201-14623B

IUCLID

Data Set

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Existing Chemical	:	ID: 90-15-3
CAS No.	:	90-15-3
EINECS Name	:	1-naphthol
EC No.	:	201-969-4
Molecular Formula	:	C10H8O

Producer related part

Company	:	Bayer Corporation
Creation date	:	26.11.2002

Substance related part

Company	:	Bayer Corporation
Creation date	:	26.11.2002
Status	:	
Memo	:	Merged dataset ECB
Printing date	:	25.07.2003
Revision date	:	
Date of last update	:	23.07.2003
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Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	
Name	:	Bayer Corporation
Contact person	:	Cynthia Graham, Ph.D.
Date	:	
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Telex	:	
Cedex	:	
Email	:	
Homepage	:	

15.07.2003

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	
Smiles Code	:	Oc(c(c(ccc1)cc2)c1)c2
Molecular formula	:	C10 H8 O1
Molecular weight	:	144.17
Petrol class	:	

11.12.2002

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	typical for marketed substance
Substance type	:	organic
Physical status	:	solid
Purity	:	>= 99 - % w/w
Colour	:	5 gardner units, maximum
Odour	:	

14.07.2003

1.1.2 SPECTRA

Type of spectra : IR

Result : 6106 (Coblentz Society Spectral Collection)
11.04.2003 (1)

Type of spectra : UV

Result : 2045 (Sadtler Research Laboratories Spectral Collection)
11.04.2003 (1)

Type of spectra : NMR

Result : 5 (Sadtler Research Laboratories Spectral Collection)

11.04.2003 (1)

Type of spectra : mass spectrum

Result : 96 (Aldermaston, Eighht Peak Index of Mass Spectra, UK)
11.04.2003 (1)

Type of spectra : other: Max Absorption

Result : 292 NM, 308 NM, 322 NM (log E= 3.67, 3.52, 3.31)
11.04.2003 (2)

Type of spectra : other: Index of Refraction

Result : 1.9224 @ 99 degree C
11.04.2003 (3)

Type of spectra : other: Index of Refraction

Result : 1.6224 @99 degree C
11.04.2003 (2)

1.2 SYNONYMS AND TRADENAMES

1-Hydroxynaphthalene

16.06.1998

1-Naphthalenol

16.06.1998

1-Naphthol

11.12.2002

1-Naphthyl alcohol

30.08.1996

alpha-Hydroxynaphthalene

11.12.2002

alpha-Naphthol

11.12.2002

alpha-Naphthyl alcohol

11.12.2002

C.I. 76605

17.10.1998

C.I. Oxidation Base 33

15.04.1998

1.3 IMPURITIES

Purity	:	
CAS-No	:	135-19-3
EC-No	:	205-182-7
EINECS-Name	:	2-naphthol
Molecular formula	:	
Value	:	<= .5 % w/w

14.07.2003

1.4 ADDITIVES

1.7 USE PATTERN

Type of use	:	type
Category	:	Non dispersive use
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
15.07.2003		
Type of use	:	industrial
Category	:	Chemical industry: used in synthesis
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
15.07.2003		
Type of use	:	industrial
Category	:	other
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
15.07.2003		
Type of use	:	use
Category	:	Colouring agents
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
15.07.2003		
Type of use	:	use
Category	:	other: Hair Dyes
15.07.2003		
Type of use	:	use
Category	:	Intermediates
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
11.02.2000		
Type of use	:	use
Category	:	other: intermediate for coloring and pesticides; in profumeria; in tannery like antiputrescente for crude skins; like copulante in the color photograph; in pyrotechnics for smoked black.
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
02.07.2003		

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

Type : TSCA
Additional information :

11.12.2002

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

Type : degradation product in water
CAS-No : 83-72-7
EC-No : 201-496-3
EINECS-Name : 2-hydroxy-1,4-naphthoquinone
IUCLID Chapter :

02.07.2003

Type : degradation product in water
CAS-No : 481-39-0
EC-No : 207-567-5
EINECS-Name : 5-hydroxy-1,4-naphthoquinone
IUCLID Chapter :

02.07.2003

Type : degradation product in water
CAS-No : 524-42-5
EC-No : 208-360-2
EINECS-Name : 1,2-naphthoquinone
IUCLID Chapter :

02.07.2003

Type : degradation product in water
CAS-No : 130-15-4
EC-No : 204-977-6
EINECS-Name : 1,4-naphthoquinone
IUCLID Chapter :

02.07.2003

2.1 MELTING POINT

Value : 95 °C
Sublimation :
Method : other: Handbook value
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Reliability : (2) valid with restrictions
Data from Handbook or collection of data
Flag : Critical study for SIDS endpoint
15.07.2003 (4) (5)

Value : 96 °C
Sublimation :
Method : other: Handbook value
Year :
GLP : no
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Reliability : (2) valid with restrictions
Data from Handbook or collection of data
15.07.2003 (6)

Value : > 94 °C

Source : SCHWEIZERHALL Paris
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
27.05.2003

Value : ca. 95 - 96 °C
Decomposition : no,

Source : Schweizerhall Pharma GmbH Hamburg
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
27.05.2003

Value : 94.5 °C
Decomposition : no,
Sublimation : yes
Method :
Year :
GLP :
Test substance :

Source : CIRS SpA Cavanella Po-Adria
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
27.05.2003

2.2 BOILING POINT

Value : 288 °C at 1000 hPa
Decomposition :
Method : other: Handbook value
Year :
GLP : no data

Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Reliability : (2) valid with restrictions
Data from Handbook or collection of data

Flag : Critical study for SIDS endpoint
15.07.2003 (4) (5)

Value : ca. 278 - 280 °C at

Source : Schweizerhall Pharma GmbH Hamburg
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
27.10.1998

Value : 288 °C at

Source : CIRS SpA Cavanella Po-Adria
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
20.10.1998

2.3 DENSITY

Type : density
Value : 1.0954 g/cm3 at 37 °C
Method : other: Handbook value
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Reliability : (2) valid with restrictions
Data from Handbook or collection of data

Flag : Critical study for SIDS endpoint
15.07.2003 (5)

Type : density
Value : 1.0989 g/cm3 at 99 °C
Method : other: Handbook value
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Reliability : (2) valid with restrictions
Data from Handbook or collection of data
15.07.2003 (4)

Type : bulk density
Value : 1.224 g/cm3 at °C
Method :
Year :
GLP :
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Source : CIRS SpA Cavanella Po-Adria
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
15.01.2003

2.4 VAPOUR PRESSURE

Value	:	36 hPa at 25 °C
Decomposition	:	
Method	:	other (measured): Handbook value
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Reliability	:	(2) valid with restrictions Data from Handbook or collection of data
Flag	:	Critical study for SIDS endpoint

15.07.2003 (7) (8)

2.5 PARTITION COEFFICIENT

Partition coefficient	:	octanol-water
Log pow	:	3 at 23 °C
pH value	:	
Method	:	OECD Guide-line 107 "Partition Coefficient (n-octanol/water), Flask-shaking Method"
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction GLP guideline study
Flag	:	Critical study for SIDS endpoint

15.07.2003 (9)

Partition coefficient	:	octanol-water
Log pow	:	2.688 at 25 °C
pH value	:	
Method	:	other (calculated): KOWWIN Program (v1.65)
Year	:	
GLP	:	no
Test substance	:	other TS: molecular structure of 1-naphthol (CAS# 90-15-3)
Reliability	:	(2) valid with restrictions Accepted calculation method

15.01.2003 (10)

Partition coefficient	:	
Log pow	:	2.85 at °C
pH value	:	

11.04.2003 (11)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

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

Description	:	
Stable	:	
Deg. product	:	
Method	:	other: Handbook value
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Result	:	Solubility in: water = (1) insoluble ethanol = (4) very soluble acetone = (3) soluble ethyl ether = (4) very soluble
Reliability	:	(2) valid with restrictions Data from Handbook or collection of data
Flag	:	Critical study for SIDS endpoint

11.02.2003 (4)

Solubility in	:	Water
Value	:	at °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	not soluble
Stable	:	
Source	:	CIRS SpA Cavanella Po-Adria EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

03.11.1998

2.7 FLASH POINT

Value	:	153 °C
Type	:	
Method	:	other: Open cup
Year	:	
GLP	:	no data
Test substance	:	

11.12.2002 (12)

Value	:	148 °C
Type	:	
Source	:	CIRS SpA Cavanella Po-Adria EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

20.10.1998

2.8 AUTO FLAMMABILITY

Value	:	541.7 °C at
Method	:	other: no data
Year	:	
GLP	:	no data

Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

11.12.2002 (12)

2.12 DISSOCIATION CONSTANT

Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Result : pKa = 9.34 @ 25 degree C
11.04.2003 (13)

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
Conc. of substance	:	at 25 °C
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	50000000000 molecule/cm3
Rate constant	:	.0000000002 cm^3/(molecule*sec)
Degradation	:	50 - % after 1.9 hour(s)
Deg. product	:	
Method	:	other (calculated): SRC
Year	:	
GLP	:	no
Test substance	:	other TS: molecular structure of 1-naphthol (CAS# 90-15-3)
Reliability	:	(2) valid with restrictions Accepted calculation method
Flag	:	Critical study for SIDS endpoint

15.07.2003 (10)

Type	:	water
Light source	:	other: mercury lamp
Light spectrum	:	313 - 365 nm
Relative intensity	:	based on intensity of sunlight
DIRECT PHOTOLYSIS		
Halflife t1/2	:	29 minute(s)
Degradation	:	% after
Quantum yield	:	
Deg. product	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Remark	:	The pKa of 1-naphthol is 9.34 indicating that it is partially ionized in the environmentally relevant pH range (e.g., 10% at pH 8.34 and 1% at pH 7.34) and suggesting that 1-naphthol's fate may be pH dependent. The non-ionised (environmentally relevant) form of 1-Naphthol is subject to rapid photolysis. Generally the midday summer sunlight photolysis rates at the latitude of the laboratory (Urbana, IL) were approximately half of those determined under the conditions of the experiment.
Result	:	Photolysis experiments on 1-naphthol solutions (pH 7) in a photoreactor using a medium pressure mercury lamp and a pyrex filter (principally 313 and 365 nm radiation) resulted in a photolysis half-life of 29 min. In the presence of a riboflavin photosensitizer, the half-life dropped to 0.26 min.

15.07.2003 (14)

3.1.2 STABILITY IN WATER

Type	:	abiotic
Deg. product	:	yes
Method	:	
Year	:	
GLP	:	no data

Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Result : Dissolved oxygen promotes aqueous-phase oxidative transformation of 1-naphthol which is controlled by pH and ionic strength. The fraction of 1-napthol transformed is negligible below pH 6.5; increasing pH >7.0 and leveling of around pH 9.0.
Transformation increases significantly with ionic strength (i):
13.5% at pH 9.2 at i= 0.01M;
70% at pH 8.9 at i=0.1M.

Degradation products include:
2-hydroxy-1,4-naphthoquinone,
5-hydroxy-1,4-naphthoquinone,
1,2-naphthoquinone,
1,4-naphthoquinone.

In the absence of dissolved oxygen, 1-naphthol is stable at all solution conditions (pH and ionic strength).

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint

15.07.2003 (15) (16)

Type : biotic
Deg. product :
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Result : In an investigation of the fate of 1-naphthol in a simulated estuarine environment, it was found that 1-naphthol was unstable in this environment. Both the loss of 1-naphthol and the formation of CO2 was aided by microbial action and light, with simulated daylight having a greater effect than the lack of sterility.

Half-lives of 1-naphthol and its mineralization in an unsterile seawater system exposed to simulated sunlight were 7 and 9 days, respectively, whereas in the absence of light they were 15 and 23 days, respectively.

The loss of 1-naphthol from seawater was much faster in the presence of mud. This was thought to be due to adsorption and enhanced biodegradation due to increased populations of microorganisms in the mud. The rate of loss of radioactivity from 1-naphthol-1-14C was nearly the same in dark and light-exposed sterile tanks and this was also true with dark and light-exposed unsterile tanks where the half-life was 2.5 days. Additional experiments showed that 1-naphthol is relatively stable in a light-exposed, oxygen-free environment and that light-induced loss is a photo-oxidation process. In a sterile, light-exposed, oxygen-free environment, the concentration of 1-naphthol decreased 0.3%/day for 30 days. After the addition of oxygen, the rate of decrease rose to 1.6%/day for 40 days. Experiments performed at 16 C to determine the affect of pH on the stability of 1-naphthol found that 1-naphthol has optimum stability at pH 6.3 (7% loss in 21 days) and is unstable at pH 8.2, the pH of seawater. At pH 4.4 and 8.0, stability is considerably reduced from its optimum value and at pH 8.5 1-naphthol was completely degraded in 21 days. A reddish-blue precipitate formed in seawater which had a molecular weight of 454 and contained a stable free radical.

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint
27.05.2003 (17)

Type : abiotic
Deg. product :
Method :
Year :
GLP :
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Remark : 1-naphthol was stable in the dark in sterile seawater over a 3 day period, but was degraded to undetectable levels in 96 hr in raw seawater. Under artificial sunlight, 1-naphthol was completely degraded after 2 hr. In studies in which 1-naphthol was added to filtered seawater adjusted to pH 6.5 and maintained at 16-18 C, there was a decline in 1-naphthol concentration. The percent decrease was greater at higher 1-naphthol concentrations with a 10.8% decline in 24 hr at 4.63 mg/L and 22% in 24 hr at 43.07 mg/L. There was no difference in the decrease when the tanks were kept in the dark. It was believed that the loss was a result of biodegradation.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
Flag : Critical study for SIDS endpoint
27.05.2003 (18) (19)

Type : abiotic
t1/2 pH7 : 11.6 - 12.5 day(s) at 25 °C
t1/2 pH9 : 3.2 hour(s) at 25 °C
t1/2 pH 5 : > 30 day(s) at 25 °C
Degradation : 100 % after 24 hour(s) at pH 9 and 25 °C
Deg. product : yes
Method : other: US EPA - FIFRA, 40 CFR, Sec.158.130; ABC Guideline N-161-1
Year :
GLP : no data
Test substance : other TS: radio-labeled Carbaryl (63-25-2); purity > 99%

Result : The only degradation product of significance was 1-naphthol, accounting for 76-78% of the activity at pH 7.0 after 30 days. Carbaryl had been entirely converted to 1-naphthol at pH 9.0 after 24 hours.
Reliability : (1) valid without restriction
Guideline study
27.05.2003 (20)

3.1.3 STABILITY IN SOIL

Type : other
Radiolabel :
Concentration : 500 mg/kg
Soil temperature : °C
Soil humidity :
Soil classification :
Year :

Result : t(1/2) degradation in soil = 0.9 day
15.07.2003 (21)

3.2.1 MONITORING DATA

Type of measurement : other: in sediments (India)
Media : sediment
Concentration : .279 - .466 mg/l
Method :

Remark : Carbaryl was produced in India for more than a decade.
02.07.2003 (22)

Type of measurement : other: industry effluents in United States
Media :
Concentration : -

Result : 3.923 mg/l (timber products);
0.137 mg/l (printing and publishing);
0.235 mg/l (organic chemicals)
02.07.2003 (23)

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media : other: air - water - soil - sediment
Method : other
Year :

Remark : Modeling was performed using equal releases (1,000 kg/hr) and equal distribution to all compartments.

Result :
Chem Name : 1-Naphthalenol
Molecular Wt: 144.17
Henry's LC : 5.7e-008 atm-m3/mole (Henry database)
Vapor Press : 0.000693 mm Hg (Mpbpwin program)
Liquid VP : 0.00183 mm Hg (super-cooled)
Melting Pt : 67.7 deg C (Mpbpwin program)
Log Kow : 2.85 (Kowwin program)
Soil Koc : 290 (calc by model)

	Concentration percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0744	0.467	1000
Water	39.8	360	1000
Soil	59.8	360	1000
Sediment	0.343	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.1e-012	966	6.51	32.2	0.217
Water	6.89e-013	671	349	22.4	11.6
Soil	1.58e-012	1.01e+003	0	33.5	0
Sediment	3.73e-013	1.45	0.0601	0.0482	0.002

Persistence Time: 292 hr
Reaction Time: 331 hr
Advection Time: 2.46e+003 hr
Percent Reacted: 88.2
Percent Advected: 11.8

Reliability : (2) valid with restrictions
Accepted calculation method

Flag : Critical study for SIDS endpoint
15.07.2003 (10)

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge
Contact time	:	14 day(s)
Degradation	:	96 (±) % after 14 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	Directive 92/69/EEC, C.4-F
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	In a 2-week biodegradation screening test (MITI test) using 1-naphthol (30 ppm) and an activated sludge innoculum, 96% of theoretical BOD was removed.
Test condition	:	Concentration of activated sludge (as concentration of suspended solid) = 30 mg/l Volume of test substance = 300 ml
Reliability	:	(1) valid without restriction Guideline study
Flag	:	Critical study for SIDS endpoint

15.07.2003 (24)

Type	:	aerobic
Inoculum	:	activated sludge, domestic, adapted
Concentration	:	200 mg/l related to COD (Chemical Oxygen Demand) related to
Contact time	:	20 day(s)
Degradation	:	92.1 (±) % after 20 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Method	:	The test substance was dissolved in a biological medium in a beaker at a concentration corresponding to 200 mg/l COD. The tested substance was the sole source of organic carbon for the microbes of the inoculum. To the biological medium, thickened adapted activated sludge was added so that the concentration of dry matter was 100 mg/l. A blank and positive standard was prepared. Initial values of COD or organic carbon of the liquid phase was determined. The beakers were then placed in a dark room with a temperature of 20 +/-3 degree C on magnetic stirrers. At 24 hours and daily intervals up to 20 days, 50-80 ml of the sample was removed for analysis. The analysis was carried out until there is no further decrease of COD. The total percentage COD and rate of degradation was determined.
Result	:	Rate of biodegradation = 38.4 mg COD/g inoculum/hr
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

27.05.2003 (25)

Type	:	aerobic
Inoculum	:	activated sludge
Contact time	:	
Degradation	:	- (±) % after
Result	:	readily biodegradable

Kinetic of testsubst.	:	10 day(s) 60 % 28 day(s) 82 %
Deg. product	:	
Method	:	other: similar to the MITI test but using an activated sludge innoculum
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted

27.05.2003 (26)

3.6 BOD5, COD OR BOD5/COD RATIO

BOD5		
Method	:	ISO 5815 "Water quality - Determination of biochemical oxygen demand after 5 days (BOD5) - Dilution and seeding method"
Year	:	1955
Concentration	:	related to
BOD5	:	mg/l
GLP	:	no
Result	:	BOD5 of alpha naphthol was 1.69 and 1.75 g/g

15.07.2003 (27) (28)

3.7 BIOACCUMULATION

Species	:	other
Exposure period	:	at °C
Concentration	:	
BCF	:	31.22
Elimination	:	
Method	:	other: BCF Program (v2.13)
Year	:	
GLP	:	no
Test substance	:	other TS: molecular structure of 1-naphthol (CAS# 90-15-3)
Reliability	:	(2) valid with restrictions Accepted calculation method

15.07.2003 (10)

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	semistatic
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
NOEC	:	< .46
LC50	:	.75
Limit test	:	
Analytical monitoring	:	yes
Method	:	EPA OPP 72-1
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Test condition	:	Juvenile bluegill sunfish (Lepomis macrochirus) with a mean body weight of 0.26 g and a mean length of 3.0 cm were used for this study. The fish were not fed 48 hr before the test period and the fish load in the test aquaria was 0.17 g/L. The toxicity test was conducted under semi-static conditions in 18.9 L glass aquaria containing 15 L test solution. The dilution water was reconstituted deionised water with a total hardness and alkalinity of 49 and 29 mg/L as CaCO3, pH 7.5 and a specific conductivity of 200 µmhos/cm. During the test the test solutions were not aerated and the light cycle was 16 hours light/8 hours dark. A stock solution in acetone (8.0 mg/ml) was prepared and then added in appropriate quantities to the dilution water. The test solutions were renewed by freshly prepared solutions 48 hours after initiation of the study. Ten fish were exposed to mean measured concentrations of 0 (negative control), 0 (solvent control (0.5ml/L), 0.46, 0.73, 1.4, 2.3 and 4.4 mg/L dilution water for a 96-hour period. The fish were examined daily for signs of intoxication and mortality, and the mortality rate was used to calculate the 24, 48, 72 and 96 hour LC50 values. The dissolved oxygen, pH and temperature were measured throughout the study. Freshly prepared and 48-hour old test solutions were analysed for 1-naphthol. The mean measured concentrations refer to means of freshly prepared (0 and 48-h) and terminal 48-h old test solutions.
Reliability	:	(1) valid without restriction GLP guideline study
Flag	:	Critical study for SIDS endpoint

15.07.2003 (29)

Type	:	semistatic
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
NOEC	:	.72
LC50	:	1.6
Limit test	:	
Analytical monitoring	:	yes
Method	:	EPA OPP 72-1
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Test condition	:	Juvenile rainbow trout (Oncorhynchus mykiss) with a mean body weight of 1.10 g and a mean length of 4.7 cm were used for this study. The fish were not fed 24 h before the test period and the fish load in the test aquaria was 0.73 g/L.

The toxicity test was conducted under semi-static conditions in 19.6 L glass aquaria containing 15 L test solution. The dilution water was reconstituted deionised water with a total hardness and alkalinity of 49 and 33 mg/L as CaCO3, a pH of 7.5 and a specific conductivity of 260 µmhos/cm. During the study the test solutions were not aerated and the light cycle was 16 hrs light/8 hours dark.
A stock solution in acetone (6.6 mg/ml) was prepared and then added in appropriate quantities to the dilution water. The test solutions were renewed by freshly prepared solutions 48 hours after initiation of the study. Ten fish were exposed to mean measured concentrations of 0 (negative control), 0 (solvent control (0.5 ml/L), 0.42, 0.72, 1.2, 2.1 and 3.5 mg/L dilution water for a 96-hour period. The fish were examined daily for signs of intoxication and mortality, and the mortality rate was used to calculate the 24, 48, 72 and 96 hour LC50 values.
The dissolved oxygen, pH and temperature were measured throughout the study. Freshly prepared and 48-hour old test solutions were analysed for alpha-naphthol. The mean measured concentrations refer to the means of freshly prepared (0 and 48 h) test solutions.

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint
15.07.2003 (30)

Type : semistatic
Species : Cyprinodon variegatus (Fish, estuary, marine)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : .89
LC50 : 1.8
Limit test :
Analytical monitoring : yes
Method : EPA OPP 72-1
Year :
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Test condition : Juvenile sheepshead minnow (Cyprinodon variegatus) with a mean body weight of 0.17 g and a mean length of 1.9 cm were used for this study. The fish were not fed 48 h before the test period and the fish load in the test aquaria was 0.11 g/L.
The toxicity test was conducted under semi-static conditions in 18.9 L glass aquaria containing 15 L test solution. The dilution water was filtered natural seawater with a salinity of 32 °/°° and a pH of 7.9. During the test the test solutions were not aerated and the light cycle was 16 hours light/8 hours dark.
A stock solution in acetone (8.0 mg/ml) was prepared and then added in appropriate quantities to the dilution water. The test solutions were renewed by freshly prepared solutions 48 hours after initiation of the study. Ten fish were exposed to mean measured concentrations of 0 (negative control), 0 (solvent control (0.5ml/L), 0.52, 0.89, 1.4, 2.4 and 4.1 mg/L dilution water for a 96-hour period. The fish were examined daily for signs of intoxication and mortality, and the mortality rate was used to calculate the 24, 48, 72 and 96 hour LC50 values.
The dissolved oxygen, pH and temperature were measured throughout the study. Freshly prepared and 48-hour old test solutions were analysed for 1-naphthol. The mean measured concentrations refer to means of freshly prepared test solutions.

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint
15.07.2003 (31)

Type : flow through
Species : Pimephales promelas (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : 4.24
Limit test :
Analytical monitoring : yes
Method : EPA OTS 797.1400
Year :
GLP : no data
Test substance : other TS: 1-naphthol; purity > 99%

Result :

Exposure Period	LC50	(range)
24 hr	7.01 mg/l	(6.74-7.30)mg/l
48 hr	4.33 mg/l	(3.29-5.71)mg/l
72 hr	4.24 mg/l	(4.12-4.37)mg/l
96 hr	4.24 mg/l	(4.12-4.37)mg/l

Toxic effexcts observed:
some loss of equilibrium at =/> 5.71 mg/l
hyperactivity at =/> 9.36 mg/l

Test condition : dissolved oxygen 7.4 (4.6-8.8) mg/l; water hardness 44.9 (42.4-46.6) mg/l as CaCO3; pH 6.9-7.7; alkalinity 42.9 (39.6-61.4) mg/l CaCO3; temp 26.4 +/- 1.4 deg C
Reliability : (1) valid without restriction
Guideline study

15.07.2003 (32) (33)

Type : flow through
Species : other: Catla catla, Mystus vittatas, Mystus cavasius, Anabas testutus
Exposure period :
Unit :
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Method : According to: Methods for Acute Toxicity Tests with fish, macroinvertebrates and amphibians. Committee on methods for toxicity test with aquatic organisims, EPA, Oregon. 1975.
Standard solutions were prepared in acetone to yield a concentrtion of 100 mg/ml. Controls received an equal quantity of acetone.
Each experiment repeated three times.
LC50 values calculated by unweighted regression method of Probit analysis.

Result :

Species	LC50	95% conf limit
Catla catla	4.3 ppm	4.2 - 4.4 ppm
Mystus vittatas	1.1 ppm	0.9 - 1.4 ppm
M. cavasius	0.33 ppm	0.25 - 0.4 ppm
Anabas testutus	3.0 ppm	2.7 - 3.4 ppm

Reliability : (1) valid without restriction
Guideline study

27.05.2003 (34)

Type : flow through
Species : other: Labeo rohita
Exposure period : 96 hour(s)
Unit :
Limit test :
Analytical monitoring : yes
Method :
Year :
GLP : no data

Test substance : other TS: 1-Naphthol (CAS 90-15-3); analytical grade

Method : According to: Methods for Acute Toxicity Tests with fish, macroinvertebrates and amphibians. Committee on methods for toxicity test with aquatic organisims, EPA, Oregon. 1975.
Standard solutions were prepared in acetone to yield a concentrtion of 100 mg/ml. Controls received an equal quantity of acetone.
Each experiment repeated three times.
LC50 values calculated by unweighted regression method of Probit analysis.

Result :

Size (wt) of fish	LC 50	95% conf. limit
1-2.5 cm (0.5g)	2.6 ppm	1.8 - 3.8 ppm
4-6 cm (4.5g)	3.13 ppm	3.0 - 3.3 ppm

Reliability : (1) valid without restriction
Guideline study

15.07.2003 (35)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type :
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : 1.8
EC50 : 3.53
Analytical monitoring : yes
Method : OECD Guide-line 202
Year :
GLP : yes
Test substance : other TS: 1-naphthol (95.7% purity)

Result : No immobilization nor toxic effects were observed in the untreated control, the solvent control and daphnids exposed to 1.0 and 1.8 mg/l. Behavioral abnormalities were observed at 5.6 mg/l after 24 hours and 3.2 mg/l after 48 hours exposure. These observations included abnormal swimming, swimming at the bottom and retarded reaction. Immobilization of 35, 100, and 100% was observed in daphnids exposed over 48 hours to concentrations of 3.2, 5.6 and 10 mg/l respectively.
The EC50 (48 hours) was calculated at 3.53 mg 1-naphthol/l, with 95% confidence limits of 3.2 and 5.6 mg/l.

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint

15.07.2003 (36)

Type : static
Species : Mysidopsis bahia (Crustacea)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : .06
LC50 : .2
Analytical monitoring : yes
Method : EPA OPPTS 850.1035
Year :
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint

15.07.2003 (37)

Type	:	
Species	:	other aquatic mollusc: Crassostrea virginica
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC50	:	2.1
Analytical monitoring	:	yes
Method	:	EPA OPPTS 850.1055
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Results are based on the measured concentrations of a-naphthol. The EC50 and 95% confidence limits were calculated by linear regression analysis. EC50 = 2.1 mg/l (1.1 - 3.1 mg/l)
Test condition	:	Test water: filtered (5um) natural seawater Salinity: 32 0/oo Test temperature: 20 degree C Nominal concentrations: 5.0, 3.0, 1.8, 1.1, 0.65 mg/l Measured Concentrations: 5.0, 3.0, 1.7, 0.93, 0.49 mg/l
Reliability	:	(1) valid without restriction Guideline study

15.07.2003 (38)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Chlorella vulgaris (Algae)
Endpoint	:	biomass
Exposure period	:	20 day(s)
Unit	:	mg/l
EC50	:	20 - 50
Limit test	:	
Analytical monitoring	:	no data
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Method	:	The unicellular green alga, Chlorella vulgaris, was maintained in Bold's basal medium. Stock solutions of 1-naphthol was prepared in acetone. Aliquots were dispensed into sterilized test-tubes to provide concentrations of 0, 5, 20, and 50 ug 1-naphthol/ml. After complete evaporation of the carrier solvent, 20 ml of culture medium were added to the tubes. After equilibrium, tubes were inoculated with exponentially growing cultures and incubated at 28 +/- 4 degree C in a growth chamber in a slanted position under continuous illumination. Each concentration was replicated five times. After 20 days, the samples were withdrawn for growth determination.
Result	:	Values (+/- SD) represent actual % inhibition in relation to controls. Negative values indicate % increase.

Concentration (mg/l)	% inhibition (+/-SD)
CELL NUMBER	
5	-3.59 (+/- 0.02)
20	19.84 (+/- 0.06)
50	68.54 (+/- 0.02)

CHLOROPHYLL-a SYNTHESIS

5	6.91 (+/- 0.30)
20	37.79 (+/- 1.12)
50	79.26 (+/- 0.60)

TOTAL PROTEIN

5	-5.64 (+/- 0.08)
20	1.36 (+/- 0.03)
50	71.79 (+/- 0.61)

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint

27.05.2003 (39)

Species : other algae: Nostoc linckia
Endpoint : other: Chlorophyll synthesis
Exposure period : 20 day(s)
Unit : mg/l
EC50 : > 20
Limit test :
Analytical monitoring : no
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Method : The nitrogen-fixing cyanobacterium, Nostoc linckia, was maintained in modified nitrogen-free Chu-10 medium supplemented with trace elements. Stock solutions of 1-naphthol was prepared in acetone. Aliquots were dispensed into sterilized test-tubes to provide concentrations of 0, 5, 10, and 20 ug 1-naphthol/ml. After complete evaporation of the carrier solvent, 20 ml of culture medium were added to the tubes. After equilibrium, tubes were inoculated with exponentially growing cultures and incubated at 28 +/- 4 degree C in a growth chamber in a slanted position under continuous illumination. Each concentration was replicated five times. After 20 days, the samples were withdrawn for growth determination.

Result : Values (+/- SD) represent actual % inhibition in relation to controls. Negative values indicate % increase.

Concentration (mg/l)	% inhibition (+/-SD)
CHLOROPHYLL-a SYNTHESIS	
5	-9.48 (+/- 0.05)
10	-0.81 (+/- 0.01)
20	2.44 (+/- 0.03)
NITROGEN-FIXING ACTIVITY	
5	-38.99 (+/- 0.02)
10	1.38 (+/- 0.03)
20	13.76 (+/- 0.43)

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (39)

Species : other algae: Synechococcus elongatus
Endpoint : biomass
Exposure period : 20 day(s)
Unit : mg/l
EC50 : 2 - 5
Method :

Year :
GLP :
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

Method : The unicellular cyanobacterium, Synechococcus elongatus, was maintained in Bold's basal medium. Stock solutions of 1-naphthol was prepared in acetone. Aliquots were dispensed into sterilized test-tubes to provide concentrations of 0, 0.5, 2.0, and 5.0 ug 1-naphthol/ml. After complete evaporation of the carrier solvent, 20 ml of culture medium were added to the tubes. After equilibrium, tubes were inoculated with exponentially growing cultures and incubated at 28 +/- 4 degree C in a growth chamber in a slanted position under continuous illumination. Each concentration was replicated five times. After 20 days, the samples were withdrawn for growth determination.

Result : Values (+/- SD) represent actual % inhibition in relation to controls. Negative values indicate % increase.

Concentration (mg/l)	% inhibition (+/-SD)
CELL NUMBER	
0.5	0.66 (+/- 0.01)
2.0	35.54 (+/- 0.31)
5.0	100.00
CHLOROPHYLL a SYNTHESIS	
0.5	-3.76 (+/- 0.09)
2.0	31.18 (+/- 0.14)
5.0	100.00
TOTAL PROTEIN	
0.5	-1.62 (+/- 0.02)
2.0	26.67 (+/- 0.07)
5.0	100.00

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (39)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type :
Species : Photobacterium phosphoreum (Bacteria)
Exposure period : 5 minute(s)
Unit : mg/l
EC50 : 3.71 - 5.61

02.07.2003 (40)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : other: immobilization
Exposure period : 21 day(s)
Unit : mg/l
EC50 : > 1
Analytical monitoring : yes
Method : OECD Guide-line 211

Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	After 21 days, immobilization did not exceed 40% in any exposed group. Therefore the 21-day EC50 for immobilization was estimated to be greater than 1.0 mg/l, the highest concentration tested.
Reliability	:	(1) valid without restriction GLP guideline study

15.07.2003 (41)

Species	:	Daphnia magna (Crustacea)
Endpoint	:	reproduction rate
Exposure period	:	
Unit	:	mg/l
NOEC	:	.25
LCEC	:	.5
MATC	:	.38
Analytical monitoring	:	yes
Method	:	OECD Guide-line 211
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Consistent and statistically significant effects on reproductive performance and growth were observed at the nominal concentrations of 0.5 and 1.0 mg/l. No significant effects were observed at lower concentrations. The maximum acceptable toxicant concentration (MATC) as the geometric mean between NOEC and LOEC, was calculated at 0.38 mg/l (nominal).
Reliability	:	(1) valid without restriction GLP guideline study

15.07.2003 (41)

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

Species	:	Chironomus
Endpoint	:	
Exposure period	:	24 other: hours
Unit	:	other: mg/l
LC50	:	1.3
EC50	:	1.3
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The effects of temperature, pH, sediment and humic acid on the toxicity and fate of 1-naphthol to the midge larvae, Chironomus riparius, were determined in static 24 hr toxicity tests. Partitioning of (14)C-1-naphthol in systems identical to the toxicity test was examined to determine if results were supported by physical chemical measurements.
Result	:	EC50 (24 h, static) midge (Chironomus thummi) = 2.1 mg/l (active ingred.); 1.3 mg/l (commercial formulation). In general, 1-naphthol toxicity increased with increasing temperature. Changes in pH did not affect toxicity except at pH 8 where 1-naphthol was more toxic to the midge at 10 and 20 deg C than at pH 4 or 6. In addition, there was no temperature effect at pH 8 as naphthol was equitoxic at all temperatures. The presence of sediment reduced toxicity in the temperate range (20-30 deg C) while humic acid had no effect on toxicity at any

temperature. Partitioning data did not always support toxicity results, illustrating the importance of coupling bioassays with physical chemical studies when evaluating water soluble chemicals.

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

15.07.2003 (42) (32) (43)

Species : other: Littorina littorea
Endpoint :
Exposure period : 96 other: hours
Unit : other: mg/l
LC50 : 23.07
Method :
Year :
GLP :
Test substance : as prescribed by 1.1 - 1.4

15.07.2003 (44)

Species : other: Scrobicularia plana
Endpoint :
Exposure period : 15 other: days
Unit : other: mg/l
LT 50 : 5

02.07.2003 (45)

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

Type : artificial soil
Species : Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint : mortality
Exposure period : 14 day(s)
Unit : mg/kg soil dw
NOEC : 316
LC50 : 472
Method : other: OECD Guideline 207 and EU Guideline 92/69/EWG
Year :
GLP : yes
Test substance : other TS: 1-naphthol (95.7% w/w purity)

Result : Mortality of 0, 0, 10% was observed in the control, 316 and 422 mg/kg groups, respectively. 100% mortality occurred at 563 mg/kg and above. The mean weight change of the surviving worms was not statistically significant at 316 and 422 mg/kg. No symptoms of intoxiction were observed in surviving worms at any treatment level after 7 and 14 days exopsure.
The LC50 after 7 and 14 days exposure was determined to be 472 mg 1-naphthol/kg artificial soil. The 95% confidence limits were estimated at 422 - 563 mg/kg.

Reliability : (1) valid without restriction
GLP guideline study

15.07.2003 (46)

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	1870 mg/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	male
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	The test substance was administered by stomach intubation to non-fasted male albino Harlan-Wistar rats.
Result	:	The observed LD50 was 2.38 (1.56 to 3.65) g/kg, and 1.87 (1.27 to 2.76) g/kg for young and older adult rats, respectively. No further information was submitted.
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint

15.07.2003 (32) (47)

Type	:	LD50
Value	:	1000 - 2000 mg/kg bw
Species	:	mouse
Strain	:	CD-1
Sex	:	male/female
Number of animals	:	4
Vehicle	:	other: propane-1,2-diol-water solution (1:1 v/v)
Doses	:	500, 1000, 2000 mg/kg bw
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: as prescribed by 1.1 - 1.4; purchased from Sigma Chemical, UK
Method	:	Two male and two female mice were dose orally at 500, 1000, and 2000 mg/kg bw. Controls included undosed and vehicle-dosed groups. Animals were observed for clinical signs and mortality for up to 14 days post dosing. All surviving mice were subjected to a full post mortem exam. Blood was examined for chemistry and hematolgy parameters and tissues were examined by standard histopathological methods.
Result	:	Mice in the 2000 mg/kg dose group developed abnormal respiration and tremors and were killed "in extremis" between 15 and 90 minutes post dosing. Animals in the 1000 mg/kg dose group showed subdued behavior with piloerection, but recovered and survived until the end of the study (14 days). One male in the 500 mg/kg group was killed "in extremis" 2 hours after dosing. Other animals in the low dose group showed subdued behavior, labored respiration, and piloerection but recovered and survived until the end of the study. There were no differences in the hematology or chemistry data obtained in the treated and control groups. Histopathological changes, considered to be treatment-related, were seen in the kidneys and stomachs of all treatment groups.
Reliability	:	(2) valid with restrictions

Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint

15.07.2003 (48)

Type : LD50
Value : 2400 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : Directive 84/449/EEC, B.1 "Acute toxicity (oral)"
Year :
GLP : no data
Test substance : no data

Source : CIRS SpA Cavanella Po-Adria
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (2) valid with restrictions
Guideline study

Flag : Critical study for SIDS endpoint

09.01.2003

Type : other: Approximate lethal dose (ALD)
Value : 1000 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle : peanut oil
Doses :

Method : The test substance was evaluated for acute oral toxicity. The test substance was administered as a 50% solution in peanut oil.

Result : Rats receiving lethal doses suffered from diarrhea and died within 18 hours after treatment. Pathological examination indicated congestion and edema of the lungs; albumin in the kidney tubules; and superficial necrosis of the stomach. The approximate lethal dose (ALD) was calculated to be 1000 mg/kg.

27.05.2003 (32) (49)

Type : LD50
Value : 1700 - 3300 mg/kg bw
Species : rat
Strain : Wistar
Sex : no data
Number of animals :
Vehicle :
Doses :
Method :
Year :
GLP :
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted

15.07.2003 (50)

Type : LD50
Value : 2590 mg/kg bw
Species : rat
Strain : Wistar

Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted

27.05.2003 (51)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	LC50
Value	:	> 97 mg/m3
Species	:	rat
Strain	:	Wistar
Sex	:	female
Number of animals	:	6
Vehicle	:	other: none
Doses	:	97 mg/m3
Exposure time	:	4 hour(s)
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Dust was generated using a Wright Dust Feed-Through with an airflow of 19 liters/min at 5 psi. Dust was delivered to a 120 liter Plexiglas chamber containing 6 animals. Concentrations were measured gravimetrically every 30 minutes. Temperature of the chamber was 24 degree C.
Result	:	No deaths occurred, but signs of toxicity included eye irritation, salivation and ataxia.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

15.07.2003 (52)

Type	:	LC0
Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	6
Vehicle	:	other: none
Doses	:	Saturated atmosphere of chemical vapor
Exposure time	:	6 hour(s)
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Substantially saturated vapor was prepared by spreading 50 to 100 grams of 1-naphthol over a 200 cm2 area on a shallow tray placed near the top of a 120 liter plexiglas chamber which is then sealed for at least 16 hours while an intermittently operated fan agitates the internal chamber atmosphere. Rats were then introduced into a gasketed drawer-type cage designed and operated to minimize vapor loss. Animals were exposed for six (6) hours and observed for mortality and toxicity for 14 days.

Result : There was no mortality or signs of toxicity when rats were exposed to a saturated vapor atmsophere of 1-naphthol for 6 hours.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

15.07.2003 (53)

Type : LC50
Value :
Species : rat
Strain :
Sex :
Number of animals : 6
Vehicle : other: none
Doses : saturated atmosphere of mist, vapor and decomposition products
Exposure time : 6 hour(s)
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted; heated to 179 degree C

Method : 1-naphthol was heated to 179 degree C. Air was passed over the heated sample and mist, vapor, and any oxidation products generated were delivered to rats in a 9 liter glass exposure chamber. Animals were exposed for six (6) hours. Animals were observed for mortality and toxicity for 14 days.
Result : There was no mortality when rats were exposed to a saturated vapor atmsophere of heated 1-naphthol for 6 hours; signs of toxicity included eye irritation and hypoactivity.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

07.01.2003 (53)

Type : LC0
Value : > 420 mg/m3
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Exposure time : 1 hour(s)
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Result : TOXIC EFFECTS: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste) - Lacrimation
Gastrointestinal - Changes in structure or function of salivary glands.

15.07.2003 (54) (55)

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : > 10000 mg/kg bw
Species : rabbit
Strain :

Sex	:	
Number of animals	:	5
Vehicle	:	
Doses	:	10000 mg/kg
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	1-Naphthol (CAS # 90-15-3) was evaluated for acute dermal toxicity. The test substance was administered to 5 albino rabbits at a dosage of 10,000 mg/kg.
Result	:	No mortality and no signs of intoxication occurred. Dermal irritation consisted of moderate erythema and edema. Gross autopsy revealed no significant findings.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

15.07.2003 (32) (56)

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	500 mg
Exposure	:	Occlusive
Exposure time	:	24 hour(s)
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	highly irritating
Classification	:	
Method	:	Draize Test
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Reliability	:	(1) valid without restriction Guideline study

15.07.2003 (54) (55)

Species	:	rabbit
Concentration	:	500 mg
Exposure	:	
Exposure time	:	
Number of animals	:	6
Vehicle	:	
PDII	:	
Result	:	highly irritating
Classification	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	1-Naphthol (CAS # 90-15-3) was evaluated for primary dermal irritation. The test substance was administered at a dosage of 500 mg to the intact and abraded skin of 6 albino rabbits. Moderate to severe erythema and edema was noted after 72 hours (irritation score of 7.09/8.00).
Reliability	:	(2) valid with restrictions

Meets generally accepted scientific method and is described in sufficient detail

15.07.2003 (32) (56)

Species	:	rabbit
Concentration	:	550 mg
Exposure	:	Open
Exposure time	:	24 hour(s)
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	moderately irritating
Classification	:	
Method	:	Draize Test
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction Guideline study

15.07.2003 (55) (57)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	100 mg
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	6
Vehicle	:	
Result	:	moderately irritating
Classification	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Slight to moderate effects of the cornea, iris, and conjunctivae were noted (irritation score of 61.7/110).
Reliability	:	(2) valid with restrictions

15.07.2003 (32) (56)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Result	:	1-Naphthol on the surface of rabbit eyes is irritating, causing damage (graded 9 on a scale of 1 to 10) and scarring of cornea and conjunctiva.
Reliability	:	(4) not assignable

Secondary literature

11.02.2003 (58) (32)

5.3 SENSITIZATION

Type	:	Guinea pig maximization test
Species	:	guinea pig
Concentration	:	1st: Induction .1 % intracutaneous 2nd: Induction .1 % occlusive epicutaneous 3rd: Challenge .1 % occlusive epicutaneous
Number of animals	:	
Vehicle	:	
Result	:	not sensitizing
Classification	:	
Method	:	other: Guinea pig maximization test
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Method	:	Maximization test; 3 x 0.1 ml intradermal injection of 1:1 naphthol (0.1%) and FCA; 2nd induction 1 week later (0.1 % 1-naphthol under occlusion; challenge 1 week later with dermal application of 0.1% or 0.05% for 48 hrs.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (59)

Type	:	Open epicutaneous test
Species	:	guinea pig
Concentration	:	1st: Induction 3 % open epicutaneous 2nd: 3rd:
Number of animals	:	
Vehicle	:	
Result	:	not sensitizing
Classification	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted
Method	:	Open epicutaneous method; induction 3% 6 days/week for 3 weeks, challenge 2 weeks later single exposure.

07.01.2003 (60)

5.4 REPEATED DOSE TOXICITY

Type	:	Sub-chronic
Species	:	rat
Sex	:	male/female
Strain	:	other: Crl:CD(SD)BR VAF/Plus
Route of admin.	:	gavage
Exposure period	:	13 weeks
Frequency of treatm.	:	daily
Post exposure period	:	1 week
Doses	:	0, 65, 130, or 400 mg/kg bw
Control group	:	yes, concurrent vehicle
NOAEL	:	130 mg/kg bw

Method : OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
Year : 1981
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Male and female Crl:CD®(SD)BR VAF/Plus® rats were assigned to eight groups (15 animals/sex/group in Groups 1 through 4 and five animals/sex/group in Groups 5 through 8). Each group received dose preparations containing the control material or 65, 130, or 400 mg of RE1141.03/kg of body weight/day (mg/kg/day) at a dose volume of 10 mL/kg.
Food was provided ad libitum, except when animals were fasted. Water was provided ad libitum. The animals were observed twice daily (a.m. and p.m.) for mortality and
moribundity.
During Weeks 1 through 4, each animal in Groups 1 through 4 was observed four times/day. At least once each week, each animal in Groups 1 through 4 was observed in its cage then removed from its cage and examined for, but not limited to, changes in skin, fur, eyes, and mucous membranes; respiratory, circulatory, autonomical, and central nervous systems; somatomotor activity; and behavior patterns; and abnormalities and signs of toxicity. Once during Week 13, each animal in Groups 1 through 4 was observed upon removal from its cage, for approximately 2 minutes in an open field, and in response to battery of elicited behaviors. Body weights were recorded for each animal on receipt, on the first day of treatment, and weekly thereafter. Food consumption data were collected weekly for animals in Groups 1 through 4. Ophthalmic examinations were done before initiation of treatment and during Week 13 for animals in Groups 1 through 4. Vaginal smears were done daily for the females to evaluate the stage of the estrous cycle starting at Week 10 and continuing through treatment.
On Day 7 (animals in Groups 5 through 8) and once during Weeks 4 and 14 (animals in Groups 1 through 4), blood and urine samples were collected for hematology, coagulation, clinical chemistry, urinalysis, and urine chemistry tests.
On Day 7, animals in Groups 5 through 8 were sacrificed and discarded following blood collection. During Week 14, animals in Groups 1 through 4 were anesthetized, weighed, exsanguinated, and necropsied. At necropsy, macroscopic observations were recorded, selected organs were weighed, and selected tissues were collected and preserved.
Microscopic examinations were done on tissues from each animal given the control material or 400 mg/kg/day. The lungs, liver, kidneys, stomach, spleen, and macroscopic
lesions were also examined microscopically from each animal given 65 or 130 mg/kg/day.
A sperm evaluation was done by Pathology Associates, A Charles River Company. Sperm collected from each male were evaluated for motility, morphology, and concentration.

Result : Daily oral administration of the test substance to Crl:CD® (SD)BR VAF/Plus® rats for 13 weeks was associated with clinical findings in males (decreased locomotor activity)
and females (stained pelage) given 400 mg/kg/day, lower body weights of males given 400 mg/kg/day, and histopathologic findings in the stomach and spleen of animals given
400 mg/kg/day and the stomach of animals given 130 mg/kg/day. There were no test material-related ophthalmic observations noted at the Week 13 examination. The estrous cycle data for Weeks 10 through 14 were similar for the females, and the sperm motility, morphology, and count were not affected by treatment with the test substance. The microscopic findings included squamous hyperplasia and hyperkeratosis of the nonglandular stomach and increased pigment deposits in the sections of the spleen. All animals survived until the scheduled sacrifice.

The no-observable-adverse-effect level for the daily administration of the test substance was 130 mg/kg/day.

Test substance : purity = 99.7%
Reliability : (1) valid without restriction
GLP guideline study
Flag : Critical study for SIDS endpoint
23.07.2003 (61)

Type : Sub-chronic
Species : mouse
Sex : male/female
Strain : CD-1
Route of admin. : gavage
Exposure period : 30 days
Frequency of treatm. : daily
Post exposure period : 1 day
Doses : 0 (undosed), 0(vehicle), 50, 100 and 200 mg/kg/day
Control group : yes
NOAEL : 100 mg/kg bw
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) purity not noted; purchased from Sigma Chemical, UK

Method : Five animals/sex/group were treated daily for 30 consecutive days at doses of 50, 100, and 200 mg/kg bw. Controls included undosed and vehicle-dosed groups. On day 31, all surviving mice were subjected to a full post mortem exam. Blood was examined for chemistry and hematolgy parameters and tissues were examined by standard histopathological methods.
Result : The only treatment-related effects noted were gastric lesions in 3 male mice at 200 mg/kg/day. No other systemic effects were observed. There were no differences in the hematology or chemistry data obtained in the treated and control groups. The NOEL was 100 mg/kg/day.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
Flag : Critical study for SIDS endpoint
23.07.2003 (48)

Type : Chronic
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : dermal
Exposure period : 2 years
Frequency of treatm. : 2x week
Post exposure period : none
Doses : 0.5% in a hair-dye formulation
Control group : yes
NOAEL : .5 %
Method :
Year :
GLP : no data
Test substance : other TS: 1-naphthol (purity not noted) in a hair-dye formulation

Method : 60 male and 60 female weanling rats, selected from each group of F1a litters of the Reproduction study, received topical applications twice weekly of the same test formulations as their parents for approximately 2 years. The rats were observed daily for clinical signs and mortality. Individual

body weights were recorded weekly for 14 weeks then monthly thereafter. The food consumption was recorded weekly.
Blood and urine was obtained from 5 rats/sex/group at 3, 12, 18, and 24 months. At 12 months, 5 rats/sex/group were sacrificed, and necropsied for tissue examination.
All statistical analyses compared each treatment group with each of three separate control groups by sex.

Result : Behavior, appearance, and body weight were similar to controls. Hematology, urinalysis, and clinical chemistry parameters were comparable to controls.
There were no significant increases in tumors in either sex compared to control groups.

Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint

23.07.2003 (62)

Type : Chronic
Species : mouse
Sex : male/female
Strain : Swiss Webster
Route of admin. : dermal
Exposure period : 21 months
Frequency of treatm. : Twice weekly
Post exposure period :
Doses : 0.05 ml/cm2
Control group :
NOAEL : .05
Method :
Year :
GLP : no data
Test substance : other TS: 1-Naphthol (CAS 90-15-3) in a hair dye formulation

Method : 50 mice/sex/group (6-8 weeks of age) were exposed topically to Formulation #7403 at a dose of 0.05 ml/cm2 twice weekly for 21 months. All animals were treated at a single site in the interscapular region clipped free of hair 24 hours before dosing. Control animals, in three separate groups of 50, were shaved but not treated. Mortality, behavior, dermal changes, and appearance were observed daily. Skin lesions were charted weekly. After 7 and 9 months of treatment, 10 animals/sex/group were randomly selected for necropsy and tissue examination. Gross and microscopic examinations were done on all mice found dead or moribund, or at termination of the study. Tissues were examined microscopically.

Result : Survival rates, body weights, relative liver and kidney weights were equivalent for treatment and control groups. Comparison of tumor and non-tumor pathology between treated and control groups revealed no biologically significant differences.

NOAEL = 0.05 ml/cm2

Test condition : Test formulation #7403 contained:
0.5% 1-naphthol
6.0% p-toluenediamine sulfate
0.7% m-aminophenol
1.0% p-aminophenol
0.25% 4-nitro-o-phenylenediamine
15.0% oleic acid
10.0% isopropanol
0.2% sodium sulfite
9.0% (29%)ammonia
4.5% glycerine
9.0% propylene glycol

Reliability	:	Formulation mixed 1:1 with 6% hydrogen peroxide just prior to application (2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

23.07.2003 (63)

Type	:	Sub-chronic
Species	:	rabbit
Sex	:	male/female
Strain	:	New Zealand white
Route of admin.	:	dermal
Exposure period	:	13 weeks
Frequency of treatm.	:	Twice weekly
Post exposure period	:	
Doses	:	1 ml/kg bw
Control group	:	yes, concurrent no treatment
NOAEL	:	1 ml/kg bw
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) in a hair dye formulation
Method	:	6 rabbits/sex/group were exposed topically to Formulation #7403 at a dose of 1ml/kg twice weekly for 13 weeks. Sites of application were alternated to minimize irritancy. The hair at application site was clipped short throughout the study. The application sites of 3 animals/sex/group were abraded on the first treatment day of each week. Animals were restrained for 1 hour after application, then shampooed, rinsed and dried. Control animals in three separate groups of 12 were treated identically except no dyes were applied. Animals were weighed weekly. Hematology, clinical chemistry determinations and urinalyses were performed on all animals at 0, 3, 7, 13 weeks. All survivors were sacrificed after 13 weeks, examined for gross abnormalities, with organs and tissues examined microscopically. Statistical anlayses was performed by ANOVA, and Student's T test.
Result	:	No evidence of compound-induced systemic toxicity was seen. Microscopic examination of 25 tissues from each animal gave no indication of histomorphologic evidence of toxicity. No dye discoloration of urine was seen at any time during the study or at necropsy.
Test condition	:	Test formulation #7403 contained: 0.5% 1-naphthol 6.0% p-toluenediamine sulfate 0.7% m-aminophenol 1.0% p-aminophenol 0.25% 4-nitro-o-phenylenediamine 15.0% oleic acid 10.0% isopropanol 0.2% sodium sulfite 9.0% (29%)ammonia 4.5% glycerine 9.0% propylene glycol
Reliability	:	Formulation mixed 1:1 with 6% hydrogen peroxide just prior to application (2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

23.07.2003 (64)

Type	:	Sub-chronic
Species	:	rat
Sex	:	male/female
Strain	:	

Route of admin.	:	gavage
Exposure period	:	12 weeks
Frequency of treatm.	:	5 days per week
Post exposure period	:	
Doses	:	20 mg/kg/day
Control group	:	
NOAEL	:	20 mg/kg bw
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) purity not noted

23.07.2003 (65)

Type	:	Sub-acute
Species	:	rat
Sex	:	male/female
Strain	:	Wistar
Route of admin.	:	oral feed
Exposure period	:	7 days
Frequency of treatm.	:	daily
Post exposure period	:	1 day
Doses	:	0, 250, 500 and 1000 mg/kg/day
Control group	:	yes, concurrent no treatment
NOAEL	:	500 mg/kg
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	a-naphthol as incorporated into the diet of Harlan-Wister albino rats for 6-8 days at dosage levels of 0, 250, 500 and 1000 mg/kg/day. The rats were returned to a control diet for one day before sacrifice. Endpoints examined included mortality, appetite, growth, liver and kidney weights, plasma, erythrocyte, and brain cholinesterase.
Result	:	Body weight gain reductions were noted in both sexes for the first four days, and in females through the dose period at 1000 mg/kg/day. No effects were seen on cholinesterase levels (plasma, RBC and brain), liver or kidney weights, nor in appetite or mortality. The report NOEL was 500 mg/kg/day.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

23.07.2003 (66)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Salmonella typhimurium TA 1535, TA100, TA1538, TA98 and TA1537
Test concentration	:	up to 3600 ug/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: according to Ames B. et al. 1975. Mut. Res. 31:347-364
Year	:	
GLP	:	no data
Test substance	:	other TS: as prescribed by 1.1 - 1.4; obtained from Merck Co, Germany
Test condition	:	Metabolic activation: S9 liver fraction (Aroclor-pretreated)
Reliability	:	(2) valid with restrictions

Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint
15.07.2003 (67)

Type : DNA damage and repair assay
System of testing : Bacillus subtilis H17, M45, HLL3, HJ15; Escherichia coli AB1157, JC2921, JC2926, JC5519 and JC5547
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :
Year :
GLP : no data
Test substance : other TS: 1-naphthol; purity not noted

Method : Agar-incorporation test:
Cells were thawed and diluted with 0.9% NaCl to 5x10E4 colony forming units/ml. Within 15 minutes after addition of top agar, 5ul droplets of cell suspensions were spotted on the agar surface. Each plate was inoculated with all 9 tester strains. 2 plates were prepared per concentration using 10-fold and 3-fold dilution series of the test substance. The minimum inhibitory concentration (MIC) was determined after 24 hour incubation at 37 degree C. The MIC is defined as the arithmetic mean of the lowest completely inhibitory concentration and the next higher diluted concentration.
The ratios between MIC of wild-types and corresponding DNA repair-deficient mutants were determined and interpreted as follows: (++, >/=10) (+, <10 to >/=2) (+/-, <2 to >/= 1.5) (-, <1.5) (0, no growth inhibition).

Spot test:
Cells were thawed and diluted with 0.9% NaCl to 5x10E5 colony forming units/ml. 5 ul of the solution was transferred to the rim of petri dishes containing ground layer and top agar without test chemicals. Immediately after inoculation, 4 E.coli or B. subtilus strains were streaked per plate. A cross was formed in the cener of whch a paper disc was place. 20 ul of serial 10-fold dilutuions of test cehmical were placed on discs. Duplicates plates were preapred. Plates were preincubated for 24 hours at 4 degreeC and subsequently for 24 hours at 37 degree C. Growth inhibition zones were determined by measuring the distance between the rim of the paper disc and inner edge of bacterial growth zone.
Differences between the growth zones of wild-types and corresponding DNA repair-deficient mutants were determined and interpreted as follows: (++, >/= 6mm) (+, <6 to >/= 3mm) (+/-, <3 to >/= 2mm) (-, <2mm) (0, no growth inhibition)

Result : All tests and strains negative; except E. coli AB1157/JC5547 was determined as + in Spot test.
Test condition : Metabolic Activation: S9 liver fraction from Aroclor 1254 Pretreated male OFA Sandoz rats.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

Flag : Critical study for SIDS endpoint
15.07.2003 (68)

Type : Ames test
System of testing : Salmonella typhimurium TA 1535, TA100, TA1538, TA98, TA1537, G46 and C3076; Escherichia coli WP2 and WP2 uvrA-
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with and without

Result : negative
Method :
Year :
GLP : no
Test substance : other TS: as prescribed by 1.1 - 1.4; purchased from Aldrich Chemical Co. WI, USA

Method : Modifiaction of Ames test (Ames B. et al. 1975. Mutat. Res. 31:347-364) utilizing concentration gradient plates as decsribed in Cline & McMahon. (1977. Res. Commun. Chem. Pathol. Pharmacol. 16:523-533).
Test condition : Four gradient plates were used to give a 10-fold concentration/plate, providing a 10,000-fold concentration range for the test.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

15.07.2003 (69)

Type : Ames test
System of testing : Salmonella typhimurium TA1537 and TA1538
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with
Result : negative
Method : other: according to Ames B. et al. 1975. Mut. Res. 31:347-364
Year :
GLP : no
Test substance : other TS: 1-naphthol (purity not noted); purchased from Matheson Coleman and Bell, Inc.

Result : Revertants per mmol = < 0.01
Revertants per plate = <70/1000
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (70) (71) (72)

Type : Mammalian cell gene mutation assay
System of testing : L5178Y TK+ cell line
Test concentration : up to 11.4 ug/ml
Cycotoxic concentr. : less than 50% cell survival at 8.6 ug/ml
Metabolic activation : with
Result : negative
Method : other: similar to OECD Guideline 476
Year :
GLP : no data
Test substance : other TS: 1-naphthol (purity not noted); purchased from Matheson Coleman and Bell, Inc.

Test condition : Metabolic activation: 5% (v/v) S9 from rodents that were not treated with enzyme inducers.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (73)

Type : Unscheduled DNA synthesis
System of testing : male Fischer 344 rat hepatocytes
Test concentration : 0.5 to 1000 nmoles/ml
Cycotoxic concentr. :
Metabolic activation :
Result : negative
Method : other: according to Williams GM. 1977. Cancer Res. 37:1845-1851.

Year	:	
GLP	:	no data
Test substance	:	other TS: as prescribed by 1.1 - 1.4; purchased from Aldrich Chemical Co. WI, USA
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

15.07.2003 (69)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Micronucleus assay
Species	:	rat
Sex	:	male/female
Strain	:	other: CFY (Sprague-Dawley descendents)
Route of admin.	:	gavage
Exposure period	:	24 hours
Doses	:	6000 mg/kg bw
Result	:	negative
Method	:	Directive 2000/32/EC, B.12
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-naphthol; purity not noted
Reliability	:	(1) valid without restriction Guideline study
Flag	:	Critical study for SIDS endpoint

15.07.2003 (74) (75)

Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	NMRI
Route of admin.	:	i.p.
Exposure period	:	2 doses with an interval of 24 hours; analysis 30 hours after second dose.
Doses	:	144 and 288 mg/kg i.p. (1 and 2 mmole/kg)
Result	:	negative
Method	:	other: according to Schmid W. 1976. Chemical Mutagens. A, Hollaender (ed) Plenum, New York. Vol 4. pp31-53
Year	:	
GLP	:	no data
Test substance	:	other TS: as prescribed by 1.1 - 1.4; obtained from Merck Co, Germany
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

15.07.2003 (67)

Type	:	Drosophila SLRL test
Species	:	Drosophila melanogaster
Sex	:	
Strain	:	other: Berlin K (wild-type) and Basc strains
Route of admin.	:	oral feed
Exposure period	:	one dose
Doses	:	
Result	:	negative
Method	:	other: according to Wurglur FE et al. 1977. Handbook of Mutagenicity Test Procedures. Elsevier. pp.335-373

Year	:	
GLP	:	no data
Test substance	:	other TS: as prescribed by 1.1 - 1.4; obtained from Merck Co, Germany
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

15.07.2003 (67)

5.7 CARCINOGENICITY

Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	dermal
Exposure period	:	2 years
Frequency of treatm.	:	2x week
Post exposure period	:	none
Doses	:	0.5% in a hair-dye formulation
Result	:	negative
Control group	:	yes
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-naphthol (purity not noted) in a hair-dye formulation
Method	:	60 male and 60 female weanling rats, selected from each group of F1a litters of the Reproduction study, received topical applications twice weekly of the same test formulations as their parents for approximately 2 years. The rats were observed daily for clinical signs and mortality. Individual body weights were recorded weekly for 14 weeks then monthly thereafter. The food consumption was recorded weekly. Blood and urine was obtained from 5 rats/sex/group at 3, 12, 18, and 24 months. At 12 months, 5 rats/sex/group were sacrificed, and necropsied for tissue examination. All statistical analyses compared each treatment group with each of three separate control groups by sex.
Result	:	Behavior, appearance, and body weight were similar to controls. Hematology, urinalysis, and clinical chemistry parameters were comparable to controls. There were no significant increases in tumors in either sex compared to control groups.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

09.01.2003 (62)

Species	:	mouse
Sex	:	male/female
Strain	:	Swiss Webster
Route of admin.	:	dermal
Exposure period	:	21 months
Frequency of treatm.	:	weekly
Post exposure period	:	
Doses	:	0.5ml/cm2
Result	:	negative
Control group	:	yes, concurrent no treatment
Method	:	
Year	:	

GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) in a hair dye formulation
Method	:	50 mice/sex/group (6-8 weeks of age) were exposed topically to Formulation #7403 at a dose of 0.05 ml/cm2 twice weekly for 21 months. All animals were treated at a single site in the interscapular region clipped free of hair 24 hours before dosing. Control animals, in three separate groups of 50, were shaved but not treated. Mortality, behavior, dermal changes, and appearance were observed daily. Skin lesions were charted weekly. After 7 and 9 months of treatment, 10 animals/sex/group were randomly selected for necropsy and tissue examination. Gross and microscopic examinations were done on all mice found dead or moribund, or at termination of the study. Diagnosis of benign or malignant tumors was made on histopathological examination.
Result	:	Survival rates, body weights, relative liver and kidney weights were equivalent for treatment and control groups. Comparison of tumor and non-tumor pathology between treated and control groups revealed no biologically significant differences.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

14.01.2003 (63)

5.8.1 TOXICITY TO FERTILITY

Type	:	Two generation study
Species	:	rat
Sex	:	
Strain	:	Sprague-Dawley
Route of admin.	:	dermal
Exposure period	:	lifetime
Frequency of treatm.	:	2x week
Premating exposure period		
Male	:	14 weeks
Female	:	14 weeks
Duration of test	:	
No. of generation studies	:	2
Doses	:	0.5% 1-naphthol in a hair-dye formulation
Control group	:	yes
NOAEL parental	:	.5 %
NOAEL F1 offspring	:	.5 %
NOAEL F2 offspring	:	.5 %
Result	:	No effects were noted on fertility of males or females, gestation, lactation or weaning indices.
Method	:	other: similar to OECD Guide-line 416
Year	:	
GLP	:	no data
Test substance	:	other TS: 1-naphthol (purity not noted) in a hair-dye formulation
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint

09.01.2003 (62)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Sprague-Dawley
Route of admin.	:	gavage
Exposure period	:	Days 7-17 of gestation
Frequency of treatm.	:	Once daily
Duration of test	:	Days 0-20 of gestation
Doses	:	20, 100 and 400 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL maternal tox.	:	20 mg/kg bw
NOAEL teratogen.	:	400 mg/kg bw
Method	:	other: Similar to OECD Test Guideline Number 414
Year	:	1998
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Method : There were 25 animals in each dosage group. Animals were intubated at approximately the same time each day. Dosages were administered at a dosage volume of 10 ml/kg, adjusted daily on the basis of the individual body weights. The animals were observed for viability twice each day for the duration of the study. The rats were examined for clinical observations, abortions, premature deliveries and deaths before and approximately 30 minutes after dosing during the dosing period, and once daily beginning on day 18 of gestation.

All animals were sacrificed on day 20 of gestation, and a gross necropsy was performed. The number of corpora lutea was recorded, and the uterus of each rat was examined for pregnancy, number and distribution of implantations, live and dead fetuses, and early and late resorptions.

Each fetus was examined for gross external alterations. Approximately one-half of the fetuses in each litter were examined for soft tissue alterations. The remaining fetuses were examined for skeletal alterations.

Remark : Vehicle = 0.5% aqueous carboxymethylcellulose
Test substance considered 100% active for dosage calculations.
Statistical methods: Clinical observations and other proportion data were evaluated using the Variance Test for Homogeneity of the Binomial Distribution. Continuous data, e.g., body weight, feed consumption and fetal anomaly data, were analyzed using Bartlett's Test of Homogeneity of Variances. In cases where this was not significant, the data were analyzed using the Anaysis of Variance, followed by Dunnett's Test to identify statistical significance of individual groups. If the Analysis of Variance was not appropriate, i.e., for nonparametric data, the Kruskal-Wallis Test was used, followed by Dunn's Method of Multiple Comparisons to identify the statistical significance of individual groups. Fischer's Exact Test was used to analyze nonparametric data if there were >75% ties. Count data obtained at Caesarean-section of the dams were evaluated using the Kruskal-Wallis Test.

Result : Actual dose received: 20, 100 and 400 mg/kg/day
Maternal data: No deaths, abortions or premature deliveries occurred in any dosage group. Compared to control animals, maternal body weight gains and food consumption in the 400 mg/kg/day dosage group were significantly reduced after dosing commenced on day 7 of gestation. In addition, significant numbers of rats in this group had adverse clinical signs, including: excess salivation, dilated pupils, decreased motor activity, ataxia, impaired righting reflex, lacrimation, lethargy, perioral or perinasal staining, rales and chromorhinorrhea.

Maternal body weights and feed consumption were unaffected in the 100

mg/kg/day dosage group. However, this group showed a statistically significant incidence of chromorhinorrhea. In addition, some animals exhibited dilated pupils and lacrimation.

No adverse effects were noted in the 20 mg/kg/day dosage group.

Fetal data: The litter averages for corpora lutea, implantations, litter sizes, live fetuses, early and late resorptions, percent resorbed conceptuses, and percent live male fetuses were comparable among all four dosage groups (0, 20, 100 and 400 mg/kg/day). There were no treatment related gross fetal alterations, soft tissue alterations or skeletal alterations.

In the 400 mg/kg/day dosage group, average fetal body weights were slightly reduced (i.e., reduced by 4% compared to control animals). This decrease was within the historical ranges for the test facility. However, it is possible that this decrease was treatment related since there was evidence of maternal toxicity at this dosage level. Importantly, none of the typical changes in skeletal ossification that are indicative of a developmental delay and which would be expected to accompany significant fetal weight decrements were observed.

Conclusion : The substance is not a selective developmental toxicant. The only adverse developmental effect was a slightly reduced body weight at a level that produced maternal toxicity. The endpoint has been adequately characterized.

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint

15.07.2003 (76)

Species : rat
Sex :
Strain :
Route of admin. : gavage
Exposure period : Gestation Days 6-15.
Frequency of treatm. :
Duration of test :
Doses : 0 (vehicle), 20, 40 or 80mg/kg/da
Control group :
NOAEL maternal tox. : > 80 mg/kg bw
NOAEL teratogen. : > 80 mg/kg bw
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Result : No maternal or fetal effects at oral doses of 0 (vehicle), 20, 40 or 80 mg/kg/day given during GD 6-15. Developmental NOEL >80 mg/kg/day

15.07.2003 (77)

Species : rat
Sex : female
Strain : CD-1
Route of admin. : dermal
Exposure period : Gestation Days: 1, 4, 7, 10, 13, 16, 19
Frequency of treatm. :
Duration of test :
Doses : 2 ml/kg/day
Control group : yes, concurrent no treatment
NOAEL maternal tox. : 2 ml/kg bw
NOAEL teratogen. : 2 ml/kg bw
Result : No evidence of teratogenic or other adverse developmental effects.
Method :

Year	:	
GLP	:	no data
Test substance	:	other TS: 1-Naphthol (CAS 90-15-3) in a hair dye formulation
Method	:	Formulation #7403 was applied topically at a dose of 2ml/kg on days 1, 4, 7, 10, 13, 16, and 19 of gestation to a group of 20 mated Charles River CD rats. Pilot study showed that potential skin irritancy would not permit more frequent application. The hair at application site was shaved closely the day before dosing. Control animals were untreated but shaved. Three separate groups of controls were maintained in order to determine the degree of variability among small groups. Positive controls received acetylsalicylic acid by gavage at a dose of 250 mg/kg on gestation days 6 through 16. Animals were weighed on application days. On day twenty of gestation, the animals were sacrificed and uteri and fetuses examined. Statistical anlayses by Chi square, Fisher's Exact, ANOVA, or Dunnett's were used (as appropriate). Statistically signifcant differences between groups were judged valid only if seen between treated and each of three control groups.
Result	:	No biologically significant soft tissue or skeletal changes of fetuses were noted. The mean number of corpora lutea, implantation sites, live fetuses, and resorptions per pregnacy; as well as numbers of litters with resorptions were not significantly affected by treatment.
Test condition	:	Test formulation #7403 contained: 0.5% 1-naphthol 6.0% p-toluenediamine sulfate 0.7% m-aminophenol 1.0% p-aminophenol 0.25% 4-nitro-o-phenylenediamine 15.0% oleic acid 10.0% isopropanol 0.2% sodium sulfite 9.0% (29%)ammonia 4.5% glycerine 9.0% propylene glycol Formulation mixed 1:1 with 6% hydrogen peroxide just prior to application
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

27.05.2003 (64)

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