
Year : 1969
GLP : no
Test substance : other TS: FSD-Na at least 75% purity
Method : NUMBER OF ANIMALS: 2 male animals
TREATMENT: single dose by gavage; 500 mg/kg
VEHICLE: no data
PARAMETERS: signs of toxicity, mortality
OBSERVATION: no data
NO FURTHER DATA
Remark : MORTALITY: 0/2
SIGNS OF TOXICITY: no signs of toxicity
NO FURTHER DATA
Reliability : (2) valid with restrictions
essential test conditions available;
LIMITED DOCUMENTATION, SMALL NUMBER OF ANIMALS

30.04.2002 (20)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : > 500 mg/kg bw
Species : rat
Strain : Wistar
Sex : male
Number of animals : 5
Vehicle : water
Doses : 500 mg/kg
Method : other: 5 males, clipped areas of the back, 500 mg/kg, open, 7 d
Year : 1969
GLP : no data
Test substance : other TS: FSD-Na at least 75% purity
Method : NUMBER OF ANIMALS: 5 male animals
TREATMENT: limit test; single dose; 500 mg/kg
VEHICLE: no data
PARAMETERS: signs of toxicity, mortality
OBSERVATION: 7d
NO FURTHER DATA
Result : MORTALITY: 0/5,
SIGNS OF TOXICITY: no signs of toxicity, no irritation
NO FURTHER DATA
Reliability : (2) valid with restrictions

essential test conditions available; open application of the test substance
LIMITED DOCUMENTATION

Flag : Critical study for SIDS endpoint
27.06.2002 (20)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type	:	LD50
Value	:	= 510 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	male
Number of animals	:	15
Vehicle	:	water
Doses	:	50, 100, 250, 375, 500, 560, 625, 750, 1000 mg/kg
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: 9 doses tested
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSD-Na at least 75% purity
Method	:	NUMBER OF ANIMALS: 15 male animals per dose; 9 dose groups TREATMENT: single dose VEHICLE: no data PARAMETERS: signs of toxicity, mortality OBSERVATION: 14 d NO FURTHER DATA
Result	:	MORTALITY: <= 250 mg/kg:0/15 375mg/kg:1/15 500mg/kg:4/15 560mg/kg:12/15 625mg/kg:14/15 >625mg/kg:15/15 SIGNS OF TOXICITY: Weakness, disturbed respiration, cyanosis for 2 to 5 days; at 100 mg/kg and above NOEL = 50 mg/kg; LDlo = 375 mg/kg NO FURTHER DATA
Reliability	:	(2) valid with restrictions essential test conditions available
27.06.2002		(20)

Type	:	LD50
Value	:	= 425 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	male
Number of animals	:	15
Vehicle	:	physiol. saline
Doses	:	100, 250, 375, 450, 500, 750 mg/kg
Route of admin.	:	i.v.
Exposure time	:	
Method	:	other: 6 doses tested
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSD-Na, at least 75% purity, suspended in water
Method	:	NUMBER OF ANIMALS: 15 male animals per dose; 6 dose groups TREATMENT: single dose VEHICLE: no data PARAMETERS: signs of toxicity, mortality

OBSERVATION: 14 d
NO FURTHER DATA

Result : MORTALITY: <= 250 mg/kg:0/15
375mg/kg:3/15
450mg/kg:9/15
500mg/kg:14/15
750mg/kg:15/15
SIGNS OF TOXICITY: disturbed respiration, premortal convulsions, at 250 mg/kg and above
NO FURTHER DATA
NOEL = 100mg/kg; LDlo = 375 mg/kg

Reliability : (2) valid with restrictions
essential test conditions available
LIMITED DOCUMENTATION

27.06.2002 (20)

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	
Exposure	:	Semiocclusive
Exposure time	:	24 hour(s)
Number of animals	:	2
Vehicle	:	
PDII	:	0
Result	:	not irritating
Classification	:	
Method	:	other:
Year	:	1969
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 2 animals TREATMENT: single dose, ear, 50 mg/animal, 24 h, semiocclusive, VEHICLE: no data PARAMETERS: redness, edema OBSERVATION: reading time: up to 7 d NO FURTHER DATA
Result	:	NO CHANGES OF SKIN
Reliability	:	(2) valid with restrictions essential test conditions available LIMITED DOCUMENTATION

02.05.2002 (21) (20)

Species	:	rabbit
Concentration	:	
Exposure	:	Semiocclusive
Exposure time	:	4 hour(s)
Number of animals	:	3
Vehicle	:	water
PDII	:	0
Result	:	not irritating
Classification	:	
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	1985
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 3 animals (Strain HC:NZW) TREATMENT: 500 mg/animal, 4 h, semiocclusive,

VEHICLE: water, moistened substance
PARAMETERS: redness, edema
OBSERVATION: time: 1, 24, 48, 72 h and 7 days

Result : no changes of skin (score "0" for erythema and edema)
Reliability : (1) valid without restriction
guideline study
full report
Flag : Critical study for SIDS endpoint
27.06.2002 (22)

Species : rabbit
Concentration : undiluted
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 6
Vehicle :
PDII : 2
Result : slightly irritating
Classification :
Method : other: Code of Federal Regulations, Title 16, Section 1500.41
Year : 1979
GLP : no data
Test substance : other TS: 23-25% FSD-Na, 4-6% Na2SO4, 69-71% water
Method : NUMBER OF ANIMALS: 6 rabbits (New Zealand White)
TREATMENT: 0,5 mL/animal, occlusive, intact as well as scarified skin
VEHICLE: liquid product undiluted, ~24% in water
PARAMETERS: redness, edema
OBSERVATION: reading time: 24, 48 and 72 h and 8 days
NO FURTHER DATA
Remark : not all effects reversible within 8 days
Result : intact skin:
ERYTHEMA:
24 h: 3/6; mean grade 0,67
72 h: 1/6; mean grade 0,17
8 d : 0/6
EDEMA:
24 h: 4/6; mean grade 1,0
72 h: 2/6; mean grade 0,5
8 d : 1/6;

scarified skin:
ERYTHEMA:
24 h: 6/6; mean grade 1,67
72 h: 6/6; mean grade 1,17
8 d : 5/6;
EDEMA:
24 h: 6/6; mean grade 1,5
72 h: 6/6; mean grade 1,33
8 d : 5/6;

NO FURTHER DATA
Reliability : (2) valid with restrictions
deviation of current guideline: test substance was applied occlusive
guideline-like study
27.06.2002 (23)
Species : rabbit
Concentration : undiluted
Exposure : Semiocclusive
Exposure time : 24 hour(s)
Number of animals : 6

Vehicle	:	
PDII	:	
Result	:	not irritating
Classification	:	
Method	:	
Year	:	1980
GLP	:	no data
Test substance	:	no data
Method	:	NUMBER OF ANIMALS: 6 TREATMENT: 500 mg/animal, 24 h, semiocclusive,intact skin VEHICLE: no data PARAMETERS: redness, edema OBSERVATION: reading time: up to 7 d NO FURTHER DATA
Remark	:	essential test conditions available LIMITED DOCUMENTATION
Result	:	IRRITATION INDEX 0.08 NO FURTHER DATA
Reliability	:	(2) valid with restrictions
27.06.2002		(24)
Species	:	human
Concentration	:	
Exposure	:	Semiocclusive
Exposure time	:	24 hour(s)
Number of animals	:	
Vehicle	:	
PDII	:	0
Result	:	not irritating
Classification	:	
Method	:	
Year	:	1969
GLP	:	no data
Test substance	:	other TS: FSD-Na, at least 75% purity, suspended in water
Method	:	NUMBER OF VOLUNTEERS: 10 TREATMENT: single dose, forearm, 50 mg/test site, 24 h, semiocclusive, PARAMETERS: redness, edema OBSERVATION: reading time: up to 7 d NO FURTHER DATA
Result	:	NO CHANGES OF SKIN
Reliability	:	(2) valid with restrictions essential test conditions available LIMITED DOCUMENTATION
27.06.2002		(21) (20)
Species	:	human
Concentration	:	
Exposure	:	Semiocclusive
Exposure time	:	48 hour(s)
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	not irritating
Classification	:	
Method	:	
Year	:	1973
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF VOLUNTEERS: 102 females TREATMENT: repeated insult patch test, 10+1 applications/person on the back 48 hours semiocclusive exposure VEHICLE: no data

PARAMETERS: redness, edema
OBSERVATION: imediately after removal of p atches
NO FURTHER DATA

Result : "...no evidence of any primary irritation..."
NO FURTHER DATA

Reliability : (4) not assignable
documentation insufficient for assessment

02.05.2002 (25)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	
Dose	:	50 other: mg
Exposure time	:	unspecified
Comment	:	
Number of animals	:	2
Vehicle	:	
Result	:	not irritating
Classification	:	
Method	:	
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSD-Na at least 75% purity
Method	:	NUMBER OF ANIMALS: 2 animals TREATMENT: single dose, instillation of 50 mg/animal in the conjunctival sac, VEHICLE: no, applied as solid PARAMETERS: changes of cornea, iris and conjunctiva OBSERVATION: reading time: 1h; 1,2,3,4,7 d after application NO FURTHER DATA
Result	:	no changes of eyes
Reliability	:	(2) valid with restrictions essential data available LIMITED DOCUMENTATION

27.06.2002 (21) (20)

Species	:	rabbit
Concentration	:	
Dose	:	70 other: mg
Exposure time	:	24 hour(s)
Comment	:	
Number of animals	:	3
Vehicle	:	
Result	:	slightly irritating
Classification	:	
Method	:	OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year	:	1985
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 3 animals TREATMENT: single dose, instillation of 0.1 m l/eye, rinsed after 24 h with saline VEHICLE: no, applied as solid PARAMETERS: changes of cornea, iris and conjunctiva OBSERVATION: reading time: 1h; 1,2,3,7 d after application
Remark	:	dose equal to 100 µL Effects: all animals affected slight reddening of conjuntivae after 1 to 72 h slight to moderate swelling of the lids after 1 to 48 h

moderate dicharge after 1 to 48 h;
Draize scores: cornea 0; iris 0; conjunctiva redness 1, chemosis 0.7
all changes reversible within 7 days

Reliability : (1) valid without restriction
guideline study, full report available

Flag : Critical study for SIDS endpoint

27.06.2002 (22)

Species : rabbit
Concentration : undiluted
Dose : 100 other: mg
Exposure time : unspecified
Comment :
Number of animals : 6
Vehicle :
Result : not irritating
Classification :
Method : other: ETAD-method
Year : 1980
GLP : no
Test substance : no data
Method : NUMBER OF ANIMALS: 6 animals
TREATMENT: single dose, ca.100 mg/eye,
VEHICLE: no, applied as solid
PARAMETERS: changes of cornea, iris and conjunctiva
OBSERVATION: at least 7 d
NO FURTHER DATA
Result : IRRITATION INDEX: 0,4
NO FURTHER DATA
Reliability : (4) not assignable
essential test conditions available
very limited documentation

27.06.2002 (24)

Species : rabbit
Concentration : undiluted
Dose : 100 other: µl
Exposure time : 24 hour(s)
Comment : not rinsed
Number of animals : 6
Vehicle :
Result : not irritating
Classification :
Method : other: Code of Federal Regulations, Title 16, Section 1500.42
Year : 1979
GLP : no
Test substance : other TS: 23-25% FSD-Na, 4-6% Na2SO4, 69-71% water
Method : NUMBER OF ANIMALS: 6 animals
TREATMENT: single dose, instillation of 0.1 ml/eye,
VEHICLE: no data
PARAMETERS: changes of cornea, iris and conjunctiva
OBSERVATION: reading time: 1,2,3,8 d after application
NO FURTHER DATA
Result : CORNEA: slight opacity 4/6 animals
IRIS: no effect
CONJUNCTIVA: no effect
all effects reversible within 2 days
Reliability : (1) valid without restriction
guideline-like study, full report available
Flag : Critical study for SIDS endpoint

27.06.2002 (26)

Species	:	rabbit
Concentration	:	undiluted
Dose	:	100 other: ul
Exposure time	:	24 hour(s)
Comment	:	
Number of animals	:	3
Vehicle	:	
Result	:	slightly irritating
Classification	:	
Method	:	OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year	:	1983
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 3 animals TREATMENT: single dose, instillation of 0.1 ml of the powdered test substance/eye, rinsed after 24 h with saline VEHICLE: none PARAMETERS: changes of cornea, iris and conjunctiva OBSERVATION: reading time: 1h; 1,2,3,7 d after application NO FURTHER DATA
Result	:	Cornea: no effect; score 0 Iris: no effect; score 0 Conjunctiva: slight redness in 3/3 rabbits; score 1 all effects reversible within 7 days
Reliability	:	(1) valid without restriction guideline study, full report available
Flag	:	Critical study for SIDS endpoint

27.06.2002 (27)

5.3 SENSITIZATION

Type	:	other: see method
Species	:	human
Number of animals	:	
Vehicle	:	no data
Result	:	not sensitizing
Classification	:	
Method	:	other: repeated insult patch test
Year	:	1973
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF SUBJECTS: 102 female volunteers TREATMENT: repeated insult patch test; 10+1 applications DOSE/VEHICLE: no data PARAMETERS: erythema, edema OBSERVATION: imediately after exposure NO FURTHER DATA
Remark	:	not irritating after 48 h exposure
Result	:	"...no indication of sensitization potential..." NO FURTHER DATA
Reliability	:	(4) not assignable documentation insufficient for assessment

02.05.2002 (25)

Type	:	other: see method
Species	:	human
Number of animals	:	
Vehicle	:	no data
Result	:	not sensitizing

Classification	:	
Method	:	
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSD-Na, at least 75% purity, solved in water
Method	:	NUMBER OF SUBJECTS: 6 volunteers TREATMENT: patches on upper arm, dose: not reported / test site: 24 h; semiocclusive induction: 9 times for 24 h, 3 times/week, challenge: once 10 d after the last induction for 24 h PARAMETERS: changes of skin OBSERVATION: no data NO FURTHER DATA
Result	:	no changes of skin were reported
Reliability	:	(2) valid with restrictions essential test conditions available limited documentation
27.06.2002		(20)
Type	:	other: see method
Species	:	guinea pig
Number of animals	:	15
Vehicle	:	water
Result	:	not sensitizing
Classification	:	
Method	:	
Year	:	1969
GLP	:	no
Test substance	:	other TS: FSS-Na, at least 75% purity
Method	:	NUMBER OF SUBJECTS: 15 animals, CONTROL GROUP: no TREATMENT: back, induction: 10 times 0.1 % solution, i.c. injection, 3 times/week, challenge: once 14 d thereafter; 0.1 % solution; i.c. injection VEHICLE: physiological saline PARAMETERS: erythema, edema, body weight OBSERVATION: 24 h after injection NO FURTHER DATA
Result	:	ERYTHEMA: equal or weaker effect after re-injection as compared to first injection (mean grade: 1.03 / 0,67) EDEMA: weaker effect after re-injection as compared to first injecti on (mean grade: 0.96 / 0,67)
Reliability	:	(2) valid with restrictions essential test conditions available; no standard protocol, no controls, no range finding test limited documentation
27.06.2002		(20)

5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	Wistar
Route of admin.	:	gavage
Exposure period	:	13 w
Frequency of treatm.	:	daily

Post exposure period	:	no data specified
Doses	:	150, 500, 1500 mg/kg bw/day in water
Control group	:	yes, concurrent vehicle
NOAEL	:	= 500 mg/kg bw
Method	:	
Year	:	1983
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	NUMBER OF ANIMALS: 20 rats/sex/group VEHICLE: water; PARAMETERS: daily observation;weekly body weight;clinical and hematological investigations, urinalysis, necropsy, organ weights (10 organs), histopathologic examination (34 organs) STATISTICS: mean values, standard deviation, U-Test according to Mann, Withney and Wilcoxon significance levels at 1 and 5 %
Result	:	MORTALITY: no treatment related mortality OBSERVATION: no clinical signs, 1500 mg/kg bw/day (both sexes): increased water intake(38 % in males, 33 % in females) and reduced body weight gain (7.5 % in males, 5 % in females) CLINICAL PATHOLOGY: no changes in hematological and urinary parameters, no changes in clinical parameters (both sexes, all dose groups) PATHOLOGY: 150 and 500 mg/kg: no effects 1500 mg/kg bw/day (both sexes): increased kidney weight (ca. 20 %, no morphologic correlate) and spleen weights (< 20 %; no morphologic correlate), changes in tubular epithelium of kidneys (dilated tubuli, flattened epithelium, necrosis, desquamation, increased rate of mitoses, proteinaceous casts, thickening of basal membrane, vacuolation of cells and nuclei, interstitial inflammatory infiltrates) testes/ovaries weight (rel.+abs.): no differences; histology males: testes, epididymis, prostate, seminal vesicles: no treatment related findings histology females: uterus, ovaries: no treatment related findings
Reliability	:	(1) valid without restriction guideline-like study; full report available
Flag	:	Critical study for SIDS endpoint
27.06.2002		(28)
Type	:	
Species	:	dog
Sex	:	male/female
Strain	:	Beagle
Route of admin.	:	oral feed
Exposure period	:	29 d
Frequency of treatm.	:	once/day, 7d/w
Post exposure period	:	no
Doses	:	3000, 7000, 15000 ppm (=ca. 119, 323, 669 mg/kg bw/day)
Control group	:	yes, concurrent no treatment
NOAEL	:	> 669 mg/kg bw
Method	:	
Year	:	1983
GLP	:	no
Test substance	:	other TS: FSD Na 100% purity
Method	:	NUMBER OF ANIMALS: 1 animal/dose/sex VEHICLE: water; PARAMETERS: clinical signs, mortality, food consumption, body weight, laboratory investigations, necropsy

(no histopathology)
range finding study

Result : MORTALITY: no treatment related mortality
OBSERVATION: slight to moderate diarrhoea, normal food consumption and body weight gain
CLINICAL PATHOLOGY: no changes in hematological, biochemical and urinary values
PATHOLOGY: m acroscopic changes in various organs were found in all groups and regarded as treatment unrelated (due to ascaridosis, histopathology was not performed)

NECROPSY FINDINGS:
0 ppm: intestinal ascaridosis in both animals, dark red mesenteric lymph nodes in both animals (in one animal lymph nodes large), approx. 5 ml clear fluid in the abdomen of the female

3000 ppm: intestinal ascaridosis in both animals, in the female in addition: several red mucosal areas in the urinary bladder, dark red-brown areas up to 5 mm in diameter in all lobes of the lung, and large, partly dark red mesenteric lymph nodes

7000 ppm: male: spleen: capsule opaque, focal, 2x1 cm; two brown foci, approx. 2 cm in diameter in the right apical lung lobe; several dark brown-grey foci, approx. 0.5 cm in diameter, in phrenic lobes; large partly dark red mesenteric lymph nodes: two mucosal reddenings approx. 3 mm in diameter in the jejunum; female: large dark red mesenteric lymph nodes; intestinal ascaridosis; jejunal mucosa red, diffuse (3cm in length)

15,000 ppm: intestinal ascaridosis in both animals; male: striated, slightly red stomach mucosa; female: large, partly dark red mesenteric lymph nodes

Reliability : (2) valid with restrictions
RANGE FINDING STUDY

30.04.2002 (29)

Type :
Species : dog
Sex : male/female
Strain : Beagle
Route of admin. : oral feed
Exposure period : 26 w
Frequency of treatm. : daily 3 hours, 7d/w
Post exposure period : no data specified
Doses : 3000, 7000, 15000 ppm (=ca. 126, 340, 620 mg/kg bw/day)
Control group : yes, concurrent no treatment
NOAEL : = 620 mg/kg bw
Method :
Year : 1984
GLP : yes
Test substance : other TS: FSD Na 100% purity
Method : NUMBER OF ANIMALS: 6 male and 6 female Beagle dogs (age: 15 - 26 weeks)
VEHICLE: diets containing 0, 3000, 7000 or 15,000 ppm of formaldehyde, reaction products with sulfonated ,1'-oxybis-methyl- benzene), sodium salts (FSD-Na)
PARAMETERS: observation, food consumption, body weight, hearing, ophthalmoscopy, haematology, clinical chemistry, urinalysis, necropsy, organ weights (10 organs), histopathology (41 organs)
Statistics:
Student's T-Test on pooled variance; Williams Test for determination of lowest significant effect (Williams Biometrics 27;103ff 1971 and 28;519ff

1972);

Result : MORTALITY: no treatment related mortality
One male each from the low and mid dose groups had to be killed in moribund state from treatment unrelated causes (enteritis).
OBSERVATION: No clinical symptoms, no treatment related findings in food consumption and body weight gain, no findings in hearing test, ophthalmoscopic examinations.
Occasional, slight to moderate diarrhoea was found in all groups (not treatment related)
CLINICAL PATHOLOGY: No findings in hematology, clinical chemistry and urinalysis
PATHOLOGY: normal organ weights, no macroscopic findings were found as compared to the controls.
Observed microscopic findings in gall bladder, stomach, lung, liver, spleen, kidney, lymph nodes, and thymus were regarded as treatment unrelated.
The only substance-related effect was an increase of the phagocytic activity in the mesenteric lymph nodes in some high-dose animals. This was concluded from the presence of increased numbers of macrophages in lymph node sinuses and from the incorporation of PAS -positive material into these cells. This effect was regarded not as a toxic lesion but as the morphological correlate of a hyperfunctional state.
testes/ovaries weight (rel.+abs.): no differences;
histology males:
testes, epididymis, prostate: no treatment related findings
histology females:
uterus, ovaries: no treatment related findings

Gross and microscopic examinations did not reveal any other substance-related effects.

The NOAEL was 15000 ppm (~620 mg/kg bw/day) after 6 months of treatment

The following findings occurred more frequently in treated dogs than in controls. They were nevertheless regarded as treatement-unrelated, since lymphoid cell accumulation in the gall bladder and stomach of minimal to moderate degree is a common and insignificant finding in normal dogs.
GALLBLADDER: minimal lymphofollicular hyperplasia in the mucosa in dogs of the mid- and high-dose groups.
(INCIDENCE M/F: 0/1 - 1/0 - 3 / 4 - 4/4)
STOMACH: minimal to moderate lymphofollicular hyperplasia in the pyloric mucosa in dogs of the mid- and high-dose groups
(INCIDENCE: M/F: 2 / 3 - 3 / 3 - 4 / 6 - 6 / 6)
A number of other spontaneous lesions occurred randomly in dogs of all groups, including the controls. The findings listed below were noted:
LUNG: multifocal chronic purulent bronchopneumonia with occasional presence of intra-alveolar nematodes; bronchitis/peribronchitis; interstitial pneumonia with or without fibrosis
LIVER: multifocal aggregation of inflammatory cells in parenchyma
SPLEEN: focal capsular thickening(/capsulitis; sclerosiderotic foci
KIDNEY: proteinaceous tubular casts
LYMPH NODES: lymphatic hyperplasia
THYMUS: medullary cysts

Reliability : (2) valid with restrictions
GUIDELINE STUDY:
Proposed Guidelines for Registering Pesticides in the United States, Hazard Evaluation: Humans and Domestic Animals, Fed. Reg. Vol. 43, No. 163
FULL REPORT AVAILABLE

Flag : Critical study for SIDS endpoint

02.05.2002 (30)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Salmonella typhimurium TA 1537, TA 100, TA 1535, TA 98
Test concentration	:	8-40-200-1000-5000 ug/plate in water
Cycotoxic concentr.	:	>1000 ug/plate
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: OECD Guide-line 471 (1983)
Year	:	1992
GLP	:	yes
Test substance	:	other TS: FSD-Na, purity 93,4 %, solved in water
Method	:	METABOLIC ACTIVATION: rat S9-mix EVALUATION CRITERIA: no bacterial toxicity; reproducible, dose related, biologically relevant changes in at least 1 strain (increase of revertant counts at least 2 fold) POSITIVE CONTROLS: NaN3, Nitrofurantoin, 4 -nitro-1,2- phenylene diamine, 2 -aminoanthracene(with S9-mix) in DMSO all positive controls produced clear effects.
Result	:	CYTOTOXICITY: concentrations up to 5000 ug/plate evaluable MUTAGENICITY: A relevant increase of the mutant count was not observed POSITIVE CONTROLS: all positive controls produced clear effects.
Reliability	:	(1) valid without restriction guideline study; FULL REPORT AVAILABLE
Flag	:	Critical study for SIDS endpoint

30.04.2002 (31)

Type	:	Chromosomal aberration test
System of testing	:	Chinese hamster V79 cells
Test concentration	:	300-600-1000 ug/ml (4h, -S9); 100-150-200 ug/ml (18h, -S9); 400-800-1400 ug/ml (4h, +S9)
Cycotoxic concentr.	:	1000 ug/ml (- S9, 4h); 200 ug/ml (-S9, 18h); 1400 ug/ml (+ S9)
Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 473
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	VEHICLE: Water, solubility: 167 mg/ml POSITIVE CONTROL: mitomycin C, cyclophsphamide CYTOTOXICITY: cell survival, mitotic index METABOLIC ACTIVATION: rat S9-mix (pretreatment with Aroclor 1254) TREATMENT: PRELIMINARY TEST: 4 h treatment, harvest after 24 h; 18 h treatment, harvest after 18 h MAIN TEST: 4 h treatment, harvest at 18 and 30 h EVALUATION: 2x100 metaphases per concentration pairwise comparison of treated, positive control and solvent control groups; Fisher´s exact test, significance level 5% Criteria: statistical significant increase of aberration rate exceeding the range of historical control data
Result	:	MUTAGENICITY: none of the treated cultures showed increased numbers of aberrant metaphases in presence as well as in absence of S9mix POSITIVE CONTROLS showed the sensitivity of the test system and the activity of the S9mix

Test substance	:	TEST SUBSTANCE: 72.1 % FSD Na, 23,5% Na2SO4, 4.9% Water
Reliability	:	(1) valid without restriction current guideline study; FULL REPORT AVAILABLE
Flag	:	Critical study for SIDS endpoint

02.05.2002 (32)

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type	:	other: 13 week repeated dose
Species	:	rat
Sex	:	
Strain	:	
Route of admin.	:	gavage
Exposure period	:	
Frequency of treatm.	:	
Premating exposure period		
Male	:	
Female	:	
Duration of test	:	
No. of generation studies	:	
Doses	:	
Control group	:	
Remark	:	No indication of adverse effects on reproductive organs were found in a 13 week study in rats with oral administration (Details: see repeated dose toxicity)

27.06.2002 (28)

Type	:	other: 6 month repeated dose
Species	:	dog
Sex	:	
Strain	:	
Route of admin.	:	oral feed
Exposure period	:	
Frequency of treatm.	:	
Premating exposure period		
Male	:	
Female	:	
Duration of test	:	
No. of generation studies	:	
Doses	:	
Control group	:	
Remark	:	No indication of adverse effects on reproductive organs were found in a 6 month study in dogs with oral administration (Details: see repeated dose toxicity)

27.06.2002 (30)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female

Strain	:	other: Charles River CRL:WI(HAN)
Route of admin.	:	gavage
Exposure period	:	gestation day 0 to 19
Frequency of treatm.	:	daily
Duration of test	:	up to gestation day 20
Doses	:	0, 50, 100, 500 or 1000 mg/kg bw/day
Control group	:	other: yes (deionized water)
NOAEL maternal tox.	:	1000 mg/kg bw
NOAEL teratogen.	:	1000 mg/kg bw
Method	:	
Year	:	1998
GLP	:	yes
Test substance	:	other TS: FSD-Na, purity 74.9- 76 % active ingredient
Method	:	NUMBER OF ANIMALS: 30 female (6/dose), 15 male rats PARAMETERS: Fertility index; gestation index; mating index; body weight gain; food consumption; clinical findings; necropsy; organ weight (liver, thyroids, kidney; spleen; gravid uterus);number of corpora lutea; total number of implantations; litter size; fetal sex distribution; number of viable fetuses; number of non-viable fetuses; placental weight; number of early/ late resorptions; preimplantation loss; post implantation loss; number of affected litters.
Result	:	MATERNAL TOXICITY: no clinical signs in dams up to 1000 mg/kg bw/day at any time no effects on food consumption and body weight development no treatment related findings at necropsy of dams FERTILITY INDEX: 83,3% for control and 50 (low dose) or 83,3% (all other doses) treated rats MATING INDEX: 100% in both groups RESORPTION/POST IMPLANTATION LOSS: no effects LITTER SIZE: no effects EXTERNAL/SCELETAL MALFORMATIONS: no statistically significant effects
Reliability	:	(2) valid with restrictions RANGE FINDING TEST GUIDELINE STUDY: US EPA FIFRA, Pesticide assessment guidelines Subdivision F, Hazard evaluation: Human and domestic animals, Nov. 1984, Guideline 83-3 FULL REPORT AVAILABLE

02.05.2002 (33)

Species	:	rat
Sex	:	female
Strain	:	Wistar
Route of admin.	:	gavage
Exposure period	:	gestation day 0 to 19
Frequency of treatm.	:	daily
Duration of test	:	up to gestation day 20
Doses	:	0 or 1000 mg/kg bw
Control group	:	other: yes (deionized water)
other: NOEL (maternal)	:	1000 mg/kg bw
other: NOEL (fetal)	:	1000 mg/kg bw
Method	:	OECD Guideline 414 "Teratogenicity"
Year	:	1998
GLP	:	yes
Test substance	:	other TS: FSD-Na, purity 75.6- 76 % active ingredient
Method	:	Limit-Test NUMBER OF ANIMALS: 60 female (30/dose), 30 male rats Duration of treatment: throughout pregnancy (days 0-19)

PARAMETERS:
MATERNAL TOXICITY:
mortality, clinical observation, b ody weight, food consumption, gross necropsy, organ weight (liver, thyroids, kidney, gravid uterus, placental weight)
FETOTOXICITY:
Fertility index; gestation index; mating index; number of corpora lutea; total number of implantations; litter size; fetal sex distribution; number of viable fetuses; number of non-viable/malformed fetuses/sex; fetal weight; number of early/ late resorptions; preimplantation loss; post implantation loss; number of affected litters.
type/ incidence of external, visceral, skeleta l malformations and variations.

Statistics:
Anova analysis of variance; Dunnett test; Healy Test(fetal and placental weights); Krukskal-Wallis Test and Dunn Test (Litter size, corpora lutea); Chi-square Test and Fisher exact test (dichotomous data)
Significanece level: 5%

Result : MATERNAL TOXICITY: no maternal toxicity (no findings at all)
food consumption: no difference between treated and control
body weight: no difference between treated and control
no treatment related findings at necropsy of dams

FETAL TOXICITY: no effect up to 1000 mg/kg bw/day, no evidence of embryo or fetal effects;

FERTILITY INDEX: 73,3% or 80% for control and treated rats, resp.
MATING INDEX: 100% in both groups
FETAL VIABILITY: 1 non-viable fetus in 24 litters of the treated group
RESORPTION/POST IMPLANTATION LOSS: no effects
LITTER SIZE: no effects
FETUSES/LITTER: no effects
FETAL WEIGHT: no effects
PLACENTAL WEIGHT: no effects
EXTERNAL/VISCERAL/SCELETAL MALFORMATIONS: no statistically significant effects

Test substance : actual doses: 0 or 1030 mg/kg bw/day

Reliability : (1) valid without restriction
GUIDELINE STUDY:
US EPA OPPTS 870.3700. Prenatal developmental toxicity studies (1998)
OECD 414 (1981)
EU guideline 87/302/EEC (1995)
(deviation from current standard: treatment from day 0 to 19)
FULL REPORT AVAILABLE

Flag : Critical study for SIDS endpoint

27.06.2002 (34)

5.8.3 TOXICITY TO REPRODUCTION,OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

27.06.2002

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

(1) Bayer AG 2001a, Internal Study, Determination of the Melting Point, 25.01.2001

(2) Bayer AG 2001, Calculation of the Vapour Pressure by SRC-MPBPWIN, v1.40 (2000)

(3) Bayer AG 2001, Calculation of log Octanol-Water Partition Coefficient by SRC-KOWWIN, v1.66 (2000)

(4) Bayer AG 2001b, Internal Study, Solubility in Water, 29.05.2001

(5) Bayer AG 2001c, Calculation of Indirect Photodegradation by SRC-AOPWIN v1.90 (2000)

(6) Bayer AG 1985a, Internal Study, Closed Bottle Test according to OECD Guideline 301 D (24.10.1985)

(7) Bayer AG 1994, Internal Study, Zahn-Wellens-Test (24.10.1994)

(8) Bayer AG 1992, Internal Study, Degradation in the OECD-Confirmatory test (22.06.1992)

(9) Bayer AG 1979, Internal Study, Bioaccumulation Study to Carp (05.04.1979)

(10) Bayer AG 1985b, Internal Study, Acute toxicity to Brachydanio rerio (30.09.1985)

(11) Bayer AG 1978, Internal Study, Acute toxicity to Leuciscus idus (August 1978)

(12) Bayer AG 1977, Internal Study, Acute toxicity to Oryzias latipes - Original reference not available

(13) Bayer AG 2001d, Internal Study, Acute toxicity to Daphnia magna (Study-No.: 1088 A/01 D)

(14) Bayer AG 2001e, Internal Study, Acute toxicity to Scenedesmus subspicatus (Study-No.: 1088 A/01 A1)

(15) Bayer AG 1985c, Internal Study, Toxicity to waste water bacteria (10.09.1985)

(16) Ramm, W., Untersuchung zur akuten oralen Toxizitaet an maennlichen und weiblichen Wistar-Ratten, jan/23/1986 Bayer AG

(17) Heimann, K-G., Bayer AG data, short report, oct/06/1982

(18) Heimann, K-G., Bayer AG data, short report, july/10/1981

(19) Bomhard, E., Bayer AG data, short report, oct/11/1978

(20) Solmecke, B; Kimmerle, G. Toxikologische Untersuchungen, Report No. 1635, nov/03/1969 Bayer AG

(21) Kimmerle, G., Bayer AG data, short report, april/17/1969

(22) Pauluhn, J; Untersuchungen zum Reiz-/Ätzpotential an Haut und Auge (Kaninchen) Report No. 14140, dec/12/1985 Bayer AG

(23) Schreiber, G. Bericht über die Prüfung auf primäre Hautreizwirkung, Data of FHG (Schmallenberg), 30. Jan 1979 (at the request of Bayer AG)

(24) Thyssen, J., Bayer AG data, short report, jan/17/1980

(25) Blau, S.: Report of Test-Kit Testing Laboratories, New York, 28. Mar. 1973 (number of report not known)

(26) Schreiber, G. Bericht über die Prüfung auf primäre Schleimhautreizwirkung Data of FHG (Schmallenberg), 30. Jan 1979 (at the request of Bayer AG)

(27) Krötlinger F. Prüfung auf primär reizende/ätzende Wirkung am Kaninchenauge Bayer AG data, internal report, study number T 1016356, sep/08/1983

(28) Mihail, F.; Nash G. Subchronische Toxikologische Untersuchungen an Ratten (3 month; gavage) Report No.: 11852, Bayer AG, june/01/1983

(29) Bathe, R. 29 day oral toxicity feeding study (range finding) with repetitive administration to Beagle dogs Data of RCC, Research and Consulting Company, Report No.R 2483, feb/03/1983(at the request of Bayer AG)

(30) Bathe R. 6-Month oral (feeding) toxicity study in Beagle dogs Research and Consulting Company, Report No.R 2730 Jan/10/1984 (at the request of Bayer AG)

(31) Gahlmann R. Salmonella/Microsome Test Report No.: 21408, may/21/1992 Bayer AG

(32) Herbold B. In vitro chromosome aberration test with chinese hamster V79 cells; Study No: T3070169; Bayer AG; Oct. 2001

(33) Astroff, A.B., A dose range finding developmental toxicity study in the Wistar rat Report 108161, Study No. 97-912-LT, 9.Nov.1998 Bayer Corp., USA

(34) Astroff, A.B. A developmental toxicity study SL in the Wistar rat Report 108607, Study No. 98-612-PL, 9.Nov.1998 Bayer Corp., USA