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Life Sciences
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Administrator
US Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attention: HPV Challenge Program
15 June 2004

RE: Submission of Test Plan and Robust Summaries for Resorcinol (CAS Number 108-46-3)
(AR 201-11357)(MR28695)

Dear Administrator,

Huntingdon Life Sciences are pleased to submit a High Production Volume (HPV) test plan for Resorcinol on behalf of our clients INDSPEC Chemical Corporation.

Enclosed is a CD-ROM containing the IUCLID data set in two formats (the word version and an exported version) and the test plan. We have not submitted these by e-mail as well at present but are happy to do so on request. Please contact me if this is required.

Please can you address any subsequent questions that you may have about the data directly to:

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cc: Barbara Buchner

201-15385

High Production Volume (HPV) Challenge Program

Data Analysis and Test Plan for

Resorcinol

CAS Number 108-46-3

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**INDSPEC Chemical Corporation
1010 William Pitt Way
Pittsburgh
PA 15238
USA**

May 2004

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1. EXECUTIVE SUMMARY

INDSPEC is committed to fulfilling the High Production Volume (HPV) commitments it made under the United States Environmental Protection Program on February 14, 2001. As part of this commitment, INDSPEC has volunteered to assess the health and environmental hazards of Resorcinol.

INDSPEC has identified data from various sources, these include company proprietary files, peer-reviewed published literature, specific test reports and/or calculated endpoints using widely accepted computer-modelling programs.

Conclusions about the nature of Resorcinol gained from analysis of all available data are as follows:

HUMAN HEALTH

Resorcinol is classified as harmful if swallowed. Long term exposure gives a NOEL of 250 – 260 mg/kg in rats and mice. When adsorbed through the skin or the G.I. tract nearly all is excreted in urine in 24 hours. Repeated administration over 30 days does not lead to storage or accumulation in tissues.

In vitro mammalian cell assays with Resorcinol demonstrated gene and chromosome mutations. However *in vivo* tests did not show any signs of genotoxicity. Long-term animal studies were without findings to demonstrate that Resorcinol has any carcinogenic effect or developmental effects.

ENVIRONMENT

The lowest no effect concentration of Resorcinol is 172 µg a.i./l (NOEC, full life cycle toxicity test for *Daphnia magna*). Resorcinol is readily biodegradable and has a very low Pow value of 0.8, and so the potential for bioaccumulation is regarded as low. Fugacity modelling indicates that 99% of Resorcinol will partition to water. A calculated Henry's constant indicates that resorcinol can be described as extensively non-volatile from water. So it can be assumed that the compound remains in water phase when discharged to the environment.

Physicochemical data, environmental fate data, ecotoxicity data and mammalian toxicity data endpoints for Resorcinol are fulfilled by using existing measured data or data calculated by the EPIWIN computer model with the exception of toxicity to fertility data. To address this data gap a study is currently being conducted with results due early 2005. No further testing is proposed for this program.

Table 1. Matrix of Available and Adequate Data for Resorcinol for SIDS endpoints

HPV Data Category	Test Endpoint	Available Data (Klimish Score)	Testing Planned
Physical and Chemical Data	Melting Point	Y (1)	N
	Boiling Point	Y(1)	N
	Vapor Pressure	Y(1)	N
	Partition Coefficient	Y(2)	N
	Water Solubility	Y(1)	N
Environmental Fate and Pathways	Photodegradation	Y(2)	N
	Stability in Water (Hydrolysis)	Y(2)	N
	Transport/Distribution	Y(2)	N
	Biodegradation	Y(2)	N
Ecotoxicity	Acute/Prolonged Toxicity to Fish	Y(2)	N
	Acute/Prolonged Toxicity to Aquatic Invertebrates (Daphnia)	Y(1)	N
	Acute Toxicity to Aquatic Plants (Algae)	Y(2)	N
Toxicity	Acute Toxicity (Oral)	Y(2)	N
	Acute Toxicity (Dermal)	Y(2)	N
	Repeated Dose	Y(1)	N
	Genetic Toxicity <i>in vitro</i> –	Y(1)	N
	Genetic Toxicity – <i>in vivo</i>	Y(1)	N
	Reproductive Toxicity	N	Y
	Developmental Toxicity	Y(2)	N

2. GENERAL SUBSTANCE INFORMATION

Resorcinol is manufactured by INDSPEC Chemical Corp. at Petrolia, Pennsylvania. The process is based on the sulfonation of benzene under conditions that promote di-substitution in the meta position, followed by fusion with anhydrous caustic. The product is purified under conditions to yield a technical grade product, typically 99.8% pure.

Resorcinol is a crystalline, aromatic chemical that is water soluble and very conductive to derivitization. Important reactions of resorcinol are: alkylation, acylation, amination, carboxylation, condensation and aldehydes and ketones, coupling with arylamines, etherification, halogenation, nitration and sulfonation.

Resorcinol is the essential component of an adhesive system used in the manufacture of tires for passenger cars, trucks, off-the-road equipment and other fibre reinforced rubber mechanical goods. Polyester, nylon, aramid, rayon and glass tires cords are treated with an aqueous adhesive containing resorcinol, formaldehyde and synthetic rubber latex. In addition to excellent adhesion, the attributes of the water based adhesive system are its ease of preparation, latitude of composition and low level of toxicity. Resorcinol and a methylene donor are also compounded into carcass skim stocks to enhance the adhesion of rubber to RFL treated tire cords. Dry bonding agents based on Resorcinol or resorcinol-formaldehyde resins have found world-wide acceptance as the adhesive system for bonding brass plated steel tire cords in radial tires.

Adhesives formulated from resorcinol-formaldehyde resins or phenol modified resorcinol-formaldehyde resins are the criteria for wood bonding applications demanding room temperature cure, structural integrity, and water proof characteristics. These adhesives retain their strength at temperatures approaching the charring point of wood and are not affected by exposure to the cryogenic temperatures of liquefied natural gas.

Resorcinol is an important chemical intermediate in the manufacture of speciality chemicals, such as light screening agents for the protection of plastics from exposure to ultraviolet light. Other uses include the manufacture of dye-stuffs, pharmaceuticals, flame retardants, agricultural chemicals, fungicidal creams and lotions, explosive primers, antioxidants, a chain extender for urethane elastomers and a treatment to improve mechanical and chemical resistance of paper machine fabrics.

3. PHYSICOCHEMICAL PROPERTIES

See IUCLID section 2 for more detailed summaries

Table 2. Physicochemical Data

End point	Reference Number	Result
Melting Point	33 ^m	109-111°C
Boiling Point	33 ^m	280°C
	41 ^m	276.7° C
Vapor Pressure	41 ^c	0.011 mm Hg (0.1463 hPa) @ 25°C
	3 ^m	0.000203 mm Hg (0.00027 hPa) @ 25°C
Kow Partition Coefficient	41 ^c	1.03
	3 ^m	0.80
Water Solubility	41 ^c	8.571E+004 g/l @ 25°C
	32 ^m	1.11E+007 mg/l @20°C

^m Measured value

^c Calculated value

Physicochemical Summary:

The physical chemical data for Resorcinol are summarised in Table 2. These values were experimentally confirmed or obtained from the well-established and scientifically accepted reference handbook the Merck Index (O'Neil, 2001) as well as EPIWIN-calculated values (USEPA and Syracuse Research Corporation, 2000).

SUMMARY:

Adequate data (Klimish code 1 or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program (see Table 2 and IUCLID documents)

4. EVALUATION OF ENVIRONMENTAL FATE DATA

See IUCLID section 3 for detailed summaries

The data for each SIDS endpoint has either been experimentally confirmed or obtained from the well-established and scientifically accepted reference handbook the Merck Index (O'Neil,

2001) as well as EPIWIN-calculated values (USEPA and Syracuse Research Corporation, 2000).

4.1 Photodegradation

Table 3. Environmental Fate Data

Photodegradation						
	Direct Photolysis		Indirect photolysis			
Endpoint	Result	Ref	Result	Ref	Result	Ref
OH Rate Constant	-	12 ^m	2E-11 cm ³ / molecule-sec	12 ^c	2.0028E-10 cm ³ / molecule-sec	42 ^c
OH half life	100 hours		1.9 hours		0.64 hours (38.452 min)	

^m Measured value

^c Calculated value

Direct photolysis value was determined experimentally, and values for photodegradation and atmospheric oxidation were calculated based upon chemical structures using EPIWIN and are shown in Table 3.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

4.2 Hydrolysis

Resorcinol does not possess any functional groups that are regarded as being susceptible to hydrolysis under environmental conditions (Lyman, W.J., Reehl, W.F. and Rosenblatt, D.H., Handbook of Chemical Property Calculation Methods, McGraw-Hill, Inc., Washington, 1990, pages 7-4 and 7-5).

The software prediction programme HYDROWIN v1.66 predicts that resorcinol will be stable to hydrolysis. The model cannot estimate hydrolysis rate constants due to the absence of any hydrolysable groups.

4.3 Chemical Transport and Distribution in the Environment

Table 4. Transport between environmental compartments Data

Transport/Distribution	Reference	Results
Fugacity Level 1	27 ^c	Air =0.0% Water =99.88% Soil=0.06% Sediment=0.07%
Estimated Koc	27 ^c	2.94 (soil and sediment)

^c Calculated value

These results demonstrate that resorcinol partitions primarily into water largely due to its high water solubility.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

4.4 Biodegradation and Bioaccumulation

Resorcinol was tested in a ready biodegradation assay and an inherently biodegradation assay. These studies were conducted to the accepted OECD guideline standards and clearly demonstrate that Resorcinol is biodegradable. Both results can therefore be regarded as reliable with out restrictions and fulfil the HPV SIDS endpoints.

Other studies conducted in aquatic media with isolated bacteria and fungal strains or with mixed cultures of activated sludge, digested sludge and soil confirm that resorcinol is biodegradable under aerobic and anaerobic conditions

A calculated value for bioconcentration factor has also been determined as below.

Table 5. Bioaccumulation

Bioaccumulation	Reference	Results
Estimated BCF	42 ^c	3.162

^c Calculated value

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Environmental Fate Summary:

Adequate data (Klimish code 1 or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

5. ECOTOXICITY DATA

See IUCLID section 4 for detailed summaries

Acute and prolonged toxicity to fish

Many studies have been conducted, by various authors, but none to recommended guidelines. However all the studies demonstrate that Resorcinol is toxic to fish in varying degrees (see Table 6 for a summary).

Table 6. Summary of available fish toxicity data

Species	Duration	Effect	Concentration (mg/l)	Test system	Reference
Leuciscus idus (Golden Orfe)	48h	LC50	38.4	Static	23
		NOEC	25		
	96h	LC50	34.7		
		NOEC	25		
Pimephales promelas (Fat head minnow)	96h	LC50	53.4	Static	2
	96h	LC50	26.8-29.5	Flow through	15
Gambusia affinis (mosquito fish)	96h	LC50	179.56-182.47	Static	28
Brachydanio rerio (Zebra fish)	7 days	LOEC (weight)	32	Semi-static	45
		EC50 (malformations)	54.8		
		LC50 (embryo lethality)	262		
Salmo gairdneri (salmon)	60 days	LC50 (embryo lethality)	320	Semi-static	45
		EC50 (malformations)	260		

With this weight of evidence it is therefore proposed that adequate data (Klimish code 2) are available for this endpoint, so no additional testing is proposed for the USEPA HPV Challenge Program

Acute and chronic toxicity to aquatic invertebrates

A concentration-time dependency was shown by experimental results obtained under static conditions for the grass shrimp (*Palaemonetes pugio*) which lives in salt water. (Reference No. 2)

Table 7. Chronic and acute toxicity data to *Daphnia magna*

Test Duration (hours)	Result (mg/l)	Reference
24	EC50= 107.6	10
48	EC50<0.8	7
48	LC50 = 1.28	19
96	LC50 = 0.25	13
Chronic Toxicity		
48	EC50>172 µg/l NOEC=172 µg/l	31
21 days	EC50>172 µg/l NOEC=172 µg/l LOEC>172 µg/l	31

There are many tests on the acute toxicity to water fleas (*Daphnia magna*) that have been conducted by various authors but not to any standardised guidelines (reference 7,10,13,19) (see Table 7). The general conclusion is that harmful effects may be dependent on duration of exposure and the test conditions concerned. As these studies did not give a clear result a chronic toxicity to *Daphnia magna* to OECD guidelines was conducted (reference 31). This study demonstrated that concentrations up to 172 µg a.i./l of Resorcinol had no adverse effects on survival, growth or reproduction of *Daphnia magna*. LOEC was determined to be >172µg a.i./l. This study clearly demonstrates that Resorcinol is very toxic to aquatic organisms, and so must be classified R50. This study can also be used to provide data for the acute toxicity endpoint as observations were made for mortality and effects on a daily basis for 21 days. After 48 hours EC>172 µg/l and NOEC = 172 µg/l.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Toxicity to aquatic plants e.g. algae

In a cell-multiplication inhibition test performed on the green alga *Chlorella pyrenoidosa*, various chemicals were tested at one concentration each. At a concentration of 1.1 mg/l resorcinol, there was no observed cell-multiplication inhibition after 72 hours (reference no. 38).

In an experiment to determine growth inhibition EC50 values of 165.2 mg/l and 143.1 mg/l were determined for common duckweed (*Lemna minor*, exposure period 12 days) and Canadian pondweed (*Elodea canadensis*, exposure period 9 days)(reference no. 40).

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Ecotoxicity Summary:

Adequate data (Klimish 1 or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program.

6. MAMMALIAN TOXICITY

See IUCLID section 5 for detailed summaries

Many studies have been conducted, by various authors, but not all to recommended guidelines. Results of these studies have been summarised in Table 8.

Table 8. Summary of available Mammalian Toxicity Data

	Dose/result	Remarks	Reference
Acute Toxicity			
Acute Oral toxicity	LD50=202 mg/kg bw	Harmful if swallowed	21
	LD50=980 mg/kg bw		36
	LD50=301mg/kg		26
Acute Dermal toxicity	Rabbit LD50=3360 mg/kg bw (LD50 24 hour contact, intact and abraded skin)	Not classified	36
Repeated Dose			
Gavage rats 14 days	27.5-450 mg/kg bw/day NOEL 450 mg/kg./day	No toxic effects	1 and 32
Gavage mice 14 days	37.5-600 mg/kg/day NOEL 100 mg/kg/day	Fatalities in 300 and 600 mg/kg group. Dose group 100 mg/kg and below free from findings	
Gavage rats 90 days	32-520 mg/kg/day / NOEL=260 mg/kg	Not classified	1 and 32
Gavage mice 90 days	28-420 mg/kg/day / NOEL=225 mg/kg		
Inhalation-Rats 14 days	34mg/m ³ 6 hours a day Other species tested were mice and guinea pigs	No evidence of toxic effects to lungs and trachea.	14

	Dose/result	Remarks	Reference
Genetic Toxicity <i>in vitro</i> –	Bacterial mutation assay (Ames test)	Negative	1 and 32
	Mammalian cell mutation (mouse lymphoma)	Positive (without S-9 mix)	
	Cytogenetic Assay (CHO cells)	Positive (with S-9 mix)	
	Sister chromatid exchange assay (CHO cells)	Positive	35
Unscheduled DNA synthesis (rat hepatocytes)	Negative		
Genetic Toxicity – <i>in vivo</i>	Micronucleus assay	Negative	16
	SLRL Drosophila test	Negative	32
	Sperm abnormality	Negative	46
Toxicity to fertility	No data available	Study ongoing	
Developmental Toxicity/ Teratogenicity	Rat, Day 1-19 of gestation, 2ml/kg	No evidence of foetotoxic, embryotoxic or teratogenic effects following oral administration in any test	8
	Rat, Day 6-15 of gestation, 40-250 mg/kg		18
	Rat, Day 6-15 of gestation, 125-500 mg/kg		11
	Rabbit, Day 6-18 of gestation, 25-100 mg/kg		18
	Rabbit, Day 6-15 of gestation, 40-250 mg/kg		37
	Hen chick eggs, single dose, 99-804 mg/chick egg		29

6.1 Acute Toxicity

Three studies have been conducted as summarised in Table 8. Although none were conducted to the recommended guideline, all give comparable results that indicate the substance requires classification that the substance is harmful if swallowed (R22). Therefore it is considered that the data requirements have been met for this SIDS endpoint. It is therefore considered that there is sufficient data to cover this end point.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

6.2 Repeated Dose Toxicity

Toxicity studies were conducted by administering Resorcinol (>99% pure) in water by gavage to groups of F344/N rats and B6C3F1 mice for each sex for 14 days and 90 days. These studies form part of NTP Technical Report on the Toxicology and Carcinogenesis studies of Resorcinol and are therefore considered valid without restriction (reference 32). No chemical-related gross or microscopic lesions were observed in either study.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

6.3 Genetic Toxicity/Mutagenicity

Many studies have been conducted over the years (see IUCLID for full details). Genetic toxicology studies that were conducted as part of NTP Technical Report on the Toxicology and Carcinogenesis studies of Resorcinol confirmed the results of these studies (see Table 8). The general conclusions were that resorcinol is not a gene mutagen in bacteria or *Drosophila*, but was reported to induce mutation and chromosomal damage in mammalian cells *in vitro*. The *in vivo* mutagenicity test data (also conducted for NTP report), however, did not reveal signs of genotoxic effects.

Adequate data (Klimish 1 and 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

6.4 Reproductive Toxicity

No suitable data is available to address this end point. A drinking water two –generation reproductive study of resorcinol in rats is currently being conducted to U.S. EPA and OECD guidelines to fulfil this SIDS endpoint.

6.5 Developmental Toxicity

Several teratogenicity studies on rats and rabbits revealed no evidence of foetotoxic, embryotoxic or teratogenic effects following oral administration (reference 8, 11, 18, 29 and 37).

Adequate data (Klimish 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

Mammalian Toxicity Summary:

With this weight of evidence it is therefore proposed that adequate data (Klimish code 1 or 2) are available for all endpoints, except toxicity to fertility. Additional testing is proposed for the USEPA HPV Challenge Program to address this data gap.

7. “BEYOND SIDS” ENDPOINTS

In addition to the studies to demonstrate effects of resorcinol on skin (reference 36) and eye irritation (reference 6) and skin sensitisation (reference 24) and carcinogenicity studies have been conducted.

Long-term gavage studies performed on rats and mice did not reveal any signs of carcinogenicity (reference 1). Nor did dermal treatment of rabbits (twice a week for 180 weeks) (reference 39), yield a higher incidence of local or systemic tumours.

Tumour initiation and promotion trails performed on mice (reference 4 and 45), rats (reference 20 and 47) and hamsters (reference 30) seem to indicate that resorcinol has a minor promotional effect and epithelial-proliferation properties.

Table 9. Summary of non SIDS acute Mammalian Toxicity Data

	Dose/result	Remarks	Reference
Skin irritation NOT SIDS ENDPOINT	500mg Corrosive	In-vivo design	36
	500mg Irritating		16
	500mg Irritating		22
Eye irritation NOT SIDS ENDPOINT	0.1ml of a 2.5% solution for 72 hours-Irritating		36
	0.1ml for 24 hours Irritating		22
Skin sensitization NOT SIDS ENDPOINT	Sensitizing		Maximisation design

8. CONCLUSIONS

As discussed above it is concluded that there are sufficient, reliable data on resorcinol for nearly all the SIDS endpoints following a thorough review of company proprietary files, peer-reviewed literature, and/or calculations using widely accepted computer modelling programs.

Test Plan Summary: Additional testing with resorcinol is proposed and currently underway to fulfil the following endpoint:

Toxicity to reproduction (OECD 416)

9. REFERENCES

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ABBREVIATIONS

BCF	predicted bioconcentration factor
cm ³	centimetre cubed
HPV	High Production Volume
IUCLID	International Uniform Chemical Information Database
K _{oc}	organic carbon partition coefficients
LC ₅₀	lethal concentration (to 50% of dosed animals)
LD ₅₀	lethal dose (to 50% of dosed animals)
LOAEL	lowest observed adverse effect level
mg/kg	milligrams per kilogram
mg/L	milligrams per Litre
mmHg	millimetre mercury
NOAEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
QSAR	Qualitative Structure Activity Relationship
SIDS	Screening Information Data Set
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration

201-15385

I U C L I D

Data Set

RECEIVED
03.11.2003

Existing Chemical : ID: 108-46-3
CAS No. : 108-46-3
EINECS Name : resorcinol
EC No. : 203-585-2
TSCA Name : 1,3-Benzenediol
Molecular Formula : C6H6O2

Producer related part
Company : Indspec Chemical Corporation
Creation date : 03.11.2003

Substance related part
Company : Indspec Chemical Corporation
Creation date : 03.11.2003

Status :
Memo :

Printing date : 15.06.2004
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Reliability (profile) :
Flags (profile) :

1. General Information

Id 108-46-3
Date 15.06.2004

1.0.1 APPLICANT AND COMPANY INFORMATION

Type :
Name : INDSPEC Chemical Corporation
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Email :
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13.11.2003

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

IUPAC Name : Resorcinol
Smiles Code : c1(O)cc(O)ccc1
Molecular formula : C6H6O2
Molecular weight : 110.11
Petrol class :

Reliability : (1) valid without restriction
27.04.2004

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :
Substance type : organic
Physical status : solid
Purity :
Colour : White-slightly colored flake or powder
Odour : Phenolic

27.04.2004

1.1.2 SPECTRA

1. General Information

Id 108-46-3
Date 15.06.2004

1.2 SYNONYMS AND TRADENAMES

1,3-Benzenediol 1,3 Dihydroxybenzene

25.03.2004

Resorcin

27.04.2004

Resorcinol

27.04.2004

1.3 IMPURITIES

Purity : typical for marketed substance
CAS-No :
EC-No :
EINECS-Name :
Molecular formula :
Value :

Remark : The impurities present depend on the manufacturing process. Sulfonation Fusion Process has catechol and phenol as major impurities
27.04.2004

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

Labelling : as in Directive 67/548/EEC
Specific limits : yes
Symbols : Xn, N, ,
Nota : C, ,
R-Phrases : (22) Harmful if swallowed
(36/38) Irritating to eyes and skin
(50) Very toxic to aquatic organisms
S-Phrases : (61) Avoid release to the environment. Refer to special instructions/Safety data sets
Remark : Labelling per U.S. Standards (ANSI Z129.1): Danger! Corrosive To The Eyes. Harmful If Swallowed. May Cause Skin Irritation. May Cause Allergic Skin Reaction. May be Harmful If Absorbed Through The Skin. Ingestion May Injure The Blood, Gastrointestinal Tract, Spleen, Liver, Kidneys, Lungs, Nervous System, Thyroid, and Skin.
27.04.2004

1.6.2 CLASSIFICATION

Classified : as in Directive 67/548/EEC

1. General Information

Id 108-46-3
Date 15.06.2004

Class of danger : dangerous for the environment
R-Phrases : (50) Very toxic to aquatic organisms
Specific limits :

11.11.2003

Classified : as in Directive 67/548/EEC
Class of danger : harmful
R-Phrases : (22) Harmful if swallowed
Specific limits :

27.04.2004

Classified : as in Directive 67/548/EEC
Class of danger : irritating
R-Phrases : (36/38) Irritating to eyes and skin
Specific limits :

14.01.2004

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use : industrial
Category : Chemical industry: used in synthesis

11.11.2003

Type of use : industrial
Category : Polymers industry

11.11.2003

Type of use : industrial
Category : Textile processing industry

11.11.2003

Type of use : use
Category : Adhesive, binding agents

27.04.2004

Type of use : use
Category : Cosmetics

Remark : The use includes funical creams/lotions, hair dyes
27.04.2004

Type of use : use
Category : Intermediates

Remark : Intermaediates for light screening agent, flame retardants, agricultural chemicals, explosive primers dye stuffs.

1. General Information

Id 108-46-3
Date 15.06.2004

27.04.2004

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : TLV (US)
Limit value : 45 mg/m³
Short term exposure limit value
Limit value : 90 mg/m³
Time schedule : 15 minute(s)
Frequency : times

14.01.2004

(2)

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

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

Remark : Options for disposal:
Disposal methods include complete incineration, land (soil) farming and decomposition in activated sludge type wastewater treatment plants.

1. General Information

Id 108-46-3
Date 15.06.2004

02.06.2004

(125)

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

2.1 MELTING POINT

Value : 109 - 111 °C
Decomposition : no, at °C
Sublimation : yes
Method : other
Year :
GLP : no data
Test substance :

Source : The Merck Index
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
17.05.2004 (93)(125)

2.2 BOILING POINT

Value : 280 °C at
Decomposition :
Method : other: no data
Year :
GLP : no data
Test substance : other TS

Source : The Merck Index
Test substance : Resorcinol (Cas No. 108-46-3) Purity not given
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
26.05.2004 (93)

Value : 276.7 °C at 1013 hPa
Decomposition : yes
Method : other
Year :
GLP :
Test substance :

Reliability : (2) valid with restrictions
26.05.2004 (125)

2.3 DENSITY

Type : density
Value : 1.272 at °C
Method : other: no data
Year :
GLP : no data
Test substance : other TS

Source : The Merck Index
Test substance : Resorcinol (Cas no. 108-46-3) Purity not given
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
26.05.2004 (93)

Type : density

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

Value : 1.227 at °C
Method : other
Year : 1998
GLP : no data
Test substance :

Reliability : (2) valid with restrictions
27.05.2004 (125) (126)

Type : bulk density
Value : 1.292 g/cm³ at 20 °C
Method : other
Year :
GLP :
Test substance :

Reliability : (4) not assignable
27.05.2004 (75)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : .1463 hPa at 25 °C
Decomposition :
Method : other (calculated)
Year : 2004
GLP : no
Test substance : other TS

Method : MPBPWIN v1.30 vapor pressure estimations (modified grain method)
Result : 0.011 mm Hg (0.1463 hPa) @ 25°C
Test substance : Resorcinol (Cas no. 108-46-3)
Reliability : (2) valid with restrictions
26.05.2004 (128)

Value : .00027 hPa at 25 °C
Decomposition :
Method : other (measured)
Year :
GLP :
Test substance :

Reliability : (4) not assignable
26.05.2004 (37)

Result : 1.33 hPa @ 108.4°C
6.65 hPa @ 138°C
13.3 hPa @ 152.3°C
53.2 hPa @ 185.3°C
133 hPa @ 210°C
266 hPa @ 230.8°C

Reliability : (2) valid with restrictions
12.05.2004 (125)

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

2.5 PARTITION COEFFICIENT

Partition coefficient :
Log pow : = .8 at 35 °C
pH value :
Result : 0.93 log Pow @ 20°C; 0.97 log Pow @ 15 °C
Reliability : (2) valid with restrictions
12.05.2004 (5)

Partition coefficient :
Log pow : 1.03 at °C
pH value :
Method : other (calculated): EPIWIN v3.01
Year : 2004
GLP : no
Test substance : other TS
Source : EPI Summary (V3.01)
26.05.2004 (128)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water
Value : 85710 mg/l at 25 °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description : of high solubility
Stable :
Deg. product :
Method : other: EPIWIN v 3.01
Year : 2004
GLP : no
Test substance : other TS
Method : Water solubility Estimate from Log KOW (WSKOW v1.33)
Source : EPI summary (v3.01)
Test substance : Resorcinol (Cas No. 108-46-3)
Reliability : (2) valid with restrictions
26.05.2004 (128)

Solubility in : Water
Value : at °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :
Remark : Equivalent to 1.11E +7 mg/l at 20°C
Result : One gram dissolves in 0.9ml water, 0.2ml dissolves in 0.9 ml water, 0.2 ml water at 80°C
Reliability : (2) valid with restrictions
26.05.2004 (93)

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

Solubility in	:	Water	
Value	:	= 58.4 vol% at 20 °C	
pH value	:	= 4.5	
concentration	:	10 vol% at 23 °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	9.15 at 25 °C	
Description	:	soluble (1000-10000 mg/L)	
Stable	:		
Deg. product	:		
Method	:	other	
Year	:		
GLP	:		
Test substance	:		
Result	:	2290 g/l @ 30 °C; 5000 g/l @ 80°C	
Reliability	:	(1) valid without restriction	
25.03.2004			(82)(87)
Solubility in	:	Water	
Value	:	= 1400 g/l at 20 °C	
pH value	:	= 4.4	
concentration	:	55 g/l at 20 °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	at 25 °C	
Description	:		
Stable	:		
Reliability	:	(2) valid with restrictions	
17.05.2004			(56)
Solubility in	:	Water	
Value	:	= 1290 g/l at 30 °C	
pH value	:		
concentration	:	at °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	at 25 °C	
Description	:		
Stable	:		
Remark	:	pKa = 11.32 @ 30°C	
Reliability	:	(2) valid with restrictions	
12.05.2004			(86)
Solubility in	:	Organic Solvents	
Value	:	at °C	
pH value	:		
concentration	:	at °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	at 25 °C	
Description	:		
Stable	:		
Remark	:	Solubility in acetone = 67 wt % @ 20°C and 75 wt % @ 60°C Solubility in ethanol = 61% wt % @ 20°C and 73% wt % @ 60°C Solubility in benzene = 2% wt % @ 20°C and 14% wt % @ 60°C	
Reliability	:	(2) valid with restrictions	
26.05.2004			(125)

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

Solubility in : Water
Value : 58 at 20 °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :

Result : 53 wt% @ 20°C
83 wt% @ 60°C
Reliability : (2) valid with restrictions
26.05.2004 (125)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Value : = 127 °C
Type : closed cup
Method : other
Year :
GLP :
Test substance :

Method : ASTM D-93-97; closed cup
Reliability : (2) valid with restrictions
12.05.2004 (125)

2.8 AUTO FLAMMABILITY

Value : = 608 °C at

Remark : This is auto ignition temperature
Reliability : (2) valid with restrictions
17.05.2004 (45)(125)

2.9 FLAMMABILITY

Result : other
Method : other
Year :
GLP :
Test substance :

Remark : Flammable limit 1.4% by volume in air @ 200°C
12.05.2004 (91)

2.10 EXPLOSIVE PROPERTIES

Result : other
Method : other

2. Physico-Chemical Data

Id 108-46-3
Date 15.06.2004

Year : 1997
GLP : no data
Test substance : no data

Method : BS 5958: Part 1: 1991 Control of Undesirable Static Electricity VDI
Fortschritt-Berichte Reihe 3: Verfahrenstechnik Nr 134
ISO Explosion Protection Systems Part 1: Determination of Explosion
Indices of Combustible Dusts in Air; ISO 6184/1 ISO Geneva (1985)

Remark : Minimum ignition temperature measured for resorcinol dust was reported at
3 mJ at dust concentration of 8 kg/m³. The deflagration index reported for
resorcinol dust was 134 which is a dust classification of St-1.

Reliability : (2) valid with restrictions
26.05.2004 (101)

2.11 OXIDIZING PROPERTIES

Result : other:N/A
25.03.2004

2.12 DISSOCIATION CONSTANT

Acid-base constant : N/A
25.03.2004

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

Remark : Henry's Law constant:
8.1 x 10E-11 atm-cu m/mole @ 25°C
2.1 x 10E-6 Pa-cu m/mole @ 20°C

Koc:
estimated at 2 to 65
measured at 10.36 with water solubility of 1230 g/l and log Kow of 0.80.

13.11.2003 (78)

3. Environmental Fate and Pathways

Id 108-46-3
Date 15.06.2004

3.1.1 PHOTODEGRADATION

DIRECT PHOTOLYSIS

Halfife t1/2 : 38.5 minute(s)
Degradation : % after
Quantum yield :

INDIRECT PHOTOLYSIS

Sensitizer :
Conc. of sensitizer :
Rate constant : .0000000020028 cm³/(molecule*sec)
Degradation : 50 % after 0 day(s)
Deg. product :
Method : other (calculated)
Year : 2004
GLP : no
Test substance : other TS

Method : EPIWIN v3.01 using AopWin v1.88
Source : EPI summary (V3.01)
Test substance : Resorcinol (Cas No. 108-46-3) No purity given
Reliability : (2) valid with restrictions
28.05.2004

(128)

Type : air
Light source : Sun light
Light spectrum : nm
Relative intensity : based on intensity of sunlight
Spectrum of substance : lambda (max, >295nm) : 274 nm
epsilon (max) : 2000
epsilon (295) :

DIRECT PHOTOLYSIS

Halfife t1/2 : = 100 hour(s)
Degradation : % after
Quantum yield : .03

INDIRECT PHOTOLYSIS

Sensitizer : OH
Conc. of sensitizer : 500000 molecule/cm³
Rate constant : = .00000000002 cm³/(molecule*sec)
Degradation : = 50 % after 1.9 hour(s)
Deg. product :
Method : other (calculated)
Year : 1981
GLP : no data
Test substance :

Remark : Concentration of substance: 10E-17 mole/l for OH radical
10 E-9 mole/l for phenol
half life: OH radical 100 hours for phenol
Peroxy radical 19.2 hours for phenol

Reliability : (2) valid with restrictions
17.05.2004

(31)

Type : water
Light source :
Light spectrum : nm
Relative intensity : based on intensity of sunlight
Deg. product :
Method :
Year : 1985

3. Environmental Fate and Pathways

Id 108-46-3
Date 15.06.2004

GLP : no data
Test substance :
Remark : By analogy with other Phenol compounds, resorcinol should degrade in water bodies by means of photochemically induced OH free radicals (concentration $10E-17$ mol/l) and peroxy free radicals (concentration; $10E-9$ mol/l).
For example; Half-life time for phenol approx 100 H (sensitizer OH)
Half-life time for hydroquinone: 20 h (sensitizer OH)
Reliability : (4) not assignable
02.06.2004 (89)

Remark : For undissociated resorcinol, a lambda max. of 274 nm and an epsilon max. of $2000 \text{ molE-1} \times 1 \times \text{cmE-1}$, as well as a quantum yield of approx 0.03 at 253.3 nm were determined.
Reliability : (4) not assignable
02.06.2004 (95)

3.1.2 STABILITY IN WATER

Type :
t1/2 pH4 : = at °C
t1/2 pH7 : at °C
t1/2 pH9 : at °C
Deg. product :
Method : other
Year :
GLP : no data
Test substance : no data
Remark : Resorcinol does not possess any functional groups that are regarded as being susceptible to hydrolysis, the soft ware prediction programme HYDROWIM v1.66 cannot estimate hydrolysis rate constants for phenols.
Reliability : (2) valid with restrictions
27.05.2004 (129)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

Type of measurement : background concentration
Media : food
Concentration :
Method :
Remark : Resorcinol was detected in roasted barley, in syrup and in coffee.
Result : Type of measurement: at contaminated site
media: air
result 8 µg per cigarette
remark: resorcinol was quantitatively determined in cigarette smoke
type of measurement: at contaminated site
media: waste water
result: 1 g/l
remark: at USA Coal Liquefaction Plant
type of measurement: at contaminated site
media: waste water

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Date 15.06.2004

26.05.2004	result: 7-22 mg/l in ammonical liquid of coking process 150 mg/l in ammonical liquid of coking process <0.1 mg/l in condensate from coking process remark: USA coking operation.	(20)(21)(44)(113)(115)(133)
Type of measurement	: concentration at contaminated site	
Media	: other: waste water	
Concentration	:	
Method	:	
Remark	: An Indian author reports that resorcinol is a major waste water constituent in the manufacture of chemicals, fertilizers and dyes. No further information supplied.	
21.01.2004		(63)
Type of measurement	: concentration at contaminated site	
Media	: other:waste water	
Concentration	:	
Method	:	
Remark	: In the U.S.A., resorcinol was detected in concentrations of 7-22 mg/l in the ammonical liquid of two typical coking ovens. In a low-temperature coking oven, the resorcinol content of this liquid was 150 mg/l. In contrast, no resorcinol was detected in the condensate of one oven's waste gas or the waste water from a plant by a method with a limit of detection of 0.1 mg/l. (The original samples were each extracted with methyl isobutyl ketone, derivatized with trimethylsilyl ether and analysed by means of GC-FID.	
21.01.2004		(21)
Type of measurement	: concentration at contaminated site	
Media	: other: waste water	
Concentration	:	
Method	:	
Remark	: In the waste water from a coal liquefaction plant in the U.S.A., mg/l levels of resorcinol were determined by means of UV analysis	
14.01.2004		(66)

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	: fugacity model level I
Media	: other: air/water/soil/sediment
Air	: 0 % (Fugacity Model Level I)
Water	: 99.88 % (Fugacity Model Level I)
Soil	: .06 % (Fugacity Model Level I)
Biota	: % (Fugacity Model Level II/III)
Soil	: % (Fugacity Model Level II/III)
Method	: other
Year	: 2002
Method	: Donald Mackay's Multimedia Environmental Models, The Fugacity Approach (1991)
Remark	: Based on KOC of 2.94 Sediment: 0.07% (fugacity model level I)
Reliability	: (2) valid with restrictions

3. Environmental Fate and Pathways

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Date 15.06.2004

07.06.2004 (61)

3.3.2 DISTRIBUTION

Media : air - biota - sediment(s) - soil - water
Method : Calculation according Mackay, Level I
Year : 2002

Reliability : (2) valid with restrictions
19.05.2004 (62)

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type : aerobic
Inoculum : activated sludge, non-adapted
Concentration : 100 mg/l related to Test substance
related to
Contact time :
Degradation : = 66.7 (±) % after 14 day(s)
Result : readily biodegradable
Deg. product :
Method : OECD Guide-line 301 C "Ready Biodegradability: Modified MITI Test (I)"
Year : 1992
GLP : yes
Test substance :

Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
26.05.2004 (90)

Type : aerobic
Inoculum : activated sludge, adapted
Concentration : related to COD (Chemical Oxygen Demand)
related to
Contact time :
Degradation : 97 (±) % after 4 day(s)
Result : inherently biodegradable
Deg. product :
Method : OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens
Test"
Year :
GLP : no
Test substance :

Reliability : (2) valid with restrictions
26.05.2004 (135)

Type : aerobic
Inoculum : Penicillium sp. (Fungi)
Concentration : 2030 mg/l related to Test substance
related to
Contact time :
Degradation : 95.3 (±) % after 3 day(s)
Result :
Deg. product :

3. Environmental Fate and Pathways

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Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:		
Remark	:	measured degradation in aqueous medium at pH 7 and 8 as a function of N source (ammonium sulphate) using shaking culture test.	
Reliability 02.06.2004	:	(4) not assignable	(63)
Type	:	aerobic	
Inoculum	:	Penicillium sp. (Fungi)	
Concentration	:	2310 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	100 (±) % after 5 day(s)	
Result	:		
Deg. product	:		
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:		
Remark	:	measured degradation in aqueous medium at pH 7 and 8 using shaking culture/static culture.	
Reliability 02.06.2004	:	(4) not assignable	(63)
Type	:	aerobic	
Inoculum	:	other bacteria: activated sludge, phenol acclimated, mixed inoculum, including garden soil, compost	
Contact time	:		
Degradation	:	95 - 98 (±) % after 2 day(s)	
Result	:	inherently biodegradable	
Deg. product	:		
Method	:	other: Determination of degradation from oxygen consumption	
Year	:	1964	
GLP	:	no data	
Test substance	:		
Reliability 26.05.2004	:	(4) not assignable	(124)
Type	:	aerobic	
Inoculum	:	other bacteria: activated sludge, perhaps acclimated	
Concentration	:	138 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	100 (±) % after 2 day(s)	
Result	:		
Deg. product	:		
Method	:	other: Modified German detergent tests	
Year	:		
GLP	:		
Test substance	:		
Remark	:	Degradation related to DOC	
Reliability 26.05.2004	:	(4) not assignable	(42)
Type	:	aerobic	
Inoculum	:	other: soil microflora from silt loam soil	

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Concentration	:	25 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	100 (±) % after 8 day(s)	
Result	:		
Deg. product	:		
Method	:	other: Test in closed bottles	
Year	:		
GLP	:	no	
Test substance	:	no data	
Remark	:	Test in closed bottles. Spectrophotometric determination at 275 nm	
Test condition	:	Medium: aqueous mineral salts	
Reliability	:	(4) not assignable	(4)
26.05.2004			
Type	:	aerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	related to COD (Chemical Oxygen Demand) related to	
Contact time	:		
Degradation	:	90 (±) % after 15 day(s)	
Result	:		
Kinetic of testsubst.	:	3 day(s) < 10 % 4 day(s) = 43 % 10 day(s) = 89 % % %	
Deg. product	:		
Method	:	other: Zahn-Wellens Test in accordance with DIN 38412, Part 25	
Year	:	1982	
GLP	:	no	
Test substance	:		
Reliability	:	(4) not assignable	(55)
26.05.2004			
Type	:	aerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	related to COD (Chemical Oxygen Demand) related to	
Contact time	:		
Degradation	:	> 95 (±) % after 10 day(s)	
Result	:		
Kinetic of testsubst.	:	5 = 87 % % % % %	
Deg. product	:		
Method	:	other: Zahn-Wellens Test in accordance with DIN 38412, Part 25	
Year	:	1980	
GLP	:	no	
Test substance	:		
Reliability	:	(4) not assignable	(55)
26.05.2004			
Type	:	aerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	related to COD (Chemical Oxygen Demand) related to	

3. Environmental Fate and Pathways

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Contact time	:		
Degradation	:	> 95 (±) % after 7 day(s)	
Result	:		
Kinetic of testsubst.	:	3 hour(s) = 2 % 1 day(s) = 28 % 3 day(s) = 75 % % %	
Deg. product	:		
Method	:	other: Zahn-Wellens Test in accordance with DIN 38412, part 25 1975	
Year	:	1975	
GLP	:	no	
Test substance	:		
Reliability 26.05.2004	:	(4) not assignable	(55)
Type	:	aerobic	
Inoculum	:	other bacteria: activated sludge, perhaps acclimated	
Concentration	:	500 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	60 (±) % after 5 day(s)	
Result	:		
Deg. product	:		
Method	:	other: modified German detergents test	
Year	:		
GLP	:	no	
Test substance	:		
Remark	:	Degradation related to DOC	
Reliability 26.05.2004	:	(4) not assignable	(42)
Type	:	aerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	200 mg/l related to COD (Chemical Oxygen Demand) related to	
Contact time	:		
Degradation	:	90 (±) % after 5 day(s)	
Result	:	inherently biodegradable	
Reliability 26.05.2004	:	(4) not assignable	(96)
Type	:	anaerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	500 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	83 (±) % after 245 day(s)	
Result	:		
Deg. product	:		
Method	:	other: Bottle Test, determination of gas production (CO ₂ and methane)	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	sludge from waste water treatment plant	
Reliability 26.05.2004	:	(4) not assignable	(7)

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Type	:	anaerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	1000 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	4 (±)% after 245 day(s)	
Result	:		
Deg. product	:		
Method	:	other: Bottle test, determination of gas production (CO2 and methane)	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Reliability	:	(4) not assignable	(7)
26.05.2004			
Type	:	anaerobic	
Inoculum	:	activated sludge, adapted	
Concentration	:	500 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	30 (±) % after 196 day(s)	
Result	:		
Deg. product	:		
Method	:	other: Bottle test, determination of gas production (CO2 and methane)	
Year	:		
GLP	:		
Test substance	:		
Reliability	:	(4) not assignable	(7)
26.05.2004			
Type	:	anaerobic	
Inoculum	:	other: anaerobic sludge, acclimated	
Concentration	:	2000 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	0 (±) % after day(s)	
Result	:	under test conditions no biodegradation observed	
Deg. product	:		
Method	:	other: Bottle test, determination of gas production (CO2 and methane)	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	No degradation after 245 days	
Reliability	:	(4) not assignable	(7)
26.05.2004			
Type	:	anaerobic	
Inoculum	:	other bacteria: anaerobic sludge, municipal, acclimated	
Concentration	:	90 mg/l related to Test substance related to	
Contact time	:		
Degradation	:	95 (±) % after 10 day(s)	
Result	:		
Deg. product	:		
Method	:	other: submerged anaerobic upflow filter	
Year	:		
GLP	:	no data	
Test substance	:	no data	

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Remark : 95% of test substance degraded in hydraulic retention times of 2-10 days.
Test condition : Acclimation period: 110 hours
Reliability : (4) not assignable
26.05.2004 (19)

Type : anaerobic
Inoculum : other bacteria: Strain Re 10 (sulfate reducers)
Concentration : 220 mg/l related to Test substance
related to
Contact time :
Degradation : 100 (±) % after 4 day(s)
Result :
Deg. product :
Method : other:Turbidity test (measurement of absorbance at 500 nm)
Year :
GLP : no data
Test substance : no data

Remark : Turbidity test (measurement of absorbance at 500 nm).
Reliability : (4) not assignable
26.05.2004 (107)

Type : anaerobic
Inoculum : domestic sewage
Concentration : 10 related to Test substance
related to
Contact time :
Degradation : 0 (±) % after 56 day(s)
Result :
Deg. product :
Method :
Year :
GLP : no data
Test substance : no data

Remark : Waste water treatment plant in Jackson MI. Degree of degradation
expressed in terms of methane production
Reliability : (4) not assignable
26.05.2004 (58)

Type : anaerobic
Inoculum : domestic sewage
Concentration : 10 related to Test substance
related to
Contact time :
Degradation : 98 (±) % after 21 day(s)
Result :
Deg. product :
Method :
Year :
GLP : no data
Test substance : no data

Remark : Waste water treatment plant in Adrian MI. Degree of biodegradation
expressed in terms of theoretical methane production
Reliability : (4) not assignable
26.05.2004 (58)

3.6 BOD5, COD OR BOD5/COD RATIO

3. Environmental Fate and Pathways

Id 108-46-3
Date 15.06.2004

BOD5
Method : other
Year :
Concentration : 66.7 mg/l related to Test substance
BOD5 : = 100 mg/l
GLP :
RATIO BOD5 / COD
BOD5/COD : ca. 1.74

Method : Equivalent to directive 84/449/EEC, C.8 "biodegradation: biochemical oxygen demand"
Reliability : (2) valid with restrictions
27.05.2004 (97)

3.7 BIOACCUMULATION

Elimination :
Method : other:calculated
Year : 2004
GLP : no
Test substance : other TS

Method : EPIWIN v3.01 using BCFWIN v2.12
Result : Log BCF = 0.500 (BCF = 3.162)
Reliability : (2) valid with restrictions
28.05.2004 (128)

3.8 ADDITIONAL REMARKS

Remark : degradation routes:
Through the agency of procaryotes and eucaryotes, resorcinol in aqueous medium can be metabolized via hydroxyhydroquinone (1,2,4-trihydroxybenzene) and maleyl acetate to beta-ketodipate and via hydroxyhydroquione and acetyl pyruvate to formic, acetic and pyruvic acids. In the presence of ozone, it can be degraded via pyrogallol (1,2,3-trihydroxybenzene) and 3-hydroxybenzoquione to glyoxalic acid, glyoxal, oxalic acid, CO₂ and H₂O

Reliability : (1) valid without restriction
26.05.2004 (16) (39) (76)

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : = 25
LC50 : = 38.4
Limit test : no
Analytical monitoring : no data
Method : other: investigation not conducted to any guideline
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Remark : LC50 (48hr): 95% confidence range: 34.7 - 46.8 mg/l
Reliability : (2) valid with restrictions
 26.05.2004

(53)

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : = 25
LC50 : = 34.7
Limit test : no
Analytical monitoring : no data
Method : other: Investigation not conducted to any guideline
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Remark : LC50 (96 hr): 95% Confidence limits: 31.6 - 38.1
Reliability : (2) valid with restrictions
 26.05.2004

(53)

Type : flow through
Species : Pimephales promelas (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : 26.8 - 29.5
Method : other:EPA-600/4-78-012 Methods for measuring the acute toxicity of Effluents to aquatic organisms (1978)
Year : 1981
GLP : no
Test substance :

Reliability : (2) valid with restrictions
 26.05.2004

(35)

Type : static
Species : Gambusia affinis (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : 188.86 - 196.48
LC50 48 hours : 185.7 - 188.3
LC50 72 hours : 183.08 - 184.92
LC50 96 hours : 179.56 - 182.47
Limit test : no

4. Ecotoxicity

Id 108-46-3

Date 15.06.2004

Analytical monitoring	:	no data	
Method	:	other:	
Year	:	2000	
GLP	:	no data	
Test substance	:	no data	
Method	:	Ten fishes were exposed to the test substance at concentrations from 180-190 mg/l. Test medium was renewed after every 24h. The dose mortality rate obtained was plotted and the LC50 values calculated. Also measured was the oxygen consumption rate which was expressed as mg of oxygen consumed/h/g of body weight.	
Conclusion	:	The 24, 48, 72 and 96 hour LC50 values were 190, 187, 184 and 181 mg/l respectively. The oxygen consumption of fish decreased significantly when exposed to the test substance.	
Reliability 26.05.2004	:	(2) valid with restrictions	(67)
Type	:	static	
Species	:	Pimephales promelas (Fish, fresh water)	
Exposure period	:	96 hour(s)	
Unit	:	mg/l	
LC50	:	= 88.6	
LC50 (48 h)	:	= 72.6	
LC50 (96 h)	:	= 53.4	
Limit test	:	no	
Analytical monitoring	:	no	
Method	:	other: Acute Toxicity with Fish, macroinvertebrates and amphipians EPA-600/3-75-009 (1975)	
Year	:	1978	
GLP	:	no	
Test substance	:	no data	
Remark	:	Nominal concentration; oxygen saturation >= 40%	
Reliability 26.05.2004	:	(2) valid with restrictions	(3)
Type	:	static	
Species	:	Pimephales promelas (Fish, fresh water)	
Exposure period	:	48 hour(s)	
Unit	:	mg/l	
NOEC	:	= 72.6	
Limit test	:		
Analytical monitoring	:	no	
Method	:	other: Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians, EPA-600/3-75-009, 1975	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	nominal concentration	
Test condition 26.05.2004	:	Saturation >=40%	(24)
Reliability 19.05.2004	:	(2) valid with restrictions	

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : static

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

Species : Daphnia magna (Crustacea)
Exposure period : 24 hour(s)
Unit : mg/l
EC50 : 107.6
Analytical monitoring : no data
Method : other
Year : 1987
GLP : no data
Test substance : no data

Method : AFNOR (1974): Determination of the mobility of Daphnia magna (90-301,12)
Result : 95% confidence range: 104.7 -109.9 mg/l
Test condition : Oxygen saturation>=40%: age of creatures at start of study<72 hour
Reliability : (2) valid with restrictions
02.06.2004 (27)

Type : flow through
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : µg/l
NOEC : 172 measured/nominal
EC50 : > 172 measured/nominal
Limit Test : no
Analytical monitoring : yes
Method : other: EPA OPPTS 850.1300
Year : 2003
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Reliability : (2) valid with restrictions
The information contained in this robust summary is obtained from a full life cycle toxicity test with water fleas (summarised in full in Section 4.5.2). Although this is not an acute toxicity study design test, observations were made of mortality and effects on a daily basis including a measurement at 48 hours. From this a NOEC of 172 µg/l and an EC50 of >172 µg/l can be obtained at 48 hours. This information is therefore considered to be useful for addressing the acute toxicity endpoint.

Therefore although the study itself is valid without restrictions, when it is used to support the acute toxicity to aquatic invertebrates endpoint it is considered to be reliable, but with restrictions.

01.06.2004 (77)

Type : static
Species : Daphnia magna (Crustacea)
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : .25
Analytical monitoring : no
Method : other: multi -species method, not conducted to guidelines
Year : 1985
GLP : no
Test substance : no data

Reliability : (2) valid with restrictions
02.06.2004 (32)

Type : static
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

EC50	:	<= .8	
Analytical monitoring	:	no data	
Method	:	other: not performed to any guidelines	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	EC50 pronounced harmful effect on 50% or more of Daphnia	
Test condition	:	At the end of the study, the creatures were treated with electro-acoustic waves and the number of harmed creatures that lay immobile on the bottom were determined. Beta-mesosaprobic and mesotrophic river water was used for dilution.	
Reliability 26.05.2004	:	(4) not assignable	(13)
Type	:	static	
Species	:	Daphnia magna (Crustacea)	
Exposure period	:	48 hour(s)	
Unit	:	mg/l	
EC50	:	1.28	
Analytical monitoring	:	no data	
Method	:	other: study not conducted to any guideline	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	95% Confidence range 0.50-1.62 mg/l	
Reliability 20.05.2004	:	(4) not assignable	(47)
Type	:		
Species	:	Palaemonetes pugio (Crustacea)	
Exposure period	:	96 hour(s)	
Unit	:	mg/l	
LC50 (24h)	:	= 169.5	
LC50 (48 h)	:	= 78	
LC50 (96h)	:	= 42.2	
Analytical monitoring	:	yes	
Method	:	other: Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians, EPA-660/3-75-009, 1975	
Year	:	1978	
GLP	:	no	
Test substance	:		
Remark	:	Artificial brackish water (pH: 8.3 - 8.7; salinity: 25+/- g/l) was used for dilution. LC50 24 h confidence intervals: 136.7-230.7 mg/l LC50 48 h 95% confidence intervals: 61-106.5 mg/l LC50 96 h 95% confidence intervals: 30.9-60.6 mg/l.	
Reliability 26.05.2004	:	(2) valid with restrictions	(3)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Chlorella pyrenoidosa (Algae)
Endpoint	:	growth rate
Exposure period	:	72 hour(s)
Unit	:	mg/l
EC0	:	1.1
Limit test	:	

4. Ecotoxicity

Id 108-46-3

Date 15.06.2004

Analytical monitoring Method	: no	
	: other: Determination of Cell Division Rate; investigation not performed to guideline "Cellmultiplication-inhibition Test"	
Year	: 1987	
GLP	: no data	
Test substance	: no data	
Remark	: Static test only one concentration tested. Toxicity of test substance measured along side that of copper complexes to demonstrate effects of copper on growth rate.	
Reliability 19.05.2004	: (2) valid with restrictions	(118)
Species	: Chlamydomonas reinhardtii (Algae)	
Endpoint	: other: Inhibition of spontaneous movement	
Exposure period	: 15 hour(s)	
Unit	: mg/l	
EC100	: = 2753	
Method	: other: Determination of the lowest concentration that cause inhibition of spontaneous movement after 15 minutes	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: Dunaliella salina (Algae)	
Endpoint	: other: Inhibition of spontaneous movement	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: = 5506	
Method	: other: Determination of the lowest concentration that causes inhibition of spontaneous movement after 15 minutes for the single cell algae	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: Euglena gracilis (Algae)	
Endpoint	: other: Inhibition of spontaneous movement	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: = 4404	
Method	: other: Determination of the lowest concentration that causes inhibition of spontaneous movement after 15 minutes for the single cell algae.	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: Cyclotella cryptica (Algae)	
Endpoint	:	
Exposure period	: 3 hour(s)	
Unit	: mg/l	
EC0	: = 11	
EC30	: = 1101	

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Date 15.06.2004

Method	: other: Measurement of chlorophyll fluorescence; investigation not performed to any guidelines.	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: Static condition.	
Result	: The intensity of chlorophyll fluorescence was reduced to 70% after 3 hours exposure to 10-2M of the test substance. The reduction in fluorescence was only to 95% after treatment with 10-4M.	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: other aquatic plant: Elodea canadensis (Canadian pondweed)	
Endpoint	: growth rate	
Exposure period	: 9 day(s)	
Unit	: mg/l	
EC50	: = 143.1	
Method	: other: Determination of growth inhibition	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: other aquatic plant: Lemna minor (little common duckweed)	
Endpoint	: growth rate	
Exposure period	: 12 day(s)	
Unit	: mg/l	
EC50	: = 165.2	
Method	: other: Determination of growth inhibition	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: other aquatic plant: Vallisneria spiralis	
Endpoint	: other: Plasma flow	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: 5506	
Method	: other: Observation plasma flow in leaves	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(123)
Species	: other aquatic plant: Vallisneria spiralis	
Endpoint	: other: plasma flow	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: = 55055	
Method	: other: Observation of plasma flow in roots	
Year	:	
GLP	: no data	
Test substance	: no data	

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

Reliability 26.05.2004	: (4) not assignable	(123)
Species	: Chlorella vulgaris (Algae)	
Endpoint	: biomass	
Exposure period	: 6 hour(s)	
Unit	: mg/l	
EC50	: 835	
Method	: other: growth inhibition test	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: Absorbance measurement at 680nm; temperature: 36.5°C Absorbance measurement at 750nm; temperature: 36.5°C Concentration was determined which caused 50% inhibition of autotrophic growth of synchronous Clorella vulgaris suspensions.	
Reliability 26.05.2004	: (4) not assignable	(72)
Species	: Dunaliella salina (Algae)	
Endpoint	: other: Inhibition of spontaneous movement	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: = 4404	
Method	: other: Determination of the lowest concentration that causes inhibition of spontaneous movement after 15 minutes for the single cell algae	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(122)
Species	: Dunaliella salina (Algae)	
Endpoint	: other: inhibition of spontaneous movement	
Exposure period	: 3 hour(s)	
Unit	: mg/l	
EC100	: 1652	
Method	: other: Determination of the lowest concentration that causes inhibition of spontaneous movement after 15 minutes for the single cell algae	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 26.05.2004	: (4) not assignable	(122)
Species	: Nitella sp. (Algae)	
Endpoint	: other: Inhibition of Plasma flow	
Exposure period	: 15 minute(s)	
Unit	: mg/l	
EC100	: = 5506	
EC100 (3 h)	: = 2202	
Method	: other: Determination of the lowest concentration that causes inhibition of plasma flow after 15 minutes	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: Test condition: 10-15°C	
Reliability	: (4) not assignable	

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Date 15.06.2004

26.05.2004 (122)

Species : other aquatic plant: Elodea canadensis (Canadian pondweed)
Endpoint : other: Chloroplast movement
Exposure period : 15 minute(s)
Unit : mg/l
EC100 : = 1101
Method : other: Observation of chloroplast movement
Year :
GLP : no data
Test substance : no data

Reliability : (4) not assignable

26.05.2004 (122)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type :
Species : Aspergillus sp. (Fungi)
Exposure period : 6 day(s)
Unit : mg/l
EC100 : 2000
Method : other: Growth inhibition test
Year :
GLP : no data
Test substance : no data

Remark : Acetone used as solubilizer; concentrations of 500, 700, 1000 and 2000 mg/l caused 45, 60, 95 and 100% inhibition of mycelium growth.

Reliability : (4) not assignable

26.05.2004 (30)

Type :
Species : other fungi: Aspergillus fumigatus
Exposure period : 5 hour(s)
Unit : mg/l
Method : other: Growth inhibition test
Year :
GLP : no data
Test substance : no data

Remark : Exposure of spores (duration of exposure 4.5h = 50% germination of control) to 1 g resorcinol/1 liquified agar had no significant effect on the spore germination rate. However, at a concentration of ≥ 500 mg/l, shortening of the germ tubes was observed.

Reliability : (4) not assignable

26.05.2004 (64)

Type :
Species : other fungi: Penicillium chrysogenum
Exposure period : 5 day(s)
Unit : mg/l
Method : other: Growth inhibition test
Year :
GLP :
Test substance :

Reliability : (4) not assignable

20.05.2004 (48)

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

Type	:		
Species	:	Saccharomyces cerevisiae (Fungi)	
Exposure period	:	48 hour(s)	
Unit	:	mg/l	
Ec100	:	> 6400	
Method	:	other: Growth inhibition test	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Reliability	:	(4) not assignable	(48)
20.05.2004			
Type	:	aquatic	
Species	:	Escherichia coli (Bacteria)	
Exposure period	:	48 hour(s)	
Unit	:	mg/l	
EC80	:	<= 40000	
Method	:	other: Growth inhibition test (test parameter: colony formation)	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	The lowest concentration that caused 70% growth inhibition.	
Reliability	:	(4) not assignable	(34)
20.05.2004			
Type	:	aquatic	
Species	:	Escherichia coli (Bacteria)	
Exposure period	:	16 hour(s)	
Unit	:	mg/l	
EC70 (48h)	:	<= 40000	
Method	:	other: Inhibition of glucose degradation: investigation not performed to any guideline.	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	SG = harmfulness threshold The effect of toxins on the metabolic process manifests itself in a slower drop in pH in the damaged cultures than in the control cultures. Temperature @ 25°C; initial pH: 7.5-7.8; dilution water: Water from the receiving stream filtered until no longer turbid.	
Reliability	:	(4) not assignable	(14)
20.05.2004			
Type	:	aquatic	
Species	:	Pseudomonas fluorescens (Bacteria)	
Exposure period	:	16 hour(s)	
Unit	:	mg/l	
EC70 (48h)	:	<= 40000	
Method	:	other: Inhibition of glucose degradation; investigation not performed to any guideline	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	SG: harmfulness threshold The effect of toxins on the metabolic process manifests itself in a slower drop in pH in the damaged cultures than in the control culture. Test condition: temperature @ 25°C; initial pH @ 7.5-7.8; Dilution water: water from the receiving stream filtered until no longer turbid.	

4. Ecotoxicity

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Reliability 20.05.2004	:	(4) not assignable	(14)
Type	:	aquatic	
Species	:	other fungi: Chaetomium cupreum	
Exposure period	:		
Unit	:		
Method	:	other: Growth inhibition test	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	The soil fungus grows in aqueous medium containing resorcinol as the sole source of carbon.	
Reliability 20.05.2004	:	(4) not assignable	(8)
Type	:	aquatic	
Species	:	other fungi: Drechslera oryzae	
Exposure period	:		
Unit	:	mg/l	
Method	:	other: Growth inhibition test	
Year	:		
GLP	:		
Test substance	:		
Remark	:	The parasitic fungus grows in aqueous medium containing resorcinol as the sole source of carbon; growth inhibition occurs from ≥ 2202 mg/l.	
Reliability 20.05.2004	:	(4) not assignable	(8)
Type	:	aquatic	
Species	:	other fungi: Fusarium oxysporum	
Exposure period	:		
Unit	:		
Method	:	other: Growth inhibition test (test parameter: colony formation)	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	The parasitic fungus grows in aqueous medium containing resorcinol as the sole source of carbon; growth inhibition occurs from ≥ 2202 mg/l	
Reliability 20.05.2004	:	(4) not assignable	(8)
Type	:	other: Agar plate	
Species	:	Fusarium sp. (Fungi)	
Exposure period	:	14 hour(s)	
Unit	:		
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:	no data	
Remark	:	Exposure of spores (duration of exposure 13.5 h = 50% germination of the control) to 1 g resorcinol/1 liquified agar had no significant effect on the spore germination rate.	
Reliability 20.05.2004	:	(4) not assignable	(64)
Type	:	other: Agar plate	
Species	:	other bacteria: Xanthomonas campestris pv. betlicola	

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Exposure period	: 48 hour(s)	
Unit	: mg/l	
Method	: other: Spot test	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: 50-250 mg/l; 3 plates/concentration; concentration-dependent growth inhibition (inhibition zone: max 35 mm); plant-pathogenic bacterium; in vivo: monthly spraying with 250 and 500 ppm for 7 months effected 68.35 and 72.15% disease control.	
Reliability 20.05.2004	: (4) not assignable	(127)
Type	: other: Colony diameter on agar plate	
Species	: other fungi: Fusarium oxysporum (soil fungus)	
Exposure period	: 6 day(s)	
Unit	: mg/l	
EC50	: ca. 1101	
Method	: other: Growth inhibition test	
Year	:	
GLP	:	
Test substance	:	
Remark	: Test condition @ 25°C	
Reliability 20.05.2004	: (4) not assignable	(116)
Type	:	
Species	: Candida utilis (Fungi)	
Exposure period	: 48 hour(s)	
Unit	:	
EC100	: > 6400	
Method	: other: Growth inhibition test	
Year	:	
GLP	: no data	
Test substance	: no data	
Reliability 20.05.2004	: (4) not assignable	(48)

4.5.1 CHRONIC TOXICITY TO FISH

Species	: Brachydanio rerio (Fish, fresh water)	
Endpoint	: other:malformations	
Exposure period	: 7 day(s)	
Unit	: mg/l	
EC50	: = 54.8	
Analytical monitoring	: no data	
Method	: OECD Guide-line draft "Early Life Stage Test (ELS-Test)"	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: 95% confidence range: 38.3-78.5 mg/l	
Test condition	: System: semi static (3 changes of water in 7 days)	
Test substance	: >=99% pure	
Reliability 26.05.2004	: (2) valid with restrictions	(131)

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

Species : Brachydanio rerio (Fish, fresh water)
Endpoint : weight of young fish
Exposure period : 7 day(s)
Unit : mg/l
LOEC : = 32
Analytical monitoring : no data
Method : OECD Guide-line draft "Early Life Stage Test (ELS-Test)"
Year :
GLP : no data
Test substance : no data

Test condition : system semi static (3 changes of water in 7 days)
Test substance : Purity:>=99%
Reliability : (2) valid with restrictions
20.05.2004 (131)

Species : Brachydanio rerio (Fish, fresh water)
Endpoint : other:embryo lethality
Exposure period : 7 day(s)
Unit : mg/l
LC50 : 262
Analytical monitoring : no data
Method : OECD Guide-line draft "Early Life Stage Test (ELS-Test)"
Year :
GLP : no data
Test substance : no data

Remark : 95% confidence limits 190-361 mg/l
Test condition : System: semi static (3 changes of water in 7 days)
Test substance : Purity:>=99%
Reliability : (2) valid with restrictions
26.05.2004 (131)

Species : Salmo gairdneri (Fish, estuary, fresh water)
Endpoint : other:embryo lethality
Exposure period : 60 day(s)
Unit : mg/l
LC50 : = 320
Analytical monitoring : no data
Method : OECD Guide-line draft "Early Life Stage Test (ELS-Test)"
Year :
GLP : no data
Test substance : no data

Remark : 95% confidence range: 100-1000 mg/l
Test condition : System: semi static (3 changes of water in 7 days)
Test substance : Purity:>=99%
Reliability : (2) valid with restrictions
26.05.2004 (131)

Species : Salmo gairdneri (Fish, estuary, fresh water)
Endpoint : other:malignancies
Exposure period : 60 day(s)
Unit : mg/l
EC50 (7d) : = 260
Method : OECD Guide-line draft "Early Life Stage Test (ELS-Test)"
Year :
GLP : no data
Test substance : no data

Remark : 95% confidence range: 224-302 mg/l
Test condition : System: semi static (3 changes of water in 7 days)

Reliability : (2) valid with restrictions
26.05.2004

(131)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : mortality
Exposure period : 21 day(s)
Unit : µg/l
NOEC : 172 measured/nominal
LOEC : > 172 measured/nominal
EC50 : > 172 measured/nominal
Analytical monitoring : yes
Method : EPA OPPTS 850.1300
Year : 2003
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Conducted to:
OECD Guideline No. 211
FIFRA Guideline 72-4
OPPTS Draft Guideline 850.1300

Result : Nominal test concentrations: 25, 50, 100, 200 and 400 µg/l

Test condition : Mean measured concentrations: 11, 35, 53, 111 and 172 µg/l
Test conditions:
21 day duration, 19 to 21°C, illumination of 16 hours light: 8 hours darkness
at 35 to 75 footcandles (380 to 810 lux).

Dilution water:
Fortified well water
ph: 8.0 to 8.2
Specific conductivity: 500 µmhos/cm
Total hardness as CaCO₃: 160 mg/l
Total alkalinity as CaCO₃: 110 mg/l

Statistical analysis:

At the termination of the study, data obtained on organism survival, reproduction (cumulative number of offspring produced) and growth (as dry weight and total body length) were statistically analyzed to identify significant treatment-related effects. The cumulative number of offspring per female in each replicate vessel was determined by dividing the number of counted offspring at the designated interval by the number of surviving female daphnids recorded during the previous biological observation interval. The number of offspring per female at each of the observation intervals was summed to provide the cumulative number of offspring per female for each replicate test vessel. Analyses were performed using the mean replicate organism response in each treatment group rather than individual response values. All statistical analyses were conducted at the 95% level of certainty except in the case of the Shapiro-Wilks Test and the Bartlett's Test, in which the 99% level of certainty was applied. The 99% level of certainty is preferred for these qualifying tests. The following procedures were used:

1. Significant differences in the percent survival were evaluated after transformation (e.g., arcsine square-root percentage) of the data.
2. The Chi Square and Shapiro Wilks' Test for normality was used to compare the observed sample distribution with a normal distribution for reproduction, length and weight. Shapiro-Wilks Test for normality (Weber et al., 1989) was used to compare the observed sample distribution with a

normal distribution for survival. The survival data were not normally distributed, therefore a non-parametric procedure, e.g., Kruskal Wallis' Test, Dunn's Test (Sokal and Rohlf, 1981) or Steel's One-Many Rank Test (Weber et al., 1989) was used for subsequent analyses.

3. As a check on the assumption of homogeneity of variance, data for reproduction, length and weight were analyzed using Hartley's Test and Bartlett's Test (Sokal and Rohlf, 1981). No homogeneity of variance test was conducted for survival because the data were not normally distributed.

4. Survival data was analyzed prior to the analysis of the reproduction and growth data (total length and dry weight); treatment levels at which significant adverse effects on survival were observed were excluded from statistical analysis of daphnid reproduction and growth. For the purpose of determining survival effects, immobilized organisms were considered dead.

5. If the data passed the two tests for normality and homogeneity, then a parametric method was used to evaluate the results of the life-cycle test, e.g., Williams' Test (Williams, 1971, 1972) or Dunnett's Test. For this study, all endpoints met the assumptions for normal distribution and homogeneity of variance and were evaluated with Williams' Test and Bonferroni's Test to establish treatment effects on organism reproduction and growth (as total body length and dry weight).

The theoretical threshold concentration expected to produce no deleterious effects at the 95% level of certainty was estimated as the Maximum Acceptable Toxicant Concentration (MATC). The MATC is equal to the geometric mean of the limits set by the lowest mean measured concentration that elicited a statistically significant effect on organism performance (Lowest-Observed-Effect Concentration, LOEC) and the highest test concentration that elicited no statistically significant difference between the exposed organisms and the control (No-Observed-Effect Concentration, NOEC). Based on these data, the MATC of Resorcinol to daphnids was estimated. Determination of these levels is based on the most sensitive of the performance criteria evaluated (e.g., organism survival, reproduction and growth at study termination).

Reliability : Protocol deviations: There were no protocol deviations recorded.
Flag : (1) valid without restriction
 : Critical study for SIDS endpoint
 02.06.2004 (77)

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

Species : Lactuca sativa (Dicotyledon)
Endpoint : growth
Exposure period : 3 day(s)
Unit : mg/l
EC50 : ca. 200
EC37 : ca. 100
EC75 : ca. 400
Method : other: no data
Year : 1976
GLP : no data
Test substance : no data

Test condition : Test parameter: Inhibition of root elongation
Reliability : (4) not assignable

4. Ecotoxicity

Id 108-46-3
Date 15.06.2004

26.05.2004 (18)

Species : other terrestrial plant: Atriplex triangularis (Halophytes)
Endpoint : other: Inhibition of Germination
Exposure period : 20 day(s)
Unit : mg/l
EC93 : = 1100
Method : other: no data
Year :
GLP : no data
Test substance : no data

Remark : 20 days exposure of seeds of the halophytic plant to 1.1 g resorcinol/l water (Tween 20 used as solubilizer) caused 93% inhibition of germination relative to control.

Reliability : (4) not assignable

26.05.2004 (69)

Species : other terrestrial plant: Chick-pea plants
Endpoint :
Exposure period :
Unit :

Remark : Chick-pea plants were sprayed at the start of blossoming and 15 days later with solutions of resorcinol (5, 20 and 50 mg/l). In comparison with the control cultures, the number of the pods per plant at the middle concentration was strongly increased. The number of peas per pod was reduced at the lowest concentration. The weight of one thousand peas and the yield per hectare were greater than in reference cultures. The content of soluble protein and soluble sugars was also higher and the content of free amino acids and starch only greater than in the reference cultures at the low concentration.

Reliability : (4) not assignable

26.05.2004 (80)

Species : other terrestrial plant: Pea plants (Cajanus cajan (L.) Millsp.)
Endpoint :
Exposure period :
Unit :

Remark : Pea plants (Cajanus cajan (L.) Millsp.), which were sprayed with resorcinol (500 l/ha; concentration 100 mg/l) 70 and 77 days after having been planted had 17% more blossoms per plant relative to the control and 9% more pods.

Reliability : (4) not assignable

26.05.2004 (114)

Species : other terrestrial plant: Imatiens balsamina
Endpoint :
Exposure period :
Unit :

Remark : In studies conducted in Imatiens balsamina, a spring cabbage, 4 out of 10 plants (control:0) managed to blossom despite 25 applications (3 drops every 2 days to a cotton bud located around the growing tip of the plant) of resorcinol (10 mg/l) and 24 hours exposure to light every day. At 8 hours light exposure every day, even the control plants became active: however, the resorcinol-treated plants formed more buds more rapidly.

Reliability : (4) not assignable

26.05.2004 (68)

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

Type : artificial soil
Species : Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint : mortality
Exposure period : 42 day(s)
Unit : mg/kg soil dw
LC100 : ca. 40000
Method : other
Year :
GLP : no data
Test substance : no data

Test condition : 24 degree C
Reliability : (4) not assignable
 27.05.2004

(43)

Type : artificial soil
Species : Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint : weight
Exposure period : 42 day(s)
Unit : mg/kg soil dw
LOEC : = 10000

Remark : Test parameter: Growth inhibition
Result : Retarded body weight gains
Reliability : (4) not assignable
 26.05.2004

(43)

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

Species : other not soil dwelling arthropod: Lasioderma serricorne
Endpoint : mortality
Exposure period : 69 day(s)
Unit : ppm
LC70 : = 100000
Method :
Year : 1990
GLP :
Test substance :

Remark : Larvae and adult animals of the beetle Lasioderma serricorne, which live in symbiosis with an intracellular yeast, received resorcinol (10%) with their feed. After 14 and 26.6 days exposure, the mortality rate was 70% (control after 14 days exposure: 0). In the case of aposymbiotic insects (free from the intracellular symbiotic yeast), the mortality rate after 61.8 days exposure was 70%.

Reliability : (4) not assignable
 26.05.2004

(29)

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 **ADDITIONAL REMARKS**

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

In Vitro/in vivo : In vivo
Type : Metabolism
Species : rat
Number of animals
 Males :
 Females :
Doses
 Males : 112 and 225 mg/kg
 Females : 112 and 225 mg/kg
Vehicle : other: corn oil
Route of administration : gavage
Exposure time : 5 day(s)
Product type guidance :
Decision on results on acute tox. tests :
Adverse effects on prolonged exposure :
Half-lives : 1st.
 2nd.
 3rd.
Toxic behaviour :
Deg. product :
Method : other
Year : 1987
GLP :
Test substance : other TS: 14C radiolabelled test substance

Result : The test substance was readily absorbed from the GI tract, rapidly metabolized and excreted by male and female rats. In both sexes, most of the dose was excreted in the urine within 24 hours after oral administration of 112 mg/kg, indicating little potential for bioaccumulation in animal tissues. Less than 3% of an oral dose was excreted in the faeces. An analysis of bile indicated that at least 50% of the dose excreted in bile undergoes enterohepatic circulation to be eventually excreted in urine. Little of the parent compound was excreted in urine; most of the dose was in the form of three major and one minor metabolite. The relative amounts of metabolites excreted changed only slightly with time and dose administered. Approximately 70% of the total radioactivity in the urine of both sexes was in the form of glucuronide conjugate. Female rats excreted a greater portion of the dose as a sulfate conjugate than males. Males excreted more of a diconjugate both sulfate and glucuronide groups. Repeated exposure to up to five daily doses resulted in no apparent alteration of the pattern of absorption, metabolism and excretion observed after a single dose.

Reliability : (2) valid with restrictions
 20.05.2004

(70)

In Vitro/in vivo : In vivo
Type : Metabolism
Species : rat
Number of animals
 Males :
 Females :
Doses
 Males : 100 mg/kg
 Females :
Vehicle : water
Route of administration : s.c.
Exposure time : 30 day(s)

5. Toxicity

Id 108-46-3

Date 15.06.2004

Product type guidance	:	
Decision on results on acute tox. tests	:	yes
Adverse effects on prolonged exposure	:	
Half-lives	:	1 st . 2 nd . 3 rd .
Toxic behaviour	:	none
Deg. product	:	yes
Method	:	
Year	:	1982
GLP	:	no data
Test substance	:	
Result	:	Repeated dosing for 30 days with maximum tolerated daily doses of 100 mg/kg did not alter pharmacokinetic parameters, nor cause overt toxic signs or adverse reactions. The animals body weight, blood values, levels of serum T3 and T4 and the gross microscopic appearance of the thyroid gland and spinal cord remained within normal limits.
Reliability	:	(2) valid with restrictions
26.05.2004		(88)
In Vitro/in vivo	:	In vivo
Type	:	Absorption
Species	:	human
Number of animals		
Males	:	3
Females	:	
Doses		
Males	:	12 mg/kg/day
Females	:	
Vehicle	:	other:hydroalcohol
Route of administration	:	dermal
Exposure time	:	28 day(s)
Product type guidance	:	
Decision on results on acute tox. tests	:	
Adverse effects on prolonged exposure	:	
Half-lives	:	1 st . 2 nd . 3 rd .
Toxic behaviour	:	
Deg. product	:	
Method	:	
Year	:	1983
GLP	:	no data
Test substance	:	
Result	:	The adsorption and metabolic disposition of 2% resorcinol applied topically in a hydroalcoholic vehicle was determined in three human subjects. The test substance penetrated the skin at a rate of 0.37 µg/cm ² /hour. After two weeks of bid application of 800 mg resorcinol to about 30% of body surface of each subject, an average of 1.64% of the dosage was being excreted in 24-hour urine specimens as the glucuronide or as the sulfate conjugate. There was no resorcinol in blood drawn at weeks 1, 2, 3 and 4 nor were there any abnormalities in thyroid function or blood chemistries at weeks 2, 3 and 4.
Reliability	:	(2) valid with restrictions
26.05.2004		(141)

5.1.1 ACUTE ORAL TOXICITY

5. Toxicity

Id 108-46-3
Date 15.06.2004

Type : LD50
Value : = 202 mg/kg bw
Species : rat
Strain : Wistar
Sex : female
Number of animals : 10
Vehicle : other: A 5% suspension in 2% thin paste of starch used for various doses
Doses : 100, 160, 250, 400, 630 mg/kg
Method : other:In house method
Year : 1979
GLP : no
Test substance :

Reliability : (2) valid with restrictions
20.05.2004 (51)

Type : LD50
Value : = 980 mg/kg bw
Species : rat
Strain : no data
Sex : male
Number of animals : 5
Vehicle : water
Doses :
Method : other: Federal Register of August 12, 1961 pages 7333-7341
Year : 1962
GLP : no
Test substance : other TS

Remark : 95% confidence limits: 740-1290 mg/kg
Dosage administered by stomach intubation to groups of non-fasted male albino rats weighing between 200-300 gms at four consecutive dosages. Rats were observed for 14 days.

Test substance : Flaked grade
Reliability : (2) valid with restrictions
20.05.2004 (103)

Type : LD50
Value : 301 mg/kg bw
Species : rat
Strain :
Sex : male
Number of animals : 5
Vehicle : water
Doses : 147, 215, 316, 464 mg/kg
Method : other:no data
Year : 1970
GLP : no data
Test substance : no data

Result : LD50 95% confidence limits: 213 - 426 mg/kg

Mortalities:

Dose mg/kg	No. of deaths	Time of death
147	0/5	N/A
215	1/5	0-4 hours
316	3/5	0-4 hours
464	4/5	0-4 hours

Clinical signs:

Clinical signs of fibrillation, tremors, convulsions, salivation, dyspnea, sedation, and emaciation were observed in all treatment groups.

5. Toxicity

Id 108-46-3
Date 15.06.2004

Gross autopsy:
No significant findings were observed during the gross autopsy of survivors.
In decendants there were gross autopsy findings of hemorrhage of lungs, inflammation of gastrointestinal tract and hyperemia of liver.

Reliability : (2) valid with restrictions
02.06.2004 (60)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : = 3360 mg/kg bw
Species : rabbit
Strain :
Sex : male
Number of animals : 4
Vehicle : physiol. saline
Doses : 4000 mg/kg
Method : other: Federal Register of August 12 1961, pages 7333-7341
Year : 1962
GLP : no
Test substance :

Remark : Four male albino rabbits weighing between 2.3-3.0 kg; Seven day laboratory observation and acclimatization period.

Result : The material produced necrosis of the skin in all the rabbits exposed to 3980 mg/kg and above. The rabbits exposed to 1000 mg/kg showed only slight hyperkeratosis following signs of moderate to severe irritation after 24 hours contact. Dosed animals did not show the same body weight gains throughout the 14 day exposure period as the control animals. No internal gross lesions were observed at autopsy.

Reliability : (2) valid with restrictions
20.05.2004 (103)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type : LC50
Value : = 215 mg/kg bw
Species : mouse
Strain :
Sex : male
Number of animals :
Vehicle :
Doses :
Route of admin. : i.p.
Exposure time :
Method : Other: no data
Year : 1966
GLP : no data
Test substance : no data

Reliability : (4) not assignable
20.05.2004 (98)

5. Toxicity

Id 108-46-3
Date 15.06.2004

Type : LC50
Value : 450 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Route of admin. : s.c.
Exposure time :
Method : other: no data
Year :
GLP : no data
Test substance : no data

Reliability : (4) not assignable
20.05.2004

(119)

Type : LC50
Value : 213 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Route of admin. : s.c.
Exposure time :
Method : other:no data
Year :
GLP : no data
Test substance : no data

Reliability : (4) not assignable
20.05.2004

(81)

5.2.1 SKIN IRRITATION

Species : rabbit
Concentration : 500 mg
Exposure :
Exposure time : 24 hour(s)
Number of animals :
Vehicle : physiol. saline
PDII : 4.4
Result : corrosive
Classification : irritating
Method : other: Federal Hazardous Substances Labeling Act (FHSLA), Federal Register Aug. 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order"

Year :
GLP :
Test substance :

Reliability : (2) valid with restrictions
26.05.2004

(103)

Species : rabbit
Concentration : 500 mg
Exposure :

5. Toxicity

Id 108-46-3
Date 15.06.2004

Exposure time : 24 hour(s)
Number of animals :
Vehicle :
PDII : 4.4
Result : irritating
Classification : irritating
Method : other: Patch-Test
Year :
GLP : no data
Test substance : no data

Reliability : (4) not assignable
26.05.2004

(37)

Species : rabbit
Concentration : 500 mg
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 6
Vehicle : physiol. saline
PDII : 2.8
Result : slightly irritating
Classification : irritating
Method : other: FDA Guidelines (Federal Register 38, no.187, 9/27/1973, p. 27019)
Year : 1979
GLP : no data
Test substance :

Reliability : (2) valid with restrictions
20.05.2004

(52)

5.2.2 EYE IRRITATION

Species : rabbit
Concentration :
Dose : .1 other: gm
Exposure time : 72 hour(s)
Comment :
Number of animals : 6
Vehicle :
Result : corrosive
Classification : irritating
Method : other: Federal Hazardous Substance Labeling Act (FHSLA), Federal Register Aug 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order"
Year : 1962
GLP :
Test substance :

Reliability : (2) valid with restrictions
26.05.2004

(103)

Species : rabbit
Concentration : 100 mg
Dose : .1 ml
Exposure time : 24 hour(s)
Comment : rinsed after (see exposure time)
Number of animals : 6
Vehicle : physiol. saline
Result : highly irritating

5. Toxicity

Id 108-46-3
Date 15.06.2004

Classification	:	irritating	
Method	:	other:FDA guidelines Federal register 30, No. 87 9/27/1973 p 27019	
Year	:	1979	
GLP	:	no data	
Test substance	:	no data	
Reliability	:	(2) valid with restrictions	(52)
26.05.2004			
Species	:	guinea pig	
Concentration	:	2.5 %	
Dose	:		
Exposure time	:		
Comment	:		
Number of animals	:		
Vehicle	:		
Result	:	not irritating	
Classification	:	not irritating	
Method	:	other:	
Year	:	1987	
GLP	:	no data	
Test substance	:	no data	
Method	:	The Draize irritation test was performed on guinea pigs by instilling 100µl of 2.5% solution into the eye. Eye irritation on three distinct tissues (cornea, conjunctiva, iris) were scored after 0.5, 1,2,3,4,6,7 and 24 h.	
Remark	:	Instillation of 100 ul of a 2.5% test substance solution (Draize method)	
Reliability	:	(4) not assignable	(11)
26.05.2004			

5.3 SENSITIZATION

Type	:	Guinea pig maximization test	
Species	:	guinea pig	
Number of animals	:	10	
Vehicle	:	physiol. saline	
Result	:	sensitizing	
Classification	:	sensitizing	
Method	:	OECD Guide-line 406 "Skin Sensitization"	
Year	:	1989	
GLP	:	yes	
Test substance	:	as prescribed by 1.1 - 1.4	
Reliability	:	(1) valid without restriction	(54)
20.05.2004			

5.4 REPEATED DOSE TOXICITY

Type	:	Sub-acute	
Species	:	rat	
Sex	:	male/female	
Strain	:	Fischer 344	
Route of admin.	:	gavage	
Exposure period	:	2 weeks	
Frequency of treatm.	:	Once daily for 5 days a week (12 doses dispensed over 17 days)	
Post exposure period	:		
Doses	:	0, 27.5, 55, 110, 225, 450 mg/kg/bw	
Control group	:	yes	

5. Toxicity

Id 108-46-3
Date 15.06.2004

NOEL	:	450 mg/kg bw	
Method	:		
Year	:	1991	
GLP	:		
Test substance	:	as prescribed by 1.1 - 1.4	
Result	:	Body weight development lay in same range as that of control; no substance-related macroscopic or histopathological changes	
Test substance	:	Obtained from NAPP Chemicals, Incorporated. Preparation in water, purity >99%	
Reliability 02.06.2004	:	(1) valid without restriction	(17) (92)
Type	:	Sub-chronic	
Species	:	rat	
Sex	:	male/female	
Strain	:	Fischer 344	
Route of admin.	:	gavage	
Exposure period	:	13 weeks	
Frequency of treatm.	:	Once a day 5 days a week	
Post exposure period	:		
Doses	:	0, 32, 65, 130, 260, 520 mg/kg/bw	
Control group	:	yes	
NOEL	:	260	
Method	:		
Year	:	1991	
GLP	:	no data	
Test substance	:		
Result	:	Body weight development lay in same range as that of control; in the 520 mg/kg body weight dose group, 8 out of 10 males and 8 out of 10 females died; no substance-related macroscopic or histopathological changes.	
Test substance	:	Obtained from NAPP Chemicals, Incorporated. Preparation in water, purity >99%	
Reliability 28.05.2004	:	(1) valid without restriction	(17) (92)
Type	:	Sub-acute	
Species	:	mouse	
Sex	:	male/female	
Strain	:	B6C3F1	
Route of admin.	:	gavage	
Exposure period	:	2 weeks	
Frequency of treatm.	:	Once a day 5 days a week (12 doses over 17 days)	
Post exposure period	:		
Doses	:	0, 37.5, 75, 100, 300, 600 mg/kg/bw	
Control group	:	yes	
NOEL	:	100 mg/kg bw	
Method	:		
Year	:	1991	
GLP	:		
Test substance	:		
Result	:	Body weight development lay in same range as that of control; in the 600 mg/kg body weight dose group, 4 out of 5 males and 5 out of 5 females died; in the 300 mg/kg body weight group, 1 out of 5 males died; no substance related macroscopic or histopathological changes.	
Test substance	:	Preparation in water, purity >99%	
Reliability 26.05.2004	:	(1) valid without restriction	(1) (92)
Type	:	Sub-chronic	

5. Toxicity

Id 108-46-3
Date 15.06.2004

Species	:	mouse	
Sex	:	male/female	
Strain	:	B6C3F1	
Route of admin.	:	gavage	
Exposure period	:	13 weeks	
Frequency of treatm.	:		
Post exposure period	:		
Doses	:	0, 28, 56, 112, 225, 420 mg/kg/bw	
Control group	:	yes	
NOEL	:	225 mg/kg bw	
Result	:	Body weight development lay in same range as that of control; in the 420 mg/kg body weight dose group, 8 out of 10 males and 8 out of 10 females died; no substance-related macroscopic or histopathological changes.	
Test substance	:	Preparation in water, purity >99%	
Reliability	:	(1) valid without restriction	
28.05.2004			(17)(92)
Type	:	Sub-acute	
Species	:	rat	
Sex	:	no data	
Strain	:		
Route of admin.	:	inhalation	
Exposure period	:	2 weeks	
Frequency of treatm.	:	6 hour per day	
Post exposure period	:	several months	
Doses	:	34 mg/m ³	
Control group	:	no data specified	
Result	:	Other species tested were rabbits and guinea pigs. No sub-related changes, particularly no damage to lungs or trachea, no signs of allergic reaction in respiratory tract.	
Reliability	:	(2) valid with restrictions	
26.05.2004			(37)
Type	:	Sub-acute	
Species	:	rat	
Sex	:	no data	
Strain	:		
Route of admin.	:	oral feed	
Exposure period	:	2 weeks	
Frequency of treatm.	:		
Post exposure period	:	Several months	
Doses	:	5% (approx. 2500 mg/kg bw)	
Control group	:	no data specified	
Result	:	Increased thyroid gland weight; reduced T4 content in plasma; lower half-life time for T4.	
Reliability	:	(4) not assignable	
26.05.2004			(6)
Type	:	Sub-acute	
Species	:	rat	
Sex	:	male	
Strain	:		
Route of admin.	:	oral feed	
Exposure period	:	4 weeks	
Frequency of treatm.	:		
Post exposure period	:		
Doses	:	0-260 mg/kg bw	
Control group	:	yes	

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Result	: No mortality and no clinical symptoms, no hispathological findings, no influence on body weight development, decrease in relative weight of adrenal gland in all treated animals.	
Reliability 26.05.2004	: (4) not assignable	(36)
Type	: Sub-acute	
Species	: rat	
Sex	: male	
Strain	:	
Route of admin.	: oral feed	
Exposure period	: 8 weeks	
Frequency of treatm.	:	
Post exposure period	:	
Doses	: 0.8% (approx. 800 mg/kg body weight/day for an assumed feed consumption of 100 g/kg body weight/day)	
Control group	: yes	
Result	: Body weight development, feed and water consumption lay in the range of those of the control; no substance-related changes in the mucous membrane of the fore stomach or glandular stomach.	
Reliability 26.05.2004	: (4) not assignable	(112)
Type	: Sub-chronic	
Species	: rat	
Sex	: male/female	
Strain	: Wistar	
Route of admin.	: inhalation	
Exposure period	: 90 days	
Frequency of treatm.	: 8 hours	
Post exposure period	:	
Doses	:	
Control group	:	
Method	: other: not concluded to any guidelines	
Year	: 1977	
GLP	: no	
Test substance	: no data	
Remark	: Number of animals: 50	
Result	: There were significant differences observed in blood chemistry and hematology values, but no valid conclusions were drawn from this data.	
	LC50 = 7.8 mg/l	
Reliability 02.06.2004	: (2) valid with restrictions	(33)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	: Ames test
System of testing	: Salmonella typhimrium TA98, TA100, TA1535, TA1537
Test concentration	: 0, 33, 100, 333, 1000, 3333 µg/plate
Cycotoxic concentr.	: N/A
Metabolic activation	: with and without
Result	: negative
Method	: other:Haworth et al. (1983)
Year	: 1991
GLP	: no data
Test substance	:

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Test substance	: Coded aliquot from Radian Corporation (Austin, TX)	
Reliability 28.05.2004	: (1) valid without restriction	(17)(92)
Type	: Cytogenetic assay	
System of testing	: Ovarial cells of the Chinese hamster (CHO)	
Test concentration	: 750, 1000, 1500 and 2000 µg/ml in the absence of S9 mix and 4000, 4500 and 5000 in the presence of S9 mix	
Cycotoxic concentr.	:	
Metabolic activation	: with and without	
Result	: positive	
Method	: other: Galloway et al (1985, 1987)	
Year	: 1991	
GLP	: no data	
Test substance	:	
Result	: Ambiguous in the absence of S9 mix, but positive in the presence of S9 mix.	
Reliability 28.05.2004	: (1) valid without restriction	(17)(92)
Type	: Mouse lymphoma assay	
System of testing	: L 5178Y TK +/-	
Test concentration	: 156.25, 312.5, 625, 1250, 2500, 5000 µg/ml	
Cycotoxic concentr.	: 5000	
Metabolic activation	: without	
Result	: positive	
Method	: other: McGreagor et al (1988a) and Clive et al (1979)	
Year	: 1991	
GLP	: no data	
Test substance	:	
Reliability 28.05.2004	: (1) valid without restriction	(17)(92)
Type	: Sister chromatid exchange assay	
System of testing	: Ovarial cells of the Chinese hamster (CHO)	
Test concentration	: 50, 167, 500 and 1670 µg/ml in the absence of S9 mix and 500, 1670 and 5000 in the presence of S9 mix.	
Cycotoxic concentr.	: 1670 µg/ml in the absence of S9 mix	
Metabolic activation	: with and without	
Result	: positive	
Method	: other: Galloway et al (1985, 1987)	
Year	: 1991	
GLP	: no data	
Test substance	:	
Reliability 28.05.2004	: (1) valid without restriction	(17)(92)
Type	: Ames test	
System of testing	: Salmonella taphimrium TA1538	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: with and without	
Result	: negative	
Method	: other: Hoechst Ag Internal Directive, 1977	
Year	:	
GLP	:	
Test substance	: as prescribed by 1.1 - 1.4	
Reliability	: (4) not assignable	

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26.05.2004 (50)

Type : Ames test
System of testing : Salmonella typhimrium TA 98, TA 100, TA 1535, TA 1537, TA 1538
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :
Year :
GLP :
Test substance :

Remark : 5-1000 µg/plate, 3 plates/concentration, independent repetition; cytotoxic range not included negative for both with and without metabolic activation.
Reliability : (4) not assignable

20.05.2004 (111)

Type : Cytogenetic assay
System of testing : Peripheral human lymphocytes
Test concentration : 20-100 µg/ml; 800 metaphases assessed
Cycotoxic concentr. :
Metabolic activation : without
Result : positive
Method :
Year :
GLP :
Test substance :

Remark : Concentration-dependent increase in the aberration rate.
Reliability : (4) not assignable

26.05.2004 (25)

Type : Cytogenetic assay
System of testing : Ovarial cells of the Chinese hamster (CHO)
Test concentration : 1600 µg/ml; 200 metaphases assessed
Cycotoxic concentr. :
Metabolic activation : with and without
Result : positive
Method :
Year :
GLP :
Test substance :

Reliability : (4) not assignable
26.05.2004 (121)

Type : Cytogenetic assay
System of testing : Peripheral human lymphocytes
Test concentration : 80-320 µg/ml
Cycotoxic concentr. : 100 metaphases/concentration
Metabolic activation : without
Result : negative
Method :
Year :
GLP :
Test substance :

Reliability : (4) not assignable
26.05.2004 (25)

Type : Cytogenetic assay

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System of testing	: Ovarial cells of the Chinese hamster (CHO)	
Test concentration	: 400-1600 µg/ml	
Cycotoxic concentr.	: 200 metaphases assessed	
Metabolic activation	: with and without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Reliability	: (4) not assignable	(25)
26.05.2004		
Type	: Ames test	
System of testing	: salmonella typhimrium TA98, TA100, TA1535, TA1537	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: with	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: 200-500 µg/plate; 3 plates/concentration; independent repetition; cytotoxic range included.	
Reliability	: (4) not assignable	(22)
02.06.2004		
Type	: Ames test	
System of testing	: Salmonella typhimrium TA98	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: with and without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: Concentrations of 10-30 µg/plate; no information on cytotoxic range	
Reliability	: (4) not assignable	(134)
20.05.2004		
Type	: Ames test	
System of testing	: Escherichia coli WP@, WP2uvrA-	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: with and without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Reliability	: (4) not assignable	(100)
20.05.2004		
Type	: Ames test	
System of testing	: Salmonella typhimrium TA98, TA100, TA1535, TA1537,TA1538	
Test concentration	:	
Cycotoxic concentr.	:	

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Metabolic activation	:	with and without	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	5-1000 µg/plate, 3 plates/concentration, independent repetition; cytotoxic range not included.	
Reliability	:	(4) not assignable	(111)
02.06.2004			
Type	:	Ames test	
System of testing	:	Salmonella typhimrium TA98, TA100, TA1535, TA1537	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	with	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	10-1000 µg/plate; no information on cytotoxic range	
Reliability	:	(4) not assignable	(84)
26.05.2004			
Type	:	Ames test	
System of testing	:	Salmonella typhimrium TA98, TA100, TA1535, TA1537, TA1538	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	with and without	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Concentration up to 3600 µg/plate; in ZLM medium: TA100: -S9 positive, +S9 ambiguous TA1535: -S9 negative, +S9 positive In other strains: negative	
Reliability	:	(4) not assignable	(41)
26.05.2004			
Type	:	Ames test	
System of testing	:	Salmonella typhimrium TA98, TA100, TA1535, TA1537	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	with and without	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Preincubation method; 33-333 µg/plate; 3 plates/concentration, independent repetition; cytotoxic.	
Reliability	:	(4) not assignable	(92)
26.05.2004			
Type	:	Ames test	

5. Toxicity

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System of testing	: Salmonella typhimrium TA100, TA1538	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: 3.3-3000 µg/plate	
Reliability	: (4) not assignable	(38)
26.05.2004		
Type	: Ames test	
System of testing	: Salmonella typhimrium TA98	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: with and without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: 500-2000 µg/plate; 3 plates/concentration	
Reliability	: (4) not assignable	(23)
26.05.2004		
Type	: Cytogenetic assay	
System of testing	: Human lymphocytes	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: no data	
Result	: positive	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: Abstract	
Reliability	: (4) not assignable	(73)
26.05.2004		
Type	: Cytogenetic assay	
System of testing	: Fibroblasts of the Chinese hamster (CHL)	
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	: without	
Result	: positive	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: With metabolic activation (S9 mix), reduction in clastogenic effect (abstract)	
Reliability	: (4) not assignable	(106)
26.05.2004		
Type	: Mitotic recombination in <i>Saccharomyces cerevisiae</i>	
System of testing	: <i>Saccharomyces cerevisiae</i> D7	
Test concentration	: 1000 µg/ml	

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Cycotoxic concentr.	:		
Metabolic activation	:	without	
Result	:	ambiguous	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	At pH of 7 test substance: negative At pH of 10 test substance: positive	
Reliability	:	(4) not assignable	(105)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Human lymphocytes	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Abstract	
Reliability	:	(4) not assignable	(57)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Human fibroblasts	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:		
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Abstract	
Reliability	:	(4) not assignable	(57)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Human embryo cells	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Embryo cells obtained from amniotic fluid (abstract)	
Reliability	:	(4) not assignable	(57)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Human lymphocytes	
Test concentration	:		
Cycotoxic concentr.	:		

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Metabolic activation	:	no data	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Abstract	
Reliability	:	(4) not assignable	(108)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Human fibroblasts	
Test concentration	:	12-50 µg/ml	
Cycotoxic concentr.	:	100 metaphases/concentration	
Metabolic activation	:	without	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability	:	(4) not assignable	(25)
26.05.2004			
Type	:	Cytogenetic assay	
System of testing	:	Peripheral human lymphocytes	
Test concentration	:	80-220 µg/ml	
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Reduced mitosis rate, chromosome aberrations (up to approx. 60% of the metaphases damaged, primarily chromatid breaks)	
Reliability	:	(4) not assignable	(109)
26.05.2004			
Type	:	Mouse lymphoma assay	
System of testing	:		
Test concentration	:	125-5000 ug/ml; concentration dependent	
Cycotoxic concentr.	:		
Metabolic activation	:	without	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Significant increase in mutant numbers in 3 independent runs	
Reliability	:	(4) not assignable	(85)
26.05.2004			
Type	:	other: Cell transformation	
System of testing	:	Kidney cells of the Syrian hamster (BHK 21/c1 13, Human fibroblasts (WI - 38) Human liver cells (Chang)	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	no data	

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Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability	:	(4) not assignable	(102)
26.05.2004			
Type	:	other: DNA-Alkaline-elution test	
System of testing	:	Rat hepatocytes	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	positive	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability	:	(4) not assignable	(132)
26.05.2004			
Type	:	other: DNA-cell binding (DCB) assay	
System of testing	:	Escherichia coli Q 13	
Test concentration	:		
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	With lysosyme and liver extract	
Reliability	:	(4) not assignable	(74)
26.05.2004			
Type	:	Sister chromatid exchange assay	
System of testing	:	Human lymphocytes	
Test concentration	:	Up to 27.5 µg/ml	
Cycotoxic concentr.	:	25 metaphases/concentration assessed	
Metabolic activation	:	no data	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability	:	(4) not assignable	(65)
26.05.2004			
Type	:	Unscheduled DNA synthesis	
System of testing	:	Primary rat hepatocytes	
Test concentration	:	110 µg/ml (maximum non-cytotoxic concentration)	
Cycotoxic concentr.	:		
Metabolic activation	:	no data	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		

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Reliability 26.05.2004	: (4) not assignable	(100)
Type	: Sister chromatid exchange assay	
System of testing	: V 79-cells of the Chinese hamster	
Test concentration	: 0.55-2.2 µg/ml	
Cycotoxic concentr.	:	
Metabolic activation	: without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	: Abstract	
Reliability 26.05.2004	: (4) not assignable	(136)
Type	: Sister chromatid exchange assay	
System of testing	: Peripheral human lymphocytes	
Test concentration	: 20-100 µg/ml	
Cycotoxic concentr.	: 400 metaphases/concentration assessed	
Metabolic activation	: without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Reliability 26.05.2004	: (4) not assignable	(25)
Type	: Sister chromatid exchange assay	
System of testing	: Ovarial cells of the Chinese hamster (CHO)	
Test concentration	: 50-1600 µg/ml	
Cycotoxic concentr.	: 50-75 metaphases/concentration assessed	
Metabolic activation	: without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Reliability 26.05.2004	: (4) not assignable	(25)
Type	: Sister chromatid exchange assay	
System of testing	: Ovarial cells of the Chinese hamster (CHO)	
Test concentration	: 400-1600 µg/l	
Cycotoxic concentr.	: 75-100 metaphases/concentration assessed	
Metabolic activation	: with and without	
Result	: negative	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Reliability 26.05.2004	: (4) not assignable	(25)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-s wild type
Route of admin. : other:feed exposure or injection
Exposure period : 72 hours
Doses : 11,000 ppm for feeding 11,940 ppm by injection
Result : ambiguous
Method : other:Zimmering et al (1985)
Year : 1991
GLP : no data
Test substance :

Result : The test substance (11,000 ppm) was negative for induction of sex-linked recessive lethal mutations in germ cells of the male flies when administered to adult flies by feeding. Administration of the test substance (11,940) by injection yielded an increase in mutations which was equivocal.

Reliability : (1) valid without restriction
 28.05.2004 (17)(92)

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male/female
Strain :
Route of admin. : oral feed
Exposure period :
Doses : 5506 µg/ml
Result : negative
Method :
Year :
GLP :
Test substance :

Reliability : (4) not assignable
 26.05.2004 (41)

Type : Inhibition of DNA-Synthesis
Species : mouse
Sex :
Strain :
Route of admin. : oral unspecified
Exposure period :
Doses : 100 mg/kg bw
Result : negative
Method :
Year :
GLP :
Test substance :

Reliability : (4) not assignable
 26.05.2004 (110)

Type : Micronucleus assay
Species : mouse
Sex : male/female
Strain :
Route of admin. : i.p.
Exposure period : 2 days
Doses : 55, 110, 220 mg/kg bw

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Date 15.06.2004

Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	2 animals/sex/dose; time of preparation: 30h; 1000 polychromatic erythrocytes per animal assessed.	
Reliability 26.05.2004	:	(4) not assignable	(41)
Type	:	Micronucleus assay	
Species	:	mouse	
Sex	:	male/female	
Strain	:		
Route of admin.	:	i.p.	
Exposure period	:		
Doses	:	75 mg/kg bw	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	5 animals/dose or control group/time of preparation 24, 48, 72 or 96h; 1000 polychromatic erythrocytes per animal assessed.	
Reliability 26.05.2004	:	(4) not assignable	(94)
Type	:	Micronucleus assay	
Species	:	mouse	
Sex	:	male	
Strain	:		
Route of admin.	:	i.p.	
Exposure period	:		
Doses	:	37.5-300 mg/kg bw	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	4 animals/dose; time of preparation 24 or 48h; 1000 polychromatic erythrocytes per animal assessed.	
Reliability 26.05.2004	:	(4) not assignable	(25)
Type	:	Micronucleus assay	
Species	:	mouse	
Sex	:	male	
Strain	:		
Route of admin.	:	i.p.	
Exposure period	:		
Doses	:	55-220 mg/kg bw	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability 26.05.2004	:	(4) not assignable	(137)

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Type : Micronucleus assay
Species : rat
Sex : male/female
Strain :
Route of admin. : oral unspecified
Exposure period : 2 days
Doses : 250 mg/kg bw
Result : negative
Method :
Year :
GLP :
Test substance :

Remark : 5 animals/sex/dose; time of preparation: 30h; 2000 polychromatic erythrocytes per animal assessed.

Reliability : (4) not assignable
26.05.2004

(59)

Type : Sister chromatid exchange assay
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : dermal
Exposure period : 20 minutes
Doses : 0.2, 2, 20, 100, 200, 300 mg/kg bw
Result : negative
Method :
Year :
GLP :
Test substance :

Remark : 2-3 animals/dose; time of preparation: 24h; 20-54 metaphases analyzed per animal.

Reliability : (4) not assignable
26.05.2004

(10)

Type : Sister chromatid exchange assay
Species : rat
Sex : male/female
Strain :
Route of admin. : i.p.
Exposure period :
Doses : 1-100 mg/kg bw
Result : negative
Method :
Year :
GLP :
Test substance :

Remark : 1-3 animals/dose; time of preparation: 24 h; 13-36 metaphases analyzed per animal.

Reliability : (4) not assignable
26.05.2004

(10)

Type : Sister chromatid exchange assay
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : oral unspecified
Exposure period :
Doses : 0.8, 4, 20, 100 mg/kg bw

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Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	3 animals/dose; time of preparation: 24 h; 12-54 metaphases analyzed per animal.	
Reliability 26.05.2004	:	(4) not assignable	(10)
Type	:	other: Sperm Abnormality test	
Species	:	mouse	
Sex	:	male	
Strain	:		
Route of admin.	:	i.p.	
Exposure period	:		
Doses	:	55-220 mg/kg bw	
Result	:	negative	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Reliability 26.05.2004	:	(4) not assignable	(137)

5.7 CARCINOGENICITY

Species	:	rat	
Sex	:	male	
Strain	:	Fischer 344	
Route of admin.	:	gavage	
Exposure period	:	104 weeks	
Frequency of treatm.	:	Daily: 5 days a week	
Post exposure period	:		
Doses	:	0, 112, 225 mg/kg bw	
Result	:	negative	
Control group	:	yes	
Method	:	other:NTP Board EPA/FDA guidelines	
Year	:	1991	
GLP	:	yes	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	60 animals/sex/dose and control group; purity: >99%; substance preparation in water; interim autopsy after 15 months of the experiment (10 animals/dose and control group).	
Result	:	Tumor type and incidence were in the same range as those of the control. Body weight development of the animals in the high dose group was retarded by 10-15% from week 87 onwards. The mortality in the high dose group was significantly higher than in the control group (no further information). The clinical symptoms included the following: ataxia, abdominal or lateral position and tremours.	
Reliability 28.05.2004	:	(1) valid without restriction	(17)
Species	:	rat	
Sex	:	female	
Strain	:	Fischer 344	
Route of admin.	:	gavage	

5. Toxicity

Id 108-46-3

Date 15.06.2004

Exposure period : 104 weeks
Frequency of treatm. : Daily: 5 days a week
Post exposure period :
Doses : 0, 50, 100, 150 mg/kg bw
Result : negative
Control group : yes
Method : other: NTP Board EPA/FDA guidelines
Year : 1991
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Remark : 60 animals/sex/dose and control group; purity >99%;substance preparation in water; interim autopsy after 15 months of the experiment (10 animals/dose and control group).

Result : Tumour type and incidence were in the same range as those of the control. Body weight development of the animals in the high dose group was retarded by 11-14% from week 95 onwards. The mortality in the high dose group was significantly higher than in the control group (no further information). The clinical symptoms included the following: ataxia, abdominal or lateral position and tremours (no further information).

Reliability : (1) valid without restriction
28.05.2004

(17)

Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 104 weeks
Frequency of treatm. : Daily:5 times/week
Post exposure period :
Doses : 0, 112, 225 mg/kg bw
Result : negative
Control group : yes
Method : other: NTP board EPA/FDA guidelines
Year : 1991
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Remark : 60 animals/sex/dose and control group; purity >99%;substance preparation in water; interim autopsy after 15 months of the experiment (10 animals/dose and control group).

Result : Tumour type and incidence were in the same range as those of the control. Body weight development of the female animals in the high dose group was retarded by 11-14% from week 85 onwards. The clinical symptoms included the following: ataxia, abdominal or lateral position and tremours (no further information).

Reliability : (1) valid without restriction
28.05.2004

(17)

Species : mouse
Sex : female
Strain : other: Sutter
Route of admin. : dermal
Exposure period : 12 weeks
Frequency of treatm. : 2 times a week
Post exposure period :
Doses : 0.025 ml of a 20% solution in acetone
Result :
Control group : yes
Method : other: no data
Year :
GLP : no data

5. Toxicity

Id 108-46-3

Date 15.06.2004

Test substance	: no data	
Remark	: Dose group: 27 animals; control: 12 animals; 2-stage study of carcinogenesis: initiator: 75 µg DMBS dermal, then resorcinol application.	
Result	: A higher carcinoma incidence relative to the control was not observed, however, the incidence of papilloma was higher (17% of animals; control: 0%).	
Reliability 20.05.2004	: (2) valid with restrictions	(9)
Species	: mouse	
Sex	: female	
Strain	: other: ICR/HA Swiss	
Route of admin.	: dermal	
Exposure period	: 368 days	
Frequency of treatm.	: 3 times/week	
Post exposure period	:	
Doses	: 10 mg (in acetone); +/- 5 µg benzapyrene/application	
Result	: negative	
Control group	: yes	
Method	: other: no data	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: 50 animals/dose and control group; test of carcinogenicity of resorcinol.	
Result	: A higher tumour incidence relative to the control group was not observed at the application site.	
Reliability 20.05.2004	: (2) valid with restrictions	(130)
Species	: mouse	
Sex	: female	
Strain	: other: ICR/HA Swiss	
Route of admin.	: dermal	
Exposure period	: 449 days	
Frequency of treatm.	: 3 times/week	
Post exposure period	:	
Doses	: 10 mg/application (in acetone)	
Result	: negative	
Control group	: yes	
Method	: other:no data	
Year	:	
GLP	: no data	
Test substance	: no data	
Remark	: 50 animals/dose and control group; 2-stage study of carcinogenesis: initiator: 150 µg benzapyrene; 14 days later: start of resorcinol application.	
Result	: A higher tumour incidence relative to the control group was not observed at the application site.	
Reliability 26.05.2004	: (2) valid with restrictions	(130)
Species	: rabbit	
Sex	: male/female	
Strain	: New Zealand white	
Route of admin.	: dermal	
Exposure period	: 180 weeks	
Frequency of treatm.	: 2 times/week	
Post exposure period	:	
Doses	: 0.02 ml of a 5, 10 or 50% solution in acetone	
Result	: negative	

5. Toxicity

Id 108-46-3

Date 15.06.2004

Control group	:	yes	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	5 animals/dose; control: 9 animals	
Result	:	A higher tumour incidence relative to the control group was not observed. Only those organs or tissue which showed macroscopic changes, plus the application site were examined (inner ear).	
Reliability	:	(2) valid with restrictions	(120)
26.05.2004			
Species	:	rat	
Sex	:	male	
Strain	:	Fischer 344	
Route of admin.	:	oral feed	
Exposure period	:	49 weeks	
Frequency of treatm.	:		
Post exposure period	:		
Doses	:	0, 0.8% (approx. 400 mg/kg bw)	
Result	:		
Control group	:	yes	
Method	:		
Year	:		
GLP	:		
Test substance	:	other TS: > 99% purity	
Remark	:	Control: 10 animals; dose: 15 animals; 2-stage study of carcinogenesis: initiator: 25 mg methyl-N-amyl-nitrosamine/kg body weight i.p. for 3 weeks (once a week); then resorcinol application; 11-12 animals/dose and control group; purity >99%.	
Result	:	Retarded body weight gain and higher tumour incidence: tongue papilloma (p <0.05) and oesophagus carcinoma (p <0.01); no increased incidence in the case of the lungs, liver, kidneys, stomach, trachea or in the nasal region.	
Reliability	:	(2) valid with restrictions	(139)
26.05.2004			
Species	:	rat	
Sex	:	male	
Strain	:	Fischer 344	
Route of admin.	:	oral feed	
Exposure period	:	51 weeks	
Frequency of treatm.	:		
Post exposure period	:		
Doses	:	0, 0.8% (approx. 400 mg/kg bw)	
Result	:	negative	
Control group	:	yes	
Method	:		
Year	:		
GLP	:		
Test substance	:		
Remark	:	Control: 10 animals; dose: 16 animals; 2-stage study of carcinogenesis: initiator: 150 mg N-methyl-N'-nitrosoguanidine/kg body weight; then resorcinol application.	
Result	:	Higher tumour incidence or hyperplasia rate in the forestomach or glandular stomach relative to the control was not observed. No other organs were examined.	
Reliability	:	(2) valid with restrictions	(49)
26.05.2004			

5. Toxicity

Id 108-46-3

Date 15.06.2004

Species : hamster
Sex : female
Strain : other: Syrian
Route of admin. : oral feed
Exposure period : 20 weeks
Frequency of treatm. : Daily (via feed)
Post exposure period :
Doses : 1.5%
Result :
Control group : yes
Method :
Year :
GLP :
Test substance : other TS: > 99% purity

Remark : 15 and 10 animals/substance and control group respectively; purity: >99%; 0.9% NaCl twice s.c. (two week interval), then, from week 4, 1.5% resorcinol in feed for 16 weeks; control: 0.9% NaCl twice s.c. (two week interval); then basal diet.

Result : Body weight development significantly raised at end of study ($p < 0.05$), relative liver weight significantly reduced ($p < 0.001$), relative pancreas weight in range of control. Pancreas, liver and gall bladder showed no signs of neoplastic changes. In the forestomach and glandular stomach, the incidence of epithelial hyperplasia was higher, but neoplastic changes (papiloma, adenoma, carcinoma) did not occur.

Reliability : (2) valid with restrictions
26.05.2004

(83)

Species : hamster
Sex : female
Strain : other: Syrian
Route of admin. : oral feed
Exposure period : 20 weeks
Frequency of treatm. : Daily (via feed)
Post exposure period :
Doses : 1.5%
Result :
Control group : yes
Method :
Year :
GLP :
Test substance : other TS;purity>99.5%

Remark : 2-stage study of carcinogenesis: initiator: 70 mg N-nitrobis(2-oxopropyl)amine/kg body weight twice s.c. (two week interval), then, from week 4, 1.5% resorcinol in the feed for 16 weeks. Control: initiation with N-nitrobis(2-oxopropyl)amine, then basal diet; 20 animals/substance and control group respectively; purity: >99.5%.

Result : Body weight development and relative liver and pancreas weights in range of the control; lower, non-significant ($p < 0.05$) incidence of both pancreas adenomas and hyperplasia of the Ductus pancreaticus (63%) relative to control (94%); incidence of neoplastic changes in liver and gall bladder (tubercles, carcinomas, adenomas) in the range of the control. In the forestomach and glandular stomach, the incidence of epithelial hyperplasia was higher, but neoplastic changes (papiloma, adenoma, carcinoma) did not occur.

Reliability : (2) valid with restrictions
26.05.2004

(83)

5. Toxicity

Id 108-46-3
Date 15.06.2004

5.8.1 TOXICITY TO FERTILITY

Type : Two generation study
Species :
Sex :
Strain :
Route of admin. :
Exposure period :
Frequency of treatm. :
Premating exposure period :
 Male :
 Female :
Duration of test :
No. of generation studies :
Doses :
Control group :

Remark : The study is currently being conducted, according to US EPA OPPTS and OECD Guidelines. Anticipated date of report, January 2005
26.05.2004

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : female
Strain :
Route of admin. : dermal
Exposure period : 19 days
Frequency of treatm. : Days 1,4,7,10,13,16 and 19 of gestation
Duration of test :
Doses : 2 ml/kg
Control group : yes
Result : No embryotoxic or teratogenic effects.
Method :
Year : 1976
GLP : no data
Test substance :

Result : No biologically significant soft tissue or skeletal changes were noted. Similarly, the mean numbers of corpora lutea, implantation sites, live fetuses and resorptions per pregnancy, as well as the number of litters with resorptions were not significantly affected by the treatment.

Reliability : (2) valid with restrictions
26.05.2004 (15)

Species : rat
Sex : female
Strain :
Route of admin. : oral unspecified
Exposure period : 6-15 day of gestation
Frequency of treatm. : daily
Duration of test :
Doses : 40, 80, 250 mg/kg bw
Control group :
Result : No embryotoxic or teratogenic effects

Remark : 23 dams/dose; no detailed information of the maximum tolerable range.
Reliability : (2) valid with restrictions

5. Toxicity

Id 108-46-3
Date 15.06.2004

20.05.2004 (46)

Species : rat
Sex : female
Strain : Sprague-Dawley
Route of admin. : oral unspecified
Exposure period : 6-15 days of gestation
Frequency of treatm. : daily
Duration of test :
Doses : 125, 250, 500 mg/kg bw
Control group : yes
Result : No embryotoxic, foetotoxic or teratogenic effects
Method :
Year : 1985
GLP :
Test substance :

Remark : 13 dams/dose; high dose lay in the maximum tolerable range.
Reliability : (2) valid with restrictions

20.05.2004 (28)

Species : rabbit
Sex : female
Strain :
Route of admin. : oral unspecified
Exposure period : 6-18 day of gestation
Frequency of treatm. : daily
Duration of test :
Doses : 25, 50, 100 mg/kg bw
Control group : yes
Result : No embryotoxic, foetotoxic or teratogenic effects

Remark : 18-26 dams/dose; no detailed information of the maximum tolerable range.
Reliability : (2) valid with restrictions

20.05.2004 (46)

Species : rabbit
Sex : female
Strain :
Route of admin. : oral unspecified
Exposure period : 6-15 day of gestation
Frequency of treatm. : daily
Duration of test :
Doses : 0, 40, 80, 250 mg/kg bw
Control group : yes
Result : No evidence of embryotoxic or teratogenic effects

Reliability : (2) valid with restrictions

20.05.2004 (117)

Species : hen
Sex :
Strain : other: White Leghorn chick eggs
Route of admin. : other: applied to inner shell membrane
Exposure period :
Frequency of treatm. : only once
Duration of test :
Doses : 99, 198, 396, 804, µg/chick egg
Control group : yes

Remark : 5 µl of resorcinol (in acetone)/chicken egg were applied to the inner shell membrane of 3 day old chick embryos. 20-30 chick eggs/dose group; 10

Result : chick eggs/controlgroup (vehicle).
: Dose at which 50% of embryo died and/or malformed: ED50=264.3 µg/egg;
dose at which 50% of the embryo died: LD50=297.3 µg/egg; external signs
of malformation include: open coelom, wing and leg defects, oedema or
lymph vesicles.

Reliability : (2) valid with restrictions
26.05.2004 (71)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

Type of experience : Human

Remark : In three probands, dermal adsorption of resorcinol through the use of hair
dyes was investigated. Hair dyes that contained radioactivite labelled
resorcinol were distrubuted through the hair and over the scalp in
accordance with instructions for use. After an exposure time of 25-28 min,
the hair was rinsed, dried and cut off in order to prevent further adsorption.
Excretion of the radioactivity via the urine was then monitored for 144 h
max (collection initially after 4 h later 24 h): a total of 0.076% of the applied
radioactivity was excreted via the urine. A half life time for elimination via
the urine was calculated as being T1/2 = 31h. From data for elimination of
the radioactivity via the urine after 24 h, an absorption rate of 2.2×10^{-10}
mol/cm² x h (0.024 µg/cm² x h) was calculated. When the test for
elimination was also 31 h and a total of 0.177% of the applied radioactivity
was excreted via the urine within 7 days.

28.04.2004 (138)

5.11 ADDITIONAL REMARKS

Type : Immunotoxicity

Remark : Cell incubated with 1.1-11.0 µg resorcinol/ml for 2 days at 37°C

Result : Formulation of specific antibodies (IgM) in human-human hybrid HB4C5
cells was inhibite as a function of concentration. the relative growth rate
(cell proliferation) diminished as a function of concentration.

09.12.2003 (79)

Type : other: Nitrosation in vitro

Remark : Nitrosation of 10 mM proline in vitro (pH 2-5; 37°C, test duration: 15
minutes) was catalyzed as a functionof pH by 1 mM resorcinol (approx. 110
µg/ml)

Result : The optimum pH value for N-nitrosation was 2.5. The maximum catalytic
effect exerted by resorcinol was, however, produced at a pH of 4, at which
there was a 26 fold increase in the N-nitroproline formation compared to
the control.

09.12.2003 (99)

Type : other: Nitrosation in vitro

Result : In BD VI rats, oral application by gavage of 1 and 5 µmol resorcinol/animal

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(110 and 551 µg/animal respectively) led to increased formation of N-nitrosoproline relative to control (administration of proline only). Excretion of N-nitrosoproline via the urine within 24h of application increased as a function of concentration approx. 7 fold and 9 fold respectively. (99)

Type : other: kinetics

Remark : In the rat, resorcinol absorbed via the skin or the G.I tract. 90% of orally administered doses are excreted again within 24 h via the urine: 3% via the faeces, and 0.1% exhaled as CO₂. 50% of the dose excreted via the bile enters the enterohepatic circulation. More than 70% of the resorcinol excreted via the urine is present as the glucuronide or sulphate conjugate, with less than 5% present as free resorcinol. Repeated administration over 30d did not lead to storage or accumulation in tissues. The half-life time for elimination from plasma following subcutaneous application lay between 8.6 and 10.5 h. In humans, the adsorption rate via the skin was 0.37 µg/cm²/h. Also in humans the resorcinol excreted via the urine following dermal application (12 mg/kg body weight/day for 4 weeks (see section 5) is in the form of the glucuronide or the sulphate conjugate. No resorcinol could be detected in the blood.

20.05.2004 (12) (26) (40) (70) (88) (104) (140) (141)

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

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT