

I U C L I D

Data Set

Existing Chemical : ID: 101-20-2
CAS No. : 101-20-2
EINECS Name : triclocarban
EC No. : 202-924-1
Molecular Weight : 315.59
Molecular Formula : C13H9Cl3N2O

Producer related part
Company : TCC Consortium
Creation date : 15.07.1999

Substance related part
Company : TCC Consortium
Creation date : 15.07.1999

Status :
Memo : TCC Consortium

Printing date : 20.12.2002
Revision date :
Date of last update : 20.12.2002

Number of pages : 44

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

Id 101-20-2
Date 20.12.2002

1.0.1 APPLICANT AND COMPANY INFORMATION

Type : lead organisation
Name : Triclocarban Consortium, Soap and Detergent Association
Contact person : Alvaro DeCarvalho
Date :
Street : 475 Park Avenue South
Town : New York, NY 10016
Country : United States
Phone : 212-725-1262
Telefax : 212-213-0685
Telex :
Cedex :
Email :
Homepage :

08.12.1999

Type : cooperating company
Name : Bayer Corporation
Contact person :
Date :
Street : 100 Bayer Road
Town : Pittsburgh, PA 15205-9741
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

14.10.2002

Type : cooperating company
Name : Clariant Corporation BU-IV Biocides
Contact person :
Date :
Street : P. O. Box 866, 625 E. Catawba Avenue
Town : Mount Holly, NC 28120
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

08.11.2002

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1. General Information

Id 101-20-2
Date 20.12.2002

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type : typical for marketed substance
Substance type : organic
Physical status : solid
Purity : > 98 % w/w
Colour :
Odour :

18.12.2002

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

3,4,4-trichlorocarbanilide

12.10.1999

N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl) urea

12.10.1999

TCC

12.10.1999

urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl) urea

12.10.1999

1.3 IMPURITIES

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1. General Information

Id 101-20-2
Date 20.12.2002

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use : type
Category : Wide dispersive use

12.10.1999

Type of use : industrial
Category : Personal and domestic use

12.10.1999

Type of use : use
Category : Non agricultural pesticides

Remark : non-agricultural pesticide for antibacterial preservation of cosmetics

12.10.1999

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

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. General Information

Id 101-20-2
Date 20.12.2002

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2. Physico-Chemical Data

Id 101-20-2

Date 20.12.2002

2.1 MELTING POINT

Value	:	255.3 °C	
Sublimation	:		
Method	:	other: Melting Point Determination (Tottoli), Procedure 2011-0353501-92 D/E	
Year	:		
GLP	:	no data	
Test substance	:	as prescribed by 1.1 - 1.4	
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail	
Flag	:	Critical study for SIDS endpoint	(1)
04.12.2002			
Value	:	= 250 °C	
Sublimation	:		
Method	:	other: Handbook value	
Year	:		
GLP	:		
Test substance	:	other TS: triclocarban, CAS# 101-20-2; purity not noted	
Reliability	:	(2) valid with restrictions Data from Handbook or collection of data	
Flag	:	Critical study for SIDS endpoint	(2)
04.12.2002			
Value	:	ca. 182 °C	
Sublimation	:		
Method	:	other: MPBPWIN ver1.65, Estimations Program; mean or weighted mp	
Year	:	1999	
GLP	:	no	
Test substance	:	other TS: molecular structure of triclocarban, CAS# 101-20-2	
Reliability	:	(2) valid with restrictions	(3)
08.11.2002			

2.2 BOILING POINT

Value	:	> 300 °C at	
Decomposition	:		
Method	:	other: MPBPWIN ver1.65, Estimations Program; adapted Stein and Brown Method	
Year	:	1999	
GLP	:		
Test substance	:	other TS: molecular structure of triclocarban, CAS# 101-20-2	
Reliability	:	(2) valid with restrictions Accepted calculation method	
Flag	:	Critical study for SIDS endpoint	(3)
17.09.2002			

2.3 DENSITY

Type	:	bulk density
-------------	---	--------------

2. Physico-Chemical Data

Id 101-20-2

Date 20.12.2002

Value : = 650 kg/m³ at °C
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Remark : 350 kg/m³ for micronised TCC
17.09.2002

(4)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : < 1 hPa at 50 °C
Decomposition :
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

14.10.2002

(4)

2.5 PARTITION COEFFICIENT

Partition coefficient :
Log pow : 4.2 at 22.6 °C
pH value :
Method : OECD Guide-line 117 "Partition Coefficient (n-octanol/water), HPLC Method"
Year : 1989
GLP : yes
Test substance : other TS: 3,4,4-trichlorocarbanilide (commercial grade)

Reliability : (1) valid without restriction
GLP Guideline study
Flag : Critical study for SIDS endpoint

04.01.2001

(5)

Partition coefficient :
Log pow : = 4.9 at °C
pH value :
Method : other (calculated): KowWIN v1.65
Year : 1999
GLP : no
Test substance : other TS: molecular structure of triclocarban, CAS# 101-20-2

Reliability : (2) valid with restrictions
Accepted calculation method

17.09.2002

(3)

Partition coefficient :
Log pow : ca. 5.8 - 6 at °C
pH value : -
Method : other (measured): ES-79-M-15, ES-80-M-23, ASTM E35.24 Draft #6
Year :
GLP : no data
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

2. Physico-Chemical Data

Id 101-20-2

Date 20.12.2002

Remark : P=0.64-1.6 e6 (1.0e6) (6)
14.10.2002

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in Value : Water
: ca. .11 mg/l at 20 °C
pH value : 6.1 - 6.3
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :
Deg. product :
Method : Directive 92/69/EEC, A.6
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
08.11.2002 (7)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 101-20-2
Date 20.12.2002

3.1.1 PHOTODEGRADATION

Type : air
Light source :
Light spectrum : nm
Relative intensity : based on intensity of sunlight
INDIRECT PHOTOLYSIS
Sensitizer : OH
Conc. of sensitizer :
Rate constant : = .000000000212164 cm³/(molecule*sec)
Degradation : = 50 % after .5 day(s)
Deg. product :
Method : other (calculated):AopWin v1.89
Year : 1999
GLP : no
Test substance : other TS: molecular structure of triclocarban, CAS# 101-20-2

Remark : estimation done using temperature of 25C
Reliability : (2) valid with restrictions
Accepted calculation method
Flag : Critical study for SIDS endpoint
14.10.2002 (3)

3.1.2 STABILITY IN WATER

Type : abiotic
t1/2 pH4 : at °C
t1/2 pH7 : at °C
t1/2 pH9 : at °C
t1/2 pH : > 1 year at °C
Deg. product :
Method : other: HYDROWIN v1.67 Estimations Program
Year : 1999
GLP : no
Test substance : other TS: molecular structure of triclocarban, CAS# 101-20-2

Reliability : (2) valid with restrictions
17.09.2002 (3)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

Type of measurement : background concentration
Media : surface water
Concentration :
Method :

Result : Analysis for TCC in surface waters in 78 sites in the United States demonstrated a geometric mean concentration of 0.020 ppb (range = <0.010 - 0.733 ppb) using a method with a detection limit of <0.010 ppb.
17.09.2002 (8)

Type of measurement : background concentration

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

Media : drinking water
Concentration :
Method :

Result : Drinking water samples from 12 metropolitan areas had non-detectable levels of TCC, using a method with a detection limit of <0.010 ppb.

07.12.1999

(8)

Type of measurement : background concentration
Media : sediment
Concentration :
Method :

Result : Analysis for TCC in lake, river and coastal sediments from 72 sites in the United States demonstrated a geometric mean concentration of 44 ppb (range = <20 - 8200 ppb) using a method with a detection limit of 20 ppb.

07.12.1999

(9)

Type of measurement : background concentration
Media : other: sewage treatment facilities
Concentration :
Method :

Result : The average influent concentration of TCC at 3 secondary sewage treatment facilities in Florida, USA was 38 ppb (range = 27-50 ppb). Average effluent concentrations of TCC ranged from 2-12 ppb, representing an average 86% reduction in TCC concentration, which is ascribed to sludge adsorption. Measurements of TCC in surface waters at effluent discharge sites show an immediate dilution of 100x. TCC in the discharge body of water ranged from <0.10 - 0.163 ppb in the water column and 64-718 ppb in the sediments. Maximum concentrations were found at effluent discharge sites.

15.10.2002

(10)

Type of measurement : background concentration
Media : other: sewage treatment facilities
Concentration :
Method :

Result : The average effluent concentration of TCC at 10 secondary sewage treatment facilities located throughout the United States was 5.4 ug/l (range = 2.1 - 12.0 ug/l). The geometric mean TCC concentration of sludge was 40 mg/kg (range = <1-283 mg/kg). Measurements of TCC concentration in sludge-amended soils dropped dramatically with soil depth: average of 0.42 mg/kg in the first 15cm; 0.07 mg/kg between 15-30cm; and 0.03 mg/kg at 30-45cm. These values confirm that TCC would be unlikely to migrate into groundwater.

15.10.2002

(11)

Type of measurement : background concentration
Media : sediment
Concentration :
Method :

Result : Analysis for TCC in lake, river and coastal sediments from 16 sites in the United States demonstrated a geometric mean

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

07.12.1999 (12)
concentration of 37 ppb (range = <20 - 1630 ppb) using a method with a detection limit of 20 ppb. 56% of the sites had non-detectable levels of TCC. Two small lakes examined because of high sewage loadings showed very low levels of TCC in sediments (<20 and 24 ppb).

Type of measurement : background concentration
Media : other: sewage treatment facilities
Concentration :
Method :

Result : Average influent and effluent concentrations of TCC were monitored at a trickling filter sewage plant in Ohio, USA. Average influent concentration of TCC was 15.0 ppb. Average effluent concentration of TCC was 5.0 ppb. The average removal of TCC was 35%.

07.12.1999 (13)

Type of measurement : background concentration
Media : surface water
Concentration :
Method :

Result : Surface water samples were collected from over 30 sites, mostly in the eastern United States. 70% of the sites had non-detectable levels of TCC. The geometric mean TCC concentration for all water samples was 0.017 ppb. There was no significant increase in TCC concentration when compared to previous results.

07.12.1999 (14)

Type of measurement : background concentration
Media : sediment
Concentration :
Method :

Result : Sediment samples were collected from over 30 sites, mostly in the eastern United States. 46% of the sites had non-detectable levels of TCC in the sediments. The geometric mean TCC concentration for all sediment samples was 46 ppb. There was no significant increase in TCC concentration when compared to previous results.

07.12.1999 (14)

Type of measurement : background concentration
Media : surface water
Concentration :
Method :

Result : Surface water samples were collected from 6 sites in the northeastern United States, where highest environmental concentrations of TCC had been found. TCC was determined by liquid chromatography (HPLC/UV) and gas chromatography with mass spectrometry (GC/MS). The range of TCC concentration from 60 water samples was <1.0 - 190 parts per trillion.

15.10.2002 (15)

Type of measurement : background concentration
Media : sediment
Concentration :
Method :

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

Result : Sediment samples were collected from 6 sites in the northeastern United States, where highest environmental concentrations of TCC had been found. TCC was determined by liquid chromatography (HPLC/UV) and gas chromatography with mass spectrometry (GC/MS). The range of TCC concentration from 18 sediment samples was <0.01 - 3.9 ppm.

15.10.2002 (15)

Type of measurement : background concentration
Media : surface water
Concentration :
Method :

Result : Surface water samples were collected from selected East Coast sites in the United States determined worst case environmental concentrations of TCC. TCC was determined by liquid chromatography with UV detection (HPLC/UV) and gas chromatography with mass spectrometry (GC/MS). The range of TCC concentration was <0.032 - 0.24 ppb.

08.12.1999 (16)

Type of measurement : background concentration
Media : sediment
Concentration :
Method :

Result : Sediment samples were collected from selected East Coast sites in the United States determined worst case environmental concentrations of TCC. TCC was determined by liquid chromatography with UV detection (HPLC/UV) and gas chromatography with mass spectrometry (GC/MS). The range of TCC concentration was <0.005 - 0.2 ppm in sediment samples.

08.12.1999 (16)

Type of measurement : background concentration
Media : other: sewage treatment facilities
Concentration :
Method :

Result : Average influent and effluent concentrations of TCC were monitored at two sewage treatment plants in Ohio, USA, and one sewage treatment plant in Europe. TCC was determined by liquid chromatography with UV detection (HPLC/UV) and liquid chromatography with mass spectrometry (LC/MS/MS). The influent concentration of TCC ranged from 7.01 - 16.32 ppb in the US and 0.30 - 0.43 ppb in Europe. The effluent concentration of TCC ranged from 0.24 - 4.83 ppb in the US and 0.054 - 0.088 ppb in Europe. TCC removal by sewage treatment plants exceeded 96% through activated sludge treatment process and only 70.4% through trickling filter process. The lower TCC levels in Europe were due to the limited usage of TCC in consumer products.

22.12.1999 (17)

3.2.2 FIELD STUDIES

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : desorption
Media : water - soil
Air : % (Fugacity Model Level I)
Water : % (Fugacity Model Level I)
Soil : % (Fugacity Model Level I)
Biota : % (Fugacity Model Level II/III)
Soil : % (Fugacity Model Level II/III)
Method : other: soil TLC Method
Year : 1979

Method : TLC Method described in Federal Register, Vol.40, No. 123, 1975 and Helling (1968,1971)
Result : immobile - strongly absorbed by soil unlikely to leach into ground water
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
Flag : Critical study for SIDS endpoint
14.10.2002 (18)

Type : adsorption
Media : water - soil
Air : % (Fugacity Model Level I)
Water : % (Fugacity Model Level I)
Soil : % (Fugacity Model Level I)
Biota : % (Fugacity Model Level II/III)
Soil : % (Fugacity Model Level II/III)
Method : other
Year : 1980

Method : 1)14C-TCC was extracted from (1g) spiked sediment with 10ml solvent(s) (n=8) at room temperature. 2)Two gram portions of sediment were extracted with 100 ml solvent (n=8) at 85C for 5 hours (Soxhlet method). 3)One gram sediment was digested with 5ml 1N NaOH at 60C for 1 hour, cooled, extracted with 10ml solvent (n=8). In all cases, aliquots measured by 14C-counting and HPLC evaluation. Residues dried at 80C and evaluated by 14C-counting.
Result : Low recovery efficiencies in all methods (up to 75% with NaOH digestion) strongly suggests an irreversible binding phenomenon of TCC to constituents in the sediment. Level of intact TCC isolated from the sediment suggested approx. 50% of 14C-TCC had undergone transformation.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
Flag : Critical study for SIDS endpoint
14.10.2002 (19)

Type : adsorption
Media : water - soil
Air : % (Fugacity Model Level I)
Water : % (Fugacity Model Level I)
Soil : % (Fugacity Model Level I)
Biota : % (Fugacity Model Level II/III)
Soil : % (Fugacity Model Level II/III)
Method : other
Year : 1999

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

Method	:	The focus of the study was to generate an organic carbon-normalized sorption coefficient (Koc) that could be used to predict the bioavailable TCC in activated sludge, effluent, river water, and sediments. Samples of the various matrices were analyzed for dissolved organic carbon (DOC) and particulate organic carbon (POC). Total organic carbon (TOC) = (DOC+POC). Mass action and mass balance equations were used to predict the water soluble or bioavailable fraction of TCC in these samples. Batch equilibrium sorption experiments were done using ¹⁴ C-labelled TCC. Sorption coefficients were calculated from the ratio of solid phase concentration to aqueous phase concentration.				
Result	:	Matrix	TOC (mg/l)	Koc (l/kg)	log Koc	Pred.avail. Fraction
		Activated sludge	936	54,800	4.74	2
		Lagoon effluent	15.4	111,965	5.05	37
		simulated river water (lagoon effluent 1:9)	1.5	111,965	5.05	85
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail				
Flag 15.10.2002	:	Critical study for SIDS endpoint				(20)
Type	:	other: Partitioning				
Media	:	other: air - water - soil - sediment				
Air	:	% (Fugacity Model Level I)				
Water	:	% (Fugacity Model Level I)				
Soil	:	% (Fugacity Model Level I)				
Biota	:	% (Fugacity Model Level II/III)				
Soil	:	% (Fugacity Model Level II/III)				
Method	:					
Year	:					
Result	:	Release of 300 kg/hr to water Media: Distribution (%)				
		Air	0			
		Water	71			
		Soil	0			
		Sediment	29			
Reliability	:	Overall persistence is estimated at 210 days. (2) valid with restrictions Accepted calculation method				(21)
20.12.2002						

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	
Contact time	:	
Degradation	:	0 (±) % after 28 day(s)

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

Result	: under test conditions no biodegradation observed	
Deg. product	:	
Method	: OECD Guide-line 301 C "Ready Biodegradability: Modified MITI Test (I)"	
Year	: 1992	
GLP	: no data	
Test substance	: as prescribed by 1.1 - 1.4	
Reliability	: (1) valid without restriction Guideline study	
Flag 14.10.2002	: Critical study for SIDS endpoint	(22)
Type	: aerobic	
Inoculum	: activated sludge, domestic, adapted	
Concentration	: 200 ug/l related to Test substance related to	
Contact time	: 10 hour(s)	
Degradation	: ca. 70 (±) % after 28 day(s)	
Result	: readily biodegradable	
Deg. product	: yes	
Method	: other: shake flask method and CFAS-continuous flow activated sludge, analysing the mineralization of the 4-chloroaniline ring and 3,4- dichloroaniline ring	
Year	: 1975	
GLP	: no data	
Test substance	: as prescribed by 1.1 - 1.4	
Result	: The p-chloroaniline ring of TCC was more rapidly degraded than the dichloroaniline ring. Analysis of effluents established that TCC undergoes primary biodegradation to its chloroaniline components which are in turn biodegraded.	
Reliability	: (2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail	
Flag 14.10.2002	: Critical study for SIDS endpoint	(23)
Type	: anaerobic	
Inoculum	: domestic sewage, non-adapted	
Concentration	: 1.22 mg/l related to Test substance related to	
Contact time	: 3 month	
Degradation	: = 0 (±) % after 3 month	
Result	: under test conditions no biodegradation observed	
Deg. product	:	
Method	: other: Bartha and Prammar, 1965	
Year	: 1979	
GLP	:	
Test substance	: as prescribed by 1.1 - 1.4	
Method	: Bartha, R. and Prammar. 1965. Features of flask and methods for measuring the persistence and biological effects of pesticides in soil. Soil Science 100:68-70.	
Result	: The radioactive measurements of the CO ₂ trap in the biometer flask showed that no detectable amounts of radioactive CO ₂ were evolved from the test substance during 12 weeks of incubation.	
Reliability	: (2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail	
Flag 14.10.2002	: Critical study for SIDS endpoint	(24)

3. Environmental Fate and Pathways

Id 101-20-2

Date 20.12.2002

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Species	: Ictalurus punctatus (Fish, fresh water)
Exposure period	: 6 day(s) at 22 °C
Concentration	: .0148 mg/l
BCF	: 137
Elimination	: yes
Method	: other: ASTM
Year	: 1980
GLP	: no
Test substance	: other TS: 14C-labelled TCC, purity = 98.2% radio-tagged
Method	: Between 13 to 40 small and 13 large channel catfish were continuously exposed to 14.8 to 35.4 ug/l radio-labelled TCC for 24 hours to 6 days in 100 gallon aquaria. Fish were sacrificed at varying time intervals during uptake and dissected tissues were oven dried. Samples of each tissue were completely oxidized to 14CO2 and counted in a scintillation counter to determine 14C-TCC uptake. Data on 14C content were obtained for each fish separately. Data were converted to ug of TCC, plotted to obtain TCC concentration and Bioconcentration Factor by Plateau Method. Data also analyzed by computer program BIOFAC (Blau and Agin, 1978) to obtain uptake rate (k1), the depuration rate (k2), the bioconcentration factor (BCK = k1/k2) and computer plotted bioconcentration curves.
Remark	: These BCF's are much lower than one would expect for a chemical such as TCC. An explanation for the low BCF's is possible because a concurrent metabolism study was conducted. TCC was metabolized to hydroxylated TCC and the sulfate and glucuronide conjugates which are apparently much more rapidly eliminated than TCC. Excretion was primarily biliary via the alimentary canal with significant amounts also excreted in the urine. Very little excretion took place across the gills. This fish metabolism pattern was quite similar to that published for mammalian systems.
Result	: BCF = 137 (whole fish); 13 (fish muscle) These data suggest TCC would not bioconcentrate from water to fish to any significant degree and that significant food chain biomagnification is not likely to occur, especially at the anticipated low exposures.
Test condition	: Dechlorinated city water: alkalinity = 38-42 ug/l; hardness = 123-142 mg/l; pH = 7.1-7.7. Temperature = 22 (+/- 2) degree C.
Reliability	: (2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail

20.12.2002

(25)

3.8 ADDITIONAL REMARKS

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type :
Species : Oncorhynchus mykiss (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
LC0 : > .18
Limit test :
Analytical monitoring : yes
Method : OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year : 1995
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Remark : Nomimal concentration = 0.5 mg/l;
Measured concentration 0.12 - 0.23 mg/l

Test condition : Control: Oxygen = 9.2 - 10.4 mg/l (93.9-103.6 % saturation); pH = 6.9-7.4;
Temperature = 11.1-16.5 degree C
Test: Oxygen = 9.7 - 11.1 mg/l (100.8-109.7 % saturation); pH = 6.9-7.4;
Temperature = 11.1-15.7 degree C

Reliability : (2) valid with restrictions
GLP Guideline study; deviations: only one concentration used

Flag : Critical study for SIDS endpoint
15.10.2002 (26)

Type : static
Species : Lepomis macrochirus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : = .049
LC50 : = .097
Limit test :
Analytical monitoring : yes
Method : other: EPA-660/3-75-009 (April, 1975)
Year : 1975
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : EPA. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians by the Committee on Methods for Toxicity Tests with Aquatic Organisms.

Result : 24 hr LC50 = > 0.32 mg/l
48 hr LC50 = > 0.29 mg/l (0.095 - 0.90 mg/l)
96 hr LC50 = 0.097 mg/l (0.0714 - 0.13 mg/l)

Test condition : Well water: Hardness =35 mg/l CaCO3; pH = 7.1; Temperature 14 (+/- 1)degree C; dissolved oxygen = > 60% of saturation.

Reliability : (2) valid with restrictions
Guideline study

Flag : Critical study for SIDS endpoint
15.10.2002 (27)

Type : static
Species : Salmo gairdneri (Fish, estuary, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : < .049
LC50 : = .12
Limit test :
Analytical monitoring : yes

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Method : other: EPA -660/3-75-009 (April, 1975)
Year : 1976
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : EPA. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians by the Committee on Methods for Toxicity Tests with Aquatic Organisms.

Result : 24 hr LC50 = > 0.32 mg/l
48 hr LC50 = > 0.32 mg/l
96 hr LC50 = 0.12 mg/l (0.084 - 0.17 mg/l)

Test condition : Well water: Hardness =35 mg/l CaCO₃; pH = 7.1; Temperature 14 (+/- 1)degree C; dissolved oxygen = > 60% of saturation.

Reliability : (2) valid with restrictions
Guideline study

Flag : Critical study for SIDS endpoint
15.10.2002 (27)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type :
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
EC0 : = .005
EC50 : ca. .01
EC100 : = .04
Analytical monitoring : yes
Method : OECD Guide-line 202
Year : 1995
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Remark : 24hr EC0 = 0.02mg/l;
24hr EC100 > 0.04mg/l

Test condition : Oxygen = 9.4-9.6 mg/l; pH = 7.8-8.0; temperature = 19.6 - 19.8 degree C.

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint
15.10.2002 (28)

Type : static
Species : Ceriodaphnia sp. (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : = .0019
EC50 : ca. .0031
EC100 : = .0063
Analytical monitoring : yes
Method : other: "Protocol for Conducting a Static Acute Toxicity Test with Ceriodaphnia" (092387/CER.SA Sept.1987) and ASTM, 1980
Year : 1987
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Result : The 48-hour EC50 was estimated by non-linear interpolation to be 3.1 ug/l with a 95% confidence interval calculated by binomial probability to be 1.9-3.8 ug/l.
24hr EC0 = 3.8ug/l;
24hr EC100 = 6.3ug/l

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Test condition : Fortified well water: pH = 8.2; Hardness = 180 mg/l CaCO₃; temperature = 24 degree C.
Reliability : (1) valid without restriction
GLP Guideline study
Flag : Critical study for SIDS endpoint
08.11.2002 (29)

Type :
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : = .0092
EC50 : = .01
Analytical monitoring : yes
Method : other: EPA-660/3-75-009 (April, 1975)
Year : 1978
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : EPA. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians by the Committee on Methods for Toxicity Tests with Aquatic Organisms.
Result : 24 hour LC50 = 16 ug/l (95% confidence limit of 15 - 18 ug/l).
48 hour LC50 = 10 ug/l (95% confidence limit of 9.2 - 12 ug/l).
Test condition : Deionized, reconstituted well water: hardness = 175 (+/- 15)mg/l CaCO₃; pH = 8.0 - 8.1; temperature 22 (+/- 1) degree C; dissolved oxygen = 89-99% of saturation.
Reliability : (1) valid without restriction
Guideline study
Flag : Critical study for SIDS endpoint
08.11.2002 (30)

Type : static
Species : Ceriodaphnia sp. (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : .0019
EC50 : .0019 - .0038
Analytical monitoring : yes
Method : other: Protocol for Conducting a Static Acute Toxicity Test with Ceriodaphnia (#092387 /CER.SA)
Year : 1987
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Test condition : Non-labelled TCC tested as 100% active ingredient;
14C-labelled TCC tested as 100% active with a specific activity of 14.37 mCi/g. Ceriodaphnia dubia age: <= 24 hours. Dilution water - pH: 8.2; total hardness as CaCO₃: 180mg/l; total alkalinity as CaCO₃: 120mg/l. Mean measured concentrations (0 and 48 hour radiometric analyses): 0.69, 1.9, 3.8, 6.3, 11, 17ug/l.
Reliability : (2) valid with restrictions
Comparable to Guideline study
08.11.2002 (31)

Type :
Species : Mysidopsis bahia (Crustacea)
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : .01 - .013
Method : other

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Year : 1979
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Result	Test Material	96hr LC50	95%conf.interval
	TCC + sediment + sewage	(ug/l)	(ug/l)
	0 ppm 0 ppm	13	10 - 16
	10 ppm 0 ppm	10	8 - 13
	50 ppm 0 ppm	11	9 - 14
	100 ppm 0 ppm	10	8 - 13
	1,000 ppm	10	8 - 13
	5,000 ppm	10	8 - 13
	10,000 ppm	10	8 - 13

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

08.11.2002 (32)

Type : flow through
Species : Mysidopsis bahia (Crustacea)
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : .015
Method : other:
Year : 1980
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Result : The calculated 96 hour LC50 for mysid shrimp exposed to TCC in flowing, natural seawater was 15 ug/l with 95% confidence limits of 7.3 - 31 ug/l
Test condition : Salinity ranged from 15-26‰, the mean (+/- SD) = 20(+/-3)‰;
Temperature = 25 (+/-0) degree C;
Dissolved Oxygen = 101-116% of saturation;
pH = 7.9-8.2

Reliability : TCC had no effect on either dissolved oxygen concentration or pH.
(2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

08.11.2002 (33)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : Scenedesmus subspicatus (Algae)
Endpoint : growth rate
Exposure period : 72 hour(s)
Unit : mg/l
EC10 : < .02
EC50 : .02 - .3
Limit test :
Analytical monitoring : yes
Method : OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year : 1995
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
14.10.2002

(34)

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Species : Scenedesmus subspicatus (Algae)
Endpoint : biomass
Exposure period : 72 hour(s)
Unit : mg/l
EC10 : <= .02
EC50 : .02 - .03
Limit test :
Analytical monitoring : yes
Method : other: "Algae Inhibition Test" Guideline 67/548/EWG (12/29/92)
Year : 1995
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Reliability : (1) valid without restriction
GLP Guideline study

14.10.2002

(34)

Species : Microcystis aeruginosa (Algae, blue, cyanobacteria)
Endpoint : growth rate
Exposure period : 14 day(s)
Unit : mg/l
NOEC : .01
EC50 : > .032
Limit test :
Analytical monitoring : yes
Method : other: according to Payne & Hall, 1979
Year : 1980
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : Payne, A.G. & Hall, R.H. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. Presented at ASTM Second Symposium on Aquatic Toxicology, Cleveland, Ohio, 10/31/77 and 11/1/77.

Test condition : Triplicate cultures for each test concentration and control were employed. Solvent for the TCC was reagent grade acetone. An equal volume of acetone (0.06ml) was added to each flask including solvent control. A control with no acetone was also maintained. Temperature was maintained at 24 (+/- 1)degree C and light at 4000 lux. Analysis of concentration was done on days 0 and 5.

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

08.11.2002

(35)

Species : Selenastrum capricornutum (Algae)
Endpoint : growth rate
Exposure period : 14 day(s)
Unit : mg/l
LOEC : 10
EC50 : ca. 36
Limit test :
Analytical monitoring : yes
Method : other: according to Payne & Hall, 1979
Year : 1980
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : Payne, A.G. & Hall, R.H. 1979. A method for measuring algal toxicity and its application to the safety assessment

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

of new chemicals. Presented at ASTM Second Symposium on Aquatic Toxicology, Cleveland, Ohio, 10/31/77 and 11/1/77.

Test condition : Triplicate cultures for each test concentration and control were employed. Solvent for the TCC was reagent grade acetone. An equal volume of acetone (0.06ml) was added to each flask including solvent control. A control with no acetone was also maintained. Temperature was maintained at 24 (+/- 1)degree C and light at 4000 lux. Analysis of concentration was done on days 0 and 5.

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

15.10.2002

(35)

Species : Navicula pelliculosa (Algae)
Endpoint : growth rate
Exposure period : 14 day(s)
Unit : mg/l
LOEC : 1
EC50 : ca. 7.8
Limit test :
Analytical monitoring : yes
Method : other: according to Payne & Hall, 1979
Year : 1980
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : Payne, A.G. & Hall, R.H. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. Presented at ASTM Second Symposium on Aquatic Toxicology, Cleveland, Ohio, 10/31/77 and 11/1/77.

Test condition : Triplicate cultures for each test concentration and control were employed. Solvent for the TCC was reagent grade acetone. An equal volume of acetone (0.06ml) was added to each flask including solvent control. A control with no acetone was also maintained. Temperature was maintained at 24 (+/- 1)degree C and light at 4000 lux. Analysis of concentration was done on days 0 and 5.

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

15.10.2002

(35)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : other
Species : domestic sewage
Exposure period : 15 minute(s)
Unit : mg/l
Method : other
Year : 1986
GLP :
Test substance : as prescribed by 1.1 - 1.4

Method : Bacterial Toxicity Test.
Sludge source: Avondale PA sewage Plant.
TSS: 3590 mg/l VSS: 2630 mg/l. Temperature 22 degree C.
TCC tested as 100% active.

Result : HA(50) =
> 40,000 mg TCC/l (prior to normalization for VSS)

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Reliability : > 15,209 mg TCC /g VSS (after normalization for VSS)
: (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
15.10.2002 (36)

Type : other
Species : domestic sewage
Exposure period : 16 day(s)
Unit : mg/l
NOEC : 100
LOEC : 100 - 1000
Method : other: Anaerobic Digester Inhibition Test
Year : 1986
GLP :
Test substance : as prescribed by 1.1 - 1.4
Test condition : initial conditions -
TSS: 36,900 mg/l; VSS: 21.500 mg/l; total alkalinity: 2,600 mg/l; CaCO₃ alkalinity: 2,480 mg/l; V acids: 150 mg/l; COD: 34,000 mg/l;pH: 7.4; test temperature = 32 degree C
Sludge source: Ocean County South Treatment PlantTest
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
15.10.2002 (37)

4.5.1 CHRONIC TOXICITY TO FISH

Species : Pimephales promelas (Fish, fresh water)
Endpoint : other: hatchability of eggs and growth and survival of fry
Exposure period : 35 day(s)
Unit : mg/l
NOEC : .005
Analytical monitoring : no data
Method : other: Critical Life Stage Test: The effects of continuous aqueous exposure of TCC on hatchability of eggs and growth and survival of fry of fathead minnow.
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Fathead minnow eggs and fry were exposed to TCC at concentrations of 0.63, 1.25, 2.5, 5.0, and 10 micrograms per liter for 35 days.
Result : No treatment-related effects were observed on egg hatchability or growth of the fry. Survival was reduced at 10 micrograms per liter.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
20.12.2002 (38)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 21 day(s)
Unit : mg/l
NOEC : .0029

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

LCEC : .0047
MATC : .0037
Analytical monitoring : yes
Method : OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"
Year : 1998
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Result : 1:8 dilution water: NOEC = 0.91 ug/l; LOEC = 1.6 ug/l; MATC = 1.2 ug/l
Reliability : (1) valid without restriction
 GLP Guideline study

08.11.2002 (39)

Species : Mysidopsis bahia (Crustacea)
Endpoint : reproduction rate
Exposure period : 28 day(s)
Unit : mg/l
NOEC : .00006
LCEC : .00013
EC50 : .00021
Method : other: EPA FIFRA Guideline 72-1
Year : 1992
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Result : 28 day LOEC (dynamic growth) = 0.500ug/l
Test condition : 28-day flow-through chronic toxicity test, no aeration.
 Doses: dilution water control, carrier control (ethylene glyciol), nominal 14C-TCC concentrations 0.062, 0.125, 0.250, 0.500, 1.00ug/l. Test temperature: 25.0C +/-2.0.
 Juvenile mysids age: <=24 hours.

Reliability : (2) valid with restrictions
 Guideline study

08.11.2002 (40)

Species : Ceriodaphnia sp. (Crustacea)
Endpoint : reproduction rate
Exposure period : 8 day(s)
Unit :
Analytical monitoring : yes
Method : OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"
Year : 1997
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Result	Dilution Water	Survival (ug/l)		Reproduction (ug/l)		
		NOEC	LC50	NOEC	EC50	(young/adult)
	ABC hard blended	2.84	>2.84	2.84	>2.84	0.75
	1:9 dilution	4.54	9.72	4.54	ND	4.54
	1:2 dilution	11.67	13.72	5.52	10.72	5.52

Reliability : (1) valid without restriction
 GLP Guideline study

08.11.2002 (41)

Species : Mysidopsis bahia (Crustacea)
Endpoint : mortality
Exposure period : 4 day(s)
Unit : mg/l
EC50 : .007 - .01
MATC : .0004 - .0006
Method : other
Year : 1980

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : Test to determine the mitigating effects of sediment (100ppm) and sewage (10,000 ppm) on the chronic toxicity of mysid shrimp.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail
08.11.2002 (42)

Species : Mysidopsis bahia (Crustacea)
Endpoint : reproduction rate
Exposure period : 12 day(s)
Unit : mg/l
NOEC : < .00012
MATC : .00006 - .00012
Method :
Year : 1980
GLP :
Test substance : as prescribed by 1.1 - 1.4
Result : Exposure to nominal TCC concentrations ≥ 0.12 ug/l significantly increased mortality of of parental mysid shrimp. There was no mortality of F1 mysids in any concentration or control in a 10-12 day post hatch period. The average number of offspring per hatch was significantly reduced in TCC concentrations ≥ 0.12 ug/l. The estimated MATC of TCC for mysid shrimp (based on nominal Concentrations) was $> 0.06 - < 0.12$ ug/l, and the application factor limits were 0.004 - 0.008.
Test condition : Salinity ranged from 15-26%, the mean (+/-SD)= 20(+/-3)%; Temperature = 25 (+/-0) degree C; Dissolved Oxygen = 101-116% of saturation; pH = 7.9-8.2

Reliability : TCC had no effect on either dissolved oxygen concentration or pH.
(2) valid with restrictions
08.11.2002 (43)

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 42 day(s)
Unit : mg/l
MATC : .00025 - .0005
Method : other
Year : 1978
GLP :
Test substance : as prescribed by 1.1 - 1.4

Method : Daphnia magna were continuously exposed to nominal TCC concentrations 0.062 - 1.0 ug/l through 2 generations (21 days/generation). Survival was measured weekly and the production of young measured daily.

Reliability : (2) valid with restrictions
08.11.2002 (44)

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 28 day(s)
Unit : mg/l
MTC : .0075 - .015
Method :

4. Ecotoxicity

Id 101-20-2

Date 20.12.2002

Year : 1979
GLP :
Test substance : as prescribed by 1.1 - 1.4

Method : Daphnia magna were continually exposed for 28 days to nominal concentrations of TCC ranging from 1.9-30 µg/l in aqueous solutions containing 50 mg/l suspended sediments and 10% secondary sewage treatment effluent. Survival was measured weekly and the production of offspring measured on weekdays.

Reliability : (2) valid with restrictions
08.11.2002

(45)

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5. Toxicity

Id 101-20-2

Date 20.12.2002

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Value : > 2000 mg/kg bw
Species : rat
Strain :
Sex : male/female
Number of animals : 10
Vehicle : other: polyethylene glycol 400
Doses :
Method : Directive 84/449/EEC, B.1 "Acute toxicity (oral)"
Year : 1991
GLP : yes
Test substance : other TS: 3,4,4'-trichlorocarbanilide (purity =98.8%) suspended in polyethylene glycol 400

Remark : 5 animals/sex
Reliability : (1) valid without restriction
GLP Guideline study
Flag : Critical study for SIDS endpoint

14.10.2002

(46)

Type : LD50
Value : > 50100 mg/kg bw
Species : rat
Strain :
Sex : male/female
Number of animals :
Vehicle :
Doses :
Method : other
Year : 1963
GLP : no
Test substance : other TS: TCC with 6-8% 4,4'-dichloro and 6-8% 3,3',4,4'-tetrachloro

Method : Diluted compound was fed by stomach tube to Sprague-Dawley albino male and female rats in increasing doses at 0.3 and 0.2 fractional log intervals. Observations were made for toxic symptoms.
Remark : The product appeared to be excreted practically unchanged.
Reliability : (2) valid with restrictions
Meets generally accepted scientific method and is described in sufficient detail

16.10.2002

(47)

Type : LD0
Value : > 5000 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method :
Year : 1979

5. Toxicity

Id 101-20-2

Date 20.12.2002

GLP :
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

14.10.2002 (48)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : > 10000 mg/kg bw
Species : rabbit
Strain :
Sex : male/female
Number of animals :
Vehicle :
Doses :
Method : other:
Year : 1963
GLP : no
Test substance : other TS: TCC with 6-8% 4,4'-dichloro and 6-8% 3,3',4,4'-tetrachloro

Method : The diluted compound was applied in increasing doses at 0.2 fractional log intervals to the closely clipped, intact skin of New Zealand white male and female rabbits. The treated areas were covered with plastic strips and the animals placed in wooden stocks for periods up to 24 hr, after which time they were assigned to individual cages. Observations were made for toxic symptoms and, since there were no deaths, no autopsies were performed.

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint

14.10.2002 (47)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type : LD50
Value : = 2100 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Route of admin. : i.p.
Exposure time :
Method :
Year : 1979
GLP :
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

14.10.2002 (48)

5.2.1 SKIN IRRITATION

Species : rabbit

5. Toxicity

Id 101-20-2

Date 20.12.2002

Concentration : undiluted
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals :
Vehicle :
PDII :
Result :
Classification : not irritating
Method :
Year : 1963
GLP : no
Test substance : other TS: TCC with 6-8% 4,4'-dichloro and 6-8% 3,3',4,4'-tetrachloro

Method : Finely ground powder as a 25% suspension in corn oil was applied to the clipped intact skin of albino rabbits and removed after 24 hours. The application was covered with plastic strips to retard evaporation and avoid contamination. Observations were made over a period of several days for irritation. The data was scored according to Draize, Woodard, and Calvary (J. Pharm. Exp. Therapeutics. vol 82. Dec. 1944).

Result : The compound was classified as non-irritating when applied as a finely ground powder as a 25% suspension in corn oil.

Reliability : (2) valid with restrictions

16.12.2002

(47)

Species : rabbit
Concentration :
Exposure :
Exposure time : 4 hour(s)
Number of animals :
Vehicle :
PDII :
Result : not irritating
Classification : not irritating
Method :
Year : 1992
GLP :
Test substance :

14.10.2002

(49)

Species : guinea pig
Concentration :
Exposure :
Exposure time : 24 hour(s)
Number of animals :
Vehicle :
PDII :
Result : irritating
Classification :
Method :
Year : 1978
GLP :
Test substance :

06.10.1999

(50)

Species : guinea pig
Concentration : 3 %
Exposure :
Exposure time :

5. Toxicity

Id 101-20-2

Date 20.12.2002

Number of animals :
Vehicle :
PDII :
Result : not irritating
Classification : not irritating
Method :
Year : 1974
GLP :
Test substance :

Result : Solutions of 0.5%, 1.0%, and 3.0% were not irritating to the skin of guinea pigs.

06.10.1999

(51)

Species : rat
Concentration : 3 %
Exposure :
Exposure time :
Number of animals :
Vehicle :
PDII :
Result : not irritating
Classification : not irritating
Method :
Year : 1974
GLP :
Test substance :

Result : Solutions of 0.5%, 1.0%, and 3.0% were not irritating to the skin of rats.

06.10.1999

(51)

5.2.2 EYE IRRITATION

Species : rabbit
Concentration : undiluted
Dose : 20 other: mg
Exposure time : 24 hour(s)
Comment :
Number of animals : 3
Vehicle :
Result : slightly irritating
Classification :
Method : other
Year : 1963
GLP : no
Test substance : other TS: TCC with 6-8% 4,4'-dichloro and 6-8% 3,3',4,4'-tetrachloro

Method : Twenty (20.0)milligrams of finely ground sample were placed in the conjunctival sac of the right eye of each of three albino rabbits. The eyes were rinsed with warm isotonic saline solution after 24 hours. Observations for irritation were made over a period of several days. The data was scored according to the method of Draize.

Result : The maximum average score was 7.3 out of a possible 110.

Reliability : (2) valid with restrictions

16.12.2002

(47)

Species : rabbit
Concentration :

5. Toxicity

Id 101-20-2

Date 20.12.2002

Dose :
Exposure time : 4 hour(s)
Comment :
Number of animals :
Vehicle :
Result : not irritating
Classification : not irritating
Method :
Year : 1992
GLP :
Test substance :

14.10.2002

(52)

5.3 SENSITIZATION

Type : Patch-Test
Species : human
Concentration : 1st: Induction undiluted semioclusive
2nd: Challenge undiluted semioclusive
3rd:
Number of animals : 50
Vehicle :
Result : not sensitizing
Classification : not sensitizing
Method : other: Shelanski Method (1953)
Year : 1963
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : 50 mg of substance applied to gauze portion of bandaids.
Patches applied to back of 50 subjects for 24 hrs, rested for 24 hours - repeated for 15 applications. After a 2 week rest period, a challenge application, of 50mg, was applied to the same site of each subject for a 24 hour exposure period. Subjects were observed for reactions.
Shelanski. 1953. Proceedings of the Toilet Goods Ass. No.19. May.

Result : The substance was neither a primary irritant, a fatiguing agent, nor a sensitizer to any of the 50 subjects.

Reliability : (2) valid with restrictions

07.11.2002

(53)

5.4 REPEATED DOSE TOXICITY

Type : Sub-chronic
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : gavage
Exposure period : 30 days
Frequency of treatm. : 5 days per week
Post exposure period :
Doses : 500 mg/kg bw and 1000 mg/kg bw
Control group : yes, concurrent no treatment
NOAEL : > 1000 mg/kg bw
Method : other:
Year : 1960

5. Toxicity

Id 101-20-2

Date 20.12.2002

GLP : no
Test substance : as prescribed by 1.1 - 1.4

Method : Each dose and control group contained 10 rats/sex. Animals were dosed with 25% aqueous solution of TCC at 500 or 1000 mg/kg bw by intubation 5 days per week for a thirty day period. Food consumption and weight gain were recorded weekly and observations were made for outward symptoms of toxicity such as reduced activity and non-grooming. At the end of the 30 day period, representative animals from each group were sacrificed. The viscera of the 1000 mg/kg bw and control groups were examined microscopically and saved for possible future examination. Macroscopic examination was made of mounted tissue from liver, kidneys, gonads, adrenals, brain, heart, and lungs.

Result : The feeding of TCC to rats at a daily level of 1000 mg/kg bw, five days per week for thirty days, was not detrimental insofar as could be determined by food consumption, growth data, and tissue examination.

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

Flag : Critical study for SIDS endpoint
16.10.2002 (54)

Type : Chronic
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : oral feed
Exposure period : 24 months
Frequency of treatm. : daily
Post exposure period : no
Doses : 25, 75, and 250 mg/kg bw
Control group : yes, concurrent no treatment
NOAEL : = 25 mg/kg bw
LOAEL : = 75 mg/kg bw
Method : other: Combined chronic toxicity/carcinogenicity test
Year :
GLP : no data
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

Method : Groups of 80 Sprague-Dawley rats/sex were administered TCC in their diet in doses of 0, 25, 75, and 250 mg/kg bw for 24 months. Interim sacrifices of 10 animals/sex/group were done at 6, 12, and 20 months to follow progression of any compound-induced pathological changes. Clinical evaluation (hematology, clinical chemistry, and urinalysis) were done on animals at interim sacrifices and at the end of the study. All animals were subject to complete necropsy. All gross lesions were examined microscopically for possible neoplastic changes. The protocol was approved by FDA prior to its initiation at Bio/Dynamics.

Result : Mortality: no evidence of treatment related mortality (p=0.53 for males and p=0.52 for females)
Observations: no differences between controls and treated animals in daily physical observations, ophthalmic changes, or food consumption.
Body Weight: slightly lower for high dose males (not statistically significant); slightly reduced and significant for high dose females during first 18 months.
Hematology: anemia seen in mid and high dose males and high dose females.
Blood chemistry: slight increase in alkaline phosphatase, BUN, glucose and total bilirubin at various time points for high dose males.
Urinalysis: no difference between control and treated

5. Toxicity

Id 101-20-2

Date 20.12.2002

animals throughout the study.

Organ weights: significant changes associated with treatment = LIVER for mid and high dosed males and females; SPLEEN for mid and high dose males and high dosed females; TESTES and HEART for high dosed males. No microscopic changes in any organs to account for increase in organ weights, therefore the changes may not be biologically significant. Gross Pathological changes: increase in incidence of small and flaccid testes was observed in high dosed males that died spontaneously or were killed moribund between 12 and 23 months. A similar increase was not apparent at terminal sacrifice.

Neoplastic findings: There was no evidence of a dose related increase in tumor incidence at any site.

Reliability : (2) valid with restrictions
Guideline study
07.11.2002 (55)

Type : Sub-chronic
Species : rat
Sex : male
Strain : Sprague-Dawley
Route of admin. : oral feed
Exposure period : 8 weeks
Frequency of treatm. : daily
Post exposure period : no
Doses : 25, 75, 250 mg/kg
Control group : no
NOAEL : 75 mg/kg bw
LOAEL : 250 mg/kg bw
Method : other: similar to Combined chronic toxicity/carcinogenicity test
Year :
GLP : no data
Test substance : other TS: triclocarban, CAS# 101-20-2; purity =98.6%

Method : Three groups of male Sprague-Dawley rats (n=35/group) were administered TCC in their diets for eight weeks. All animals were observed twice daily for morbidity and mortality. Clinical observations for obvious signs of toxicity were performed once daily. Body weights, food consumption, and detailed clinical observations were recorded weekly. Blood was collected from 5/group every two weeks from the abdominal aorta for evaluation of blood levels of TCC. Animals were discarded without necropsy.

Result : Clinically the animals appeared normal throughout the study. Mean body weights were lower for the high dose group, as was decreased food consumption. No compound-related pathology or histopathology noted.

Reliability : (3) invalid
Meets generally accepted scientific method and is described in sufficient detail; Deficiencies: no control group, no histology of tissues, no blood chemistry

16.10.2002 (56)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : Salmonella typhimurium strains TA98, TA100, TA1535, TA1537
Test concentration : 0, 8, 40, 200, 1000, 5000 ug/plate (test 1); 0, 125, 250, 500, 1000, 2000, 4000 ug/plate (test 2)
Cycotoxic concentr. : up to 2000 ug/plate resulted in no cytotoxic effect, however the test substance precipitated at 2000 ug and higher
Metabolic activation : with and without

5. Toxicity

Id 101-20-2

Date 20.12.2002

Result : negative
Method : OECD Guide-line 471
Year : 1991
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Solvent and negative control:
DMSO

Positive controls:
Sodium azide (10 ug/plate) TA 1535
Nitrofurantoin (0.2 ug/plate) TA 100
4-nitro-1,2-phenylene diamine (10 ug/plate) TA 1537
4-nitro-1,2-phenylene diamine (0.5 ug/plate) TA 98
2-aminoanthracene (3 ug/plate)

Metabolic Activation:

S9 mix prepared from livers of male Sprague-Dawley rats treated with a single ip injection of Aroclor 1254 at a dose of 500 mg/kg

Remark : Due to substance precipitation beginning at 2000 ug/plate, doses of 4000 ug and 5000 ug could not be used for assessment. In spite of the low doses used, the positive controls increased the mutant counts significantly over negative control levels, demonstrating the sensitivity of the test system.

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint
16.12.2002

(57)

Type : Chromosomal aberration test
System of testing : Chinese hamster ovary (CHO-K1) cells
Test concentration : 31.3, 62.5, 125, 250, 500, 1000, 1500, 2000 ug/ml
Cycotoxic concentr. : >3160 ug/ml activated and non activated (4 hrs); =3160 ug/ml non-activated (20 hrs)

Metabolic activation : with and without
Result : negative
Method : EPA OPPTS 870.5375
Year :
GLP : yes
Test substance : other TS: triclocarban, purity 100%

Remark : Aroclor 1254-induced rat liver S-9 fraction was used as the metabolic activation system. In the absence of substantial toxicity (>50% cell growth inhibition relative to solvent control) dose levels were selected based on test article precipitate in the test medium. Mitomycin C was used as the positive control in the non-activated study and Cyclophosphamid was used as the positive control in the activated study. Statistical analysis of percent aberrant cells was performed using the Fisher's exact test (pairwise comparison of aberrant cells of each treatment group with that of solvent control).

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint
16.10.2002

(58)

Type : Ames test
System of testing : Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, TA1538
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :

5. Toxicity

Id 101-20-2

Date 20.12.2002

Year : 1982
GLP :
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

16.10.2002

(59)

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : oral feed
Exposure period : 24 months
Frequency of treatm. : ad libitum
Post exposure period : no
Doses : 0, 25, 75, 250 mg/kg
Result : negative
Control group : yes
Method : EPA OTS 798.3320
Year :
GLP : no data
Test substance : other TS: triclocarban, CAS# 101-20-2; purity not noted

Result : No significant adverse effects seen in the low dose animals. Mid and high dose effects: compound related testicular denegeration; anemia, increased liver and spleen weights (male and female); microscopic changes in spleen, bone marrow, liver, kidney (liver changes determined to be adaptive).
No treatment-related increase in mortality. No statistically significant effect on body weight in males, however significantly reduced body weight gain in females of mid and high dose groups.
No evidence of a dose related increase in tumor incidence at any site. No statistically significant difference in tumor incidence between controls and high dose animals (except for a significant reduction in incidence of fibroadenomas and papillary carcinomas in high dose females).

Reliability : (1) valid without restriction
Guideline study

07.11.2002

(55)

5.8.1 TOXICITY TO FERTILITY

Type : other: three generation study
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : oral feed
Exposure period : F0: dosing began 60 days prior to mating, then continuously thereafter. F1 and F2: dosing for 80-day growth period before mating, then continuously thereafter.
Frequency of treatm. : continuously in diet
Premating exposure period
 Male : F0 = 60 days; F1 and F2 = 80 days
 Female : F0 = 60 days; F1 and F2 = 80 days
Duration of test : three generations

5. Toxicity

Id 101-20-2

Date 20.12.2002

No. of generation studies	:	
Doses	:	250, 500, 1000, 3000 ppm
Control group	:	yes, concurrent vehicle
NOAEL parental	:	3000 ppm
NOAEL F1 offspring	:	1000 ppm
NOAEL F2 offspring	:	3000 ppm
Method	:	other: Three generation reproduction study
Year	:	1979
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Dosing, continually in diet, began at least 60 days prior to mating. 1 male:2 females housed together for 15 days. non-pregnated females housed 1:1 with fertile male. Each parental generation was mated twice, with a 14 day rest period between weaning of litter and second mating. The first litters were raised to weaning, the second litter was used to continue the study. Body weights and food consumption were measured weekly during the study. Observations for mortality and adverse effects were done twice daily. Detailed physical exams were done weekly on all generations. All animals dying spontaneously or killed in a moribund condition were examined and tissues preserved in 10% formalin. Dead or stillborn pups were given a gross postmortem exam and preserved in 70% ethanol. All adult males and females were given a gross postmortem exam and tissues preserved. At weaning (day 21), pups not chosen as future parents were sacrificed and examined and only grossly abnormal tissues preserved. Data were analyzed between control and treated groups.
Result	:	No treatment-related effect was evident on mortality or physical in-life evaluations. Body weight and food consumption were not adversely affected by treatment throughout the study. Mating indices and male fertility were not adversely affected by treatment for all generations. Pregnancy rates were comparable to controls for dose groups 250 - 1000 ppm. The pregnancy rate was unusually low for the high dose group (3000 ppm) during the second litter interval of the F1 generation. Gestation length, pup viability, litter size at birth, litter survival indices, pup growth, and survival to weaning were comparable to controls for dose groups 250 - 1000 ppm. The mean number of live pups at birth was lower than controls for both litter intervals of only the F1 generation of the high dose group (3000 ppm).
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint
16.12.2002		(60)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	oral feed
Exposure period	:	F0: dosing began 60 days prior to mating, then continuously thereafter. F1 and F2: dosing for 80-day growth period before mating, then continuously thereafter.
Frequency of treatm.	:	continuously in diet
Duration of test	:	three generations
Doses	:	250, 500, 1000, 3000ppm
Control group	:	yes, concurrent vehicle
NOAEL maternal tox.	:	> 3000 ppm

5. Toxicity

Id 101-20-2

Date 20.12.2002

NOAEL teratogen.	:	> 3000 - ppm
Result	:	No treatment-related effects were seen on any pups from all generations.
Method	:	other: Three generation study
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Dosing, continually in diet, began at least 60 days prior to mating. 1 male:2 females housed together for 15 days. non-pregnated females housed 1:1 with fertile male. Each parental generation was mated twice, with a 14 day rest period between weaning of litter and second mating. The first litters were raised to weaning, the second litter was used to continue the study. Body weights and food consumption were measured weekly during the study. Observations for mortality and adverse effects were done twice daily. Detailed physical exams were done weekly on all generations. All animals dying spontaneously or killed in a moribund condition were examined and tissues preserved in 10% formalin. Dead or stillborn pups were given a gross postmortem exam and preserved in 70% ethanol. All adult males and females were given a gross postmortem exam and tissues preserved. At weaning (day 21), pups not chosen as future parents were sacrificed and examined and only grossly abnormal tissues preserved. Data were analyzed between control and treated groups.
Result	:	No treatment-related effects were seen on any pups from all generations (including dead pups). Litter viability and survival rates were comparable to controls. One dead female F1b pup had clubbed legs and a filamentous tail (250 ppm group); one dead female F1b pup had a spina bifida malformation (1000 ppm group); in the F2b litter, one dead pup was edematous (250 ppm) and one had a kinked tail (250 ppm); no malformations seen in the F3 litters.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific method and is described in sufficient detail
Flag	:	Critical study for SIDS endpoint
07.11.2002		(60)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6. Analyt. Meth. for Detection and Identification

Id 101-20-2
Date 20.12.2002

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7. Eff. Against Target Org. and Intended Uses

Id 101-20-2
Date 20.12.2002

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8. Meas. Nec. to Prot. Man, Animals, Environment

Id 101-20-2
Date 20.12.2002

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

9. References

Id 101-20-2
Date 20.12.2002

- (1) Bayer AG. 2000. Val.01.09.00
- (2) Hawley's Chemical Dictionary, 11th edition
- (3) Meylan W. and Howard P. (1999) EPIWin Modeling Program. Syracuse Research Corporation. Environmental Science Center, 6225 Running Ridge Road, North Syracuse, NY 13212-2510.
- (4) Bayer AG data
- (5) Bayer AG study, 1991
- (6) Monsanto data
- (7) Bayer AG. 1995. Study # A 90/0065/o07 LEV
- (8) Monsanto Study # MSL-1264 (9/22/1980) TCC Environmental Monitoring- Surface Waters and Drinking Waters.
- (9) Monsanto Study #MSL-1332 (10/28/1980)
- (10) Monsanto Study#MSL-1441 (1/28/1981)
- (11) Monsanto Study#MSL-1442 (2/11/1981)
- (12) Monsanto Study#MSL-1756 (9/9/1981)
- (13) Monsanto Study#MSL-1759 (9/24/1981)
- (14) Monsanto Study#ES-84-SS-6 (10/23/1984)
- (15) Monsanto Study#MSL-5342 (1/13/1986)
- (16) Monsanto Study#MSL-7813 (4/25/1988)
- (17) Procter &Gamble Report # BCS-330/BCL-831 (6/18/98)
- (18) Monsanto Study #SRI7939
- (19) Monsanto Study #MSL-1272
- (20) Procter & Gamble Report#E98-001 (3/31/99)
- (21) PBT Profiler, 2002, USEPA, <http://www.pbtprofiler.net>
- (22) Bayer AG Report 284 A/91 R, 1/31/1992
- (23) Gledhill, W.E. 1975. Water Research 9:649-654
- (24) Monsanto, 1979, SRI International Project# 7939
- (25) Monsanto, 1980, Project # 03-000-760.11-7603495, Report # MSL-1277
- (26) Bayer AG, 1995, Study #536A/95F
- (27) Monsanto, 1976. EG&G Bionomics Study# BN-76-339
- (28) Bayer AG, 1995, Study 536 A/95D

9. References

Id 101-20-2

Date 20.12.2002

- (29) Monsanto, 1988. Springborn Life Sciences Study# 252.0887.6119.132, REPORT # 87-12-2582, Monsanto Project #SB-87-9147
- (30) Monsanto, 1978, Project# N-80-418, EG&G Bionomics Aquatic Toxicology Laboratory, Report# BW-78-11-347
- (31) Monsanto, 1987, Springborn Life Sciences Report# 87-12-2582
- (32) Monsanto, 1979, EG&G Bionomics Marine Research Laboratory Project# BP-79-10-157
- (33) Monsanto, 1980, Project # BN-80-463, EG&G Bionomics Aquatic Toxicology Laboratory, Project # H47-500, Report # BP-80-9-152R
- (34) Bayer AG, 1995, Study #536A/95AL
- (35) Monsanto, 1980, EG&G Bionomics Report# BP-80-9-151R, Project # H67-500
- (36) Procter & Gamble Study #85-057
- (37) Procter & Gamble, 1986, Study # 85-051
- (38) Monsanto study performed by EG&G Bionomics Labs. 1992.
EPA/OTS Doc. No. 88-920007745 Rec: 8/28/92
NTIS/OTS 0538665
- (39) ABC Laboratories #44442
- (40) Monsanto, 1992, Study #XX-92-9893, performed at Battelle/Marine Sciences Laboratory.
- (41) Procter & Gamble, 1997, ABC Laboratories Study #BP96E021
- (42) Monsanto, 1980, Project # BN-80-462, EG&G Bionomics Marine Research Laboratory, Project # H95, Report BP-79-10-154R
- (43) Monsanto, 1980, Project # BN-80-463, EG&G Bionomics Aquatic Toxicology Laboratory, 1980, Project # H47-500, Report # BP-80-9-152R
- (44) Monsanto, 1978, Project# BN-80-415, EG&G Bionomics Aquatic Toxicology Laboratory, Report# BW-78-5-149
- (45) Monsanto, 1979, Project # BN-80-416, EG&G Bionomics Report# BW-79-11-559
- (46) Bayer AG Study # 20662 (9/24/1991)
- (47) Monsanto, 1963, Younger Laboratories Project# Y-63-23
- (48) Marty, J.P. and Wepierre, J. 1979. Labo-Pharma 286:306-310
- (49) Bayer Report # 20929 (Jan. 08, 1992)
- (50) Lautier, F. et al. 1978. La Pharmacie Hospitaliere Francaise. 43:59-69.
- (51) Morikawa, F. et al. 1974. J. Soc. Cosmet. Chem. 25:113-130
- (52) Bayer Report # 20929 (Jan. 8, 1992)
- (53) Monsanto, 1963, Industrial Biology Laboratories Project# SH-63-7
- (54) Monsanto, 1960, Younger Laboratories Project# Y-60-39
- (55) Monsanto, performed at Bio/dynamics.

9. References

Id 101-20-2
Date 20.12.2002

- (56) Monsanto, 1985, Hazleton Laboratories Report # 241-180
- (57) Bayer Report #21078 (Feb 14, 1992)
- (58) SDA Project No. 2002-01-TCC, Bioreliance Study No. AA55XE.331.BTL; 2002
- (59) Bonin, A.M. et al. 1982. Mutation Research. 105:303-308.
- (60) Monsanto, 1983, Bio/dynamics Project # 79-2398 (BD-79-058)

10. Summary and Evaluation

Id 101-20-2
Date 20.12.2002

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT