

201-14933B |

# I U C L I D

## Data Set

03 DEC 19 PM 1:51

RECEIVED  
OPPT/CBIC

**Existing Chemical** : ID: 26761-45-5  
**CAS No.** : 26761-45-5  
**EINECS Name** : 2,3-epoxypropyl neodecanoate  
**EC No.** : 247-979-2  
**TSCA Name** : Neodecanoic acid, oxiranylmethyl ester  
**Molecular Formula** : C13H24O3

**Producer related part**  
**Company** : ExxonMobil Biomedical Sciences Inc.  
**Creation date** : 05.09.2003

**Substance related part**  
**Company** : ExxonMobil Biomedical Sciences Inc.  
**Creation date** : 05.09.2003

**Status** :  
**Memo** :

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**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

## 1.0.1 APPLICANT AND COMPANY INFORMATION

Type :  
Name : Deutsche Exxon Chemical G.m.b.H  
Contact person :  
Date :  
Street : Neusser Landstrasse, 16  
Town : 5000 Koeln  
Country : Germany  
Phone : 0221.7703.1  
Telefax : 0021.7703.355  
Telex : 8885260  
Cedex :  
Email :  
Homepage :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

Type :  
Name : EXXON CHEMICAL HOLLAND BV  
Contact person :  
Date :  
Street : Botlekweg 121  
Town : 3197 KA Botlek Rt.  
Country : Netherlands  
Phone : 31.1819.55971  
Telefax : 31.1819.55983  
Telex :  
Cedex :  
Email :  
Homepage :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

Type :  
Name : Exxon Chemical Mediterranea S.p.A.  
Contact person :  
Date :  
Street : via Paleocapa 7  
Town : 20121 MILANO  
Country : Italy  
Phone : (02) 8803 1  
Telefax : 8803 231  
Telex : 333072 I  
Cedex :  
Email :  
Homepage :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

Type :  
Name : SERVO DELDEN BV  
Contact person :  
Date :  
Street : LANGESTRAAT 167  
Town : 7491 AE DELDEN

Country : Netherlands  
Phone : 05407-75000  
Telefax : 05407-75075  
Telex :  
Cedex :  
Email :  
Homepage :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

Type :  
Name : Shell Nederland Chemie B.V.  
Contact person :  
Date :  
Street : P.O. Box 3030  
Town : 3190 GH Hoogvliet-Rotterdam  
Country : Netherlands  
Phone : +31-10-2317005  
Telefax : +31-10-2317125  
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Cedex :  
Email :  
Homepage :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

## 1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

## 1.0.3 IDENTITY OF RECIPIENTS

## 1.0.4 DETAILS ON CATEGORY/TEMPLATE

### 1.1.0 SUBSTANCE IDENTIFICATION

#### 1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :  
Substance type : organic  
Physical status : liquid  
Purity :  
Colour :  
Odour :

Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

#### 1.1.2 SPECTRA

**1.2 SYNONYMS AND TRADENAMES****Cardura E 10**

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
03.05.1994

**Glycidyl ester of Versatic 10**

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
18.08.1993

**Glydexx N-10**

**Source** : EXXON CHEMICAL HOLLAND BV Botlek Rt.  
Exxon Chemical Mediterranea S.p.A. MILANO  
Deutsche Exxon Chemical G.m.b.H Koeln  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
10.12.1997

**Neodecanoic acid glycidyl ester**

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
18.08.1993

**Neodecanoic acid-1,2-epoxypropyl ester**

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
08.09.2003

**1.3 IMPURITIES****1.4 ADDITIVES****1.5 TOTAL QUANTITY**

**Quantity** : 50000 - 100000 tonnes in

**Source** : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
11.02.2000

**1.6.1 LABELLING****1.6.2 CLASSIFICATION****1.6.3 PACKAGING**

**1.7 USE PATTERN**

<b>Type of use</b>	:	type
<b>Category</b>	:	Non dispersive use
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	type
<b>Category</b>	:	Use resulting in inclusion into or onto matrix
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	type
<b>Category</b>	:	Wide dispersive use
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	industrial
<b>Category</b>	:	Chemical industry: used in synthesis
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	industrial
<b>Category</b>	:	Paints, lacquers and varnishes industry
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	use
<b>Category</b>	:	Intermediates
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	use
<b>Category</b>	:	Solvents
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
<b>Type of use</b>	:	use
<b>Category</b>	:	other
<b>Source</b> 11.02.2000	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

**1.7.1 DETAILED USE PATTERN****1.7.2 METHODS OF MANUFACTURE****1.8 REGULATORY MEASURES**

**1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES**

**Remark** : None established  
**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
18.08.1993

**1.8.2 ACCEPTABLE RESIDUES LEVELS****1.8.3 WATER POLLUTION****1.8.4 MAJOR ACCIDENT HAZARDS****1.8.5 AIR POLLUTION****1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES****1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS****1.9.2 COMPONENTS****1.10 SOURCE OF EXPOSURE****1.11 ADDITIONAL REMARKS**

**Remark** : Not dangerous for conveyance under UN,IMO,ADR/RID and  
IATA/ICAO codes.  
Waste/product disposal-recover or recycle if  
possible,otherwise incineration with wet scrubbing  
facilities.  
**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
25.04.1994

**1.12 LAST LITERATURE SEARCH****1.13 REVIEWS**

## 2.1 MELTING POINT

<b>Value</b>	: -68 °C	
<b>Sublimation</b>	:	
<b>Method</b>	: other: no data	
<b>Year</b>	:	
<b>GLP</b>	:	
<b>Test substance</b>	: other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)	
<b>Test substance</b>	: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)	
<b>Conclusion</b>	: Based on measured data, Glydexx N-10 has a melting point of < -68 Degree C.	
<b>Reliability</b>	: (2) valid with restrictions This robust summary has a reliability rating of 2 because there were insufficient data on test parameters, replication, and results to support a reliability rating of higher than 2. This robust summary represents a "key study" for melting point.	
<b>Flag</b>	: Critical study for SIDS endpoint	
09.09.2003		(9)

## 2.2 BOILING POINT

<b>Value</b>	: 251 - 278 °C at 1013 hPa	
<b>Source</b>	: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)	
18.08.1993		
<b>Value</b>	: 484 - 491 °C at	
<b>Decomposition</b>	:	
<b>Method</b>	: other: no data	
<b>Year</b>	:	
<b>GLP</b>	:	
<b>Test substance</b>	: other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)	
<b>Result</b>	: Glydexx N-10 has a boiling point over a narrow temperature range: 484 Degree to 491 Degree C.	
<b>Test substance</b>	: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)	
<b>Conclusion</b>	: Based on measured data, Glydexx N-10 has a boiling point of 484 Degree to 491 Degree C.	
<b>Reliability</b>	: (2) valid with restrictions This robust summary has a reliability rating of 2 because there were insufficient data on test parameters, replication, and results to support a reliability rating of higher than 2. This robust summary represents a "key study" for boiling point.	
<b>Flag</b>	: Critical study for SIDS endpoint	
09.09.2003		(9)

## 2.3 DENSITY

<b>Type</b>	: density	
<b>Value</b>	: ca. 958 - 968 kg/m3 at 20 °C	

**Method** : other  
**Year** :  
**GLP** :  
**Test substance** :  
  
**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
 EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
 18.08.1993

### 2.3.1 GRANULOMETRY

### 2.4 VAPOUR PRESSURE

**Value** : .15 hPa at 20 °C  
**Decomposition** :  
**Method** :  
**Year** :  
**GLP** :  
**Test substance** : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)  
  
**Result** : Glydexx N-10 vapor pressure at two temperatures:  
 0.15 hPa at 20 Degree C  
 0.75 hPa at 50 Degree C  
**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)  
**Conclusion** : Based on measured data, Glydexx N-10 has a vapor pressure of 0.15 hPa at 20 Degree C and 0.75 hPa at 50 Degree C.  
**Reliability** : (2) valid with restrictions  
 This robust summary has a reliability rating of 2 because there were insufficient data on test parameters, replication, and results to support a reliability rating of higher than 2. This robust summary represents a "key study" for vapor pressure.  
**Flag** : Critical study for SIDS endpoint  
 09.09.2003 (9)

**Value** : ca. 3.3 hPa at 100 °C  
  
**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
 EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
 18.08.1993

### 2.5 PARTITION COEFFICIENT

**Partition coefficient** :  
**Log pow** : = 4.4 at 20 °C  
**pH value** :  
**Method** : OECD Guide-line 117 "Partition Coefficient (n-octanol/water), HPLC Method"  
**Year** : 1989  
**GLP** : yes  
**Test substance** :  
  
**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
 EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
 08.09.2003 (4)



<b>Method</b>	:	other (calculated): Calculated value using KOWWIN version 1.65, a subroutine of the computer program EPIWIN version 3.04.
<b>Year</b>	:	
<b>GLP</b>	:	
<b>Test substance</b>	:	other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
<b>Remark</b>	:	Estimation Temperature: 25 Degree C
<b>Result</b>	:	The hydrolyzed form of Glydexx N-10 has a calculated log Pow of 2.58. This endpoint was calculated for the diol form because Glydexx N-10 is an epoxide that is subject to hydrolysis at a sufficiently rapid rate in aqueous solution such that the epoxide form would not be found in solution.
<b>Test condition</b>	:	Octanol / Water Partition Coefficient (Pow) estimations calculated by KOWWIN subroutine, which is based on an atom/fragment contribution method of:  Meylan W and Howard P (1995). Atom/fragment contribution method for estimating octanol-water partition coefficients. J. Pharm. Sci. 84, 83-92.
<b>Test substance</b>	:	Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
<b>Conclusion</b>	:	Based on calculated data, the hydrolyzed form of Glydexx N-10 has a log Pow of 2.58.  Describing the partitioning behavior of Glydexx N-10, which is an epoxide, in the diol form is more appropriate for evaluating its environmental and biological partitioning behavior because this form will be the prevalent form in aquatic habitats and in biological systems.
<b>Reliability</b>	:	(2) valid with restrictions This robust summary has a reliability rating of 2 because the data are calculated based on chemical structure as modeled by EPIWIN. This robust summary represents a "key study" for log Kow.
<b>Flag</b>	:	Critical study for SIDS endpoint
09.09.2003		(5)

## 2.6.1 SOLUBILITY IN DIFFERENT MEDIA

<b>Deg. product</b>	:	
<b>Method</b>	:	other: Calculated value using MPBPWIN version 1.40, a subroutine of the computer program EPIWIN version 3.04
<b>Year</b>	:	
<b>GLP</b>	:	
<b>Test substance</b>	:	other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
<b>Remark</b>	:	Estimation Temperature: 25 Degree C
<b>Result</b>	:	The hydrolyzed form of Glydexx N-10 has a calculated water solubility of 156.3 mg/L. This endpoint was calculated for the diol form because Glydexx N-10 is an epoxide that is subject to hydrolysis at a sufficiently rapid rate in aqueous solution such that the epoxide form would not be found in solution.
<b>Test condition</b>	:	Water solubility calculated by WSKOWWIN subroutine, which is based on a Kow correlation method described by: Meylan W, Howard P and Boethling R (1995). Improved method for estimating water solubility from octanol/water partition coefficient. Environ. Toxicol. Chem. 15,100-106.
<b>Test substance</b>	:	Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
<b>Conclusion</b>	:	Based on calculated data, the hydrolyzed form of Glydexx N-10 has a water solubility of 156.3 mg/L.

**Reliability**

Describing the partitioning behavior of Glydexx N-10, which is an epoxide, in the diol form is more appropriate for evaluating its environmental and biological partitioning behavior because this form will be the prevalent form in aquatic habitats and in biological systems.

: (2) valid with restrictions

This robust summary has a reliability rating of 2 because the data are calculated based on chemical structure as modeled by EPIWIN. This robust summary represents a "key study" for water solubility.

**Flag**

: Critical study for SIDS endpoint

09.09.2003

(5)

**2.6.2 SURFACE TENSION****2.7 FLASH POINT****Value**

: = 126 °C

**Type**

: closed cup

**Method**

: other

**Year**

:

**GLP**

:

**Test substance**

:

**Source**

: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

18.08.1993

**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**

## 3.1.1 PHOTODEGRADATION

Type	: air
Light source	: Sun light
Light spectrum	: nm
Relative intensity	: based on intensity of sunlight
Conc. of substance	: at 20 °C
<b>INDIRECT PHOTOLYSIS</b>	
Sensitizer	: OH
Conc. of sensitizer	: 1000000 molecule/cm <sup>3</sup>
Rate constant	: = .00000000000944 cm <sup>3</sup> /(molecule*sec)
Degradation	: = 50 % after .9 day(s)
Deg. product	:
Method	: OECD Guide-line draft "Photochemical Oxidative Degradation in the Atmosphere"
Year	: 1989
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Source	: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
05.10.1993	
Type	: other: N/A
Light source	: Sun light
Light spectrum	: nm
Relative intensity	: = 1 based on intensity of sunlight
Deg. product	:
Method	: other (calculated): Calculated values using AOPWIN version 1.89, a subroutine of the computer program EPIWIN version 3.04
Year	:
GLP	:
Test substance	: other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Remark	: Degradation Products: Unknown
Result	: Indirect Photolysis:

In the environment, several important transformation processes degrade organic chemicals emitted into the troposphere. The dominant transformation process for many substances is the daylight reaction with hydroxyl (OH-) radicals (1,2). The rate at which an organic compound reacts with OH- radicals is a direct measure of its atmospheric persistence (3).

AOPWIN estimates the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic substances. The rate constants estimated by the program are then used to calculate atmospheric half-lives for organic substances based upon an average atmospheric concentration of hydroxyl radicals.

Atmospheric oxidation reactions only take place in the presence of sunlight. Therefore, the atmospheric half-life is normalized to a 12-hour day.

The following is the AOP value calculated by the EPIWIN program for neodecanoic acid, 1,2-epoxypropyl ester (Glydexx N-10, CAS No. 26761-45-5):

Calculated\* OH- Rate Constant

Substance	half-life (da)	(cm <sup>3</sup> /molecule-sec)
Glydexx N-10	1.11	9.64 E-12

\* Atmospheric half-life values are based on a 12-hr day.

#### References

1. Atkinson R (1988). Estimation of gas-phase hydroxyl radical rate constants for organic chemicals. Environ. Toxicol. Chem. 7,435-442.
2. Atkinson R (1989). Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds. J. Phys. Chem. Ref. Data Monograph No. 1, Amer. Inst. Physics & Amer. Chem. Soc., New York, NY, USA.
3. Meylan W and Howard P (1993). Computer estimation of the atmospheric gas-phase reaction rate of organic compounds with hydroxyl radicals and ozone. Chemosphere. 12,2293-2299.

**Test condition** : Indirect photodegradation, or atmospheric oxidation potential, is based on the structure-activity relationship methods developed by R. Atkinson under the following conditions:

Temperature: 25°C

Sensitizer: OH- radical

Concentration of Sensitizer: 1.5E6 OH- radicals/cm<sup>3</sup>

**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)

**Conclusion** : Atmospheric oxidation reactions from hydroxyl radical attack can significantly contribute to the degradation of neodecanoic acid, 1,2-epoxypropyl ester (CAS No. 26761-45-5, Glydexx N-10). Glydexx N-10 has a relatively high vapor pressure, which suggests that it can partition into the air phase to a significant extent where oxidation reactions occur. Results using the Mackay Level I model to assess the potential partitioning behavior of this substance support this assessment.

Glydexx N-10 is calculated to have an atmospheric half-life of 1.11 days, based on a OH- rate constant of 9.64 E-12 cm<sup>3</sup>/molecule-sec. These data suggest that this substance will degrade at a relatively rapid rate in the air phase.

**Reliability** : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are not measured. These data represent a key study for characterizing the AOP of neodecanoic acid, 1,2-epoxypropyl ester (Glydexx N-10). The results include values calculated using the AOPWIN program as contained in the EPIWIN model and represent a potential atmospheric half-life for this substance.

**Flag** : Critical study for SIDS endpoint  
09.09.2003

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### 3.1.2 STABILITY IN WATER

**Type** : abiotic  
**t1/2 pH4** : at °C  
**t1/2 pH7** : at °C  
**t1/2 pH9** : at °C  
**Deg. product** :  
**Method** : other: Technical discussion  
**Year** :  
**GLP** :  
**Test substance** : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)

**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)

**Conclusion**

- : The epoxide group in Glydext N-10 (neodecanoic acid, 1,2-epoxypropyl ester) is subject to rapid hydrolysis in water at pH 7, forming the diol with a half-life that could approximate 2 weeks or less, depending on structure (1,2). A second group in the parent substance, the ester, can also hydrolyze. However, this reaction is estimated to occur at a much slower rate with estimated half-lives of greater than 4 years depending on pH, at levels greater than or equal to pH 7 (3). A technical discussion of this process as it applies to Glydext N-10 follows below.

## Hydrolysis of as a Function of Molecular Structure

Hydrolysis of an organic molecule occurs when that molecule (R-X) reacts with water (H<sub>2</sub>O) to form a new carbon-oxygen bond after the carbon-X bond is cleaved (4,5). Mechanistically, this reaction is referred to as a nucleophilic substitution reaction, where X is the leaving group being replaced by the incoming nucleophilic oxygen from the water molecule. The leaving group, X, must be a molecule other than carbon because for hydrolysis to occur, the R-X bond cannot be a carbon-carbon bond.

The carbon atom lacks sufficient electronegativity to be a good leaving group and carbon-carbon bonds are too stable (high bond energy) to be cleaved by nucleophilic substitution. Under strongly acidic conditions a carbon-carbon double bond can react with water by an addition reaction mechanism (4). The reaction product is an alcohol. This reaction is not considered to be hydrolysis because the carbon-carbon linkage is not cleaved and because the reaction is freely reversible (4).

Substances that have a potential to hydrolyze include alkyl halides, amides, carbamates, epoxides, carboxylic acid esters and lactones, phosphate esters, and sulfonic acid esters (5). Two groups in neodecanoic acid, 1,2-epoxypropyl ester are subject to hydrolysis and include an epoxide and ester.

The epoxide can be hydrolyzed to form the diol. Hydrolysis for this group is estimated to occur at a rapid rate, based on data for 14 epoxides at pH 7 (1), as summarized by Harris (1982), that ranged in half-life from approximately 1 minute to 8 days. In comparison, the ester group is estimated to hydrolyze at a significantly slower rate. The aqueous base/acid-catalyzed hydrolysis half-life at pH 8 and 7 (25degC) is estimated as 4.4 and 44.3 years, respectively.

## References

1. Mabey W and Mill T (1978). Critical review of hydrolysis of organic compounds in water under environmental conditions. J. Phys. Chem. Ref. Data 7,383-415.
2. Harris J (1982). Rate of hydrolysis. In: Handbook of Chemical Property Estimation Methods, Lyman W, Reehl W and Rosenblatt D (eds.), Chapter 7. McGraw-Hill Book Company, New York, USA.
3. EPIWIN (1999). Estimation Program Interface for Windows, version 3.04. Syracuse Research Corporation, Syracuse, NY, USA.
4. Gould E (1959). Mechanism and structure in organic chemistry. Holt, Reinhart, and Winston, New York, NY, USA.
5. Neely W (1985). Hydrolysis. In: Environmental Exposure from Chemicals. Vol. 1. Neely W and Blau G (eds.), pp. 157-173. CRC Press, Boca Raton, FL, USA.

**Reliability**

- : (1) valid without restriction  
These data represent a key study for characterizing the potential of neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydext N-10), to undergo hydrolysis to the diol form.

**Flag**

- : Critical study for SIDS endpoint

09.09.2003

(10)

**3.1.3 STABILITY IN SOIL****3.2.1 MONITORING DATA****3.2.2 FIELD STUDIES****3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS**

<b>Type</b>	: volatility
<b>Media</b>	: water - air
<b>Air</b>	: % (Fugacity Model Level I)
<b>Water</b>	: % (Fugacity Model Level I)
<b>Soil</b>	: % (Fugacity Model Level I)
<b>Biota</b>	: % (Fugacity Model Level II/III)
<b>Soil</b>	: % (Fugacity Model Level II/III)
<b>Method</b>	: other
<b>Year</b>	: 1982
<b>Remark</b>	: The volatilisation halflife of CARDURA E10 in a model river of 1 m deep and a current of 1 m/s at a wind velocity of 3 m/s is calculated to be 15.8 hours
<b>Source</b>	: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
01.12.2003	(14)

**3.3.2 DISTRIBUTION**

<b>Media</b>	: air - biota - sediment(s) - soil - water
<b>Method</b>	: Calculation according Mackay, Level I
<b>Year</b>	: 1981
<b>Result</b>	: Air : 24.02 %m; Water : 75.72 %m; Soil : 0.13 %m; Sediment: 0.12 %m; Biota : 0.00 %m.
<b>Source</b>	: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
01.12.2003	(15)
<b>Media</b>	:
<b>Method</b>	: Calculation according Mackay, Level I
<b>Year</b>	:
<b>Remark</b>	: Estimation Temperature: 20 Degree C
<b>Result</b>	: Distribution data can be used as an estimate of substance partitioning behavior. The following Mackay Level I model distribution values were determined using measured and calculated physicochemical input data:

Substance	Calculated Percent Distribution		
	Air	Water	Soil
Glydexx N-10	99.69	0.23	0.08
Diol Form	0.00	74.38	25.04

**Test condition**

- Distribution of the parent substance, neodecanoic acid, 1,2-epoxypropyl ester, and its diol form to compartments not listed above (sediment, suspended sediment, biota) was calculated as less than 1%.
- : The EQC Level I is a steady state, equilibrium model that utilizes the input of basic chemical properties including molecular weight, melting point, log Kow, vapor pressure, and water solubility to calculate distribution within a standardized regional environment.

Distribution data from the equilibrium model provide basic information on the potential partitioning behavior of a substance between selected environmental compartments (i.e., air, water, soil, sediment, suspended sediment, biota).

Physicochemical input values for Glydexx N-10 were either calculated (1) or measured (2). Because Glydexx N-10 is an epoxide, subject to hydrolysis resulting in the formation of the diol when exposed to water, distribution was also evaluated for the hydrolyzed form.

Distribution of the parent substance was calculated using the following model input parameters:

Molecular Weight 228.33  
 Temperature 20°C  
 Log Kow 2.58 (EPIWIN)  
 Water Solubility 156.3g/m3 (EPIWIN)  
 Vapor Pressure 1467 Pa (MSDS)  
 Melting Point -68°C (MSDS)

[Note: Log Kow and water solubility values cannot be measured for the epoxide form and must be calculated. However, EWIPWIN calculates the same values for the diol form as seen below.]

Distribution of the diol form was calculated using the following model input parameters:

Molecular Weight 246.35  
 Temperature 20°C  
 Log Kow 2.58 (EPIWIN)  
 Water Solubility 156.3g/m3 (EPIWIN)  
 Vapor Pressure 9.3E-5 Pa (EPIWIN)  
 Melting Point -68°C (MSDS value for the parent substance;  
 the EPIWIN value for the diol was not used  
 as it was felt the estimated value,  
 100.8°C, was incorrect)

1. EPIWIN (1999). Estimation Program Interface for Windows, version 3.04. Syracuse Research Corporation, Syracuse, NY, USA.
2. Exxon Chemical Company (1998). Glydexx N-10 Material Safety Data Sheet, March 21, 1998.

**Test substance**

- : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10 and its diol form)

**Conclusion**

- : The partitioning data represent a potential distribution for Glydexx N-10 and its diol form. Data for the parent and hydrolyzed form are presented because of the potential for the parent to hydrolyze in the presence of water. Glydexx N-10, the parent, is calculated to partition primarily to air, which is explained by its relatively high vapor pressure. In comparison, the diol form is calculated to partition largely between water and soil. This shift in partitioning behavior is explained by the much lower vapor pressure of the diol form.

**Reliability**

- : (2) valid with restrictions  
 This robust summary has a reliability rating of 2 because some of the physicochemical input data are not measured. These data represent a key study for characterizing the potential distribution of neodecanoic acid, 1,2-

epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10) and its diol form.  
Computer modeling is an accepted method for assessing the  
environmental distribution of chemicals.

**Flag** : Critical study for SIDS endpoint  
09.09.2003 (16)

### 3.4 MODE OF DEGRADATION IN ACTUAL USE

**Result** : In air Cardura E10 will be degraded rapidly by reaction with  
OH-radicals

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
08.09.2003

### 3.5 BIODEGRADATION

**Type** : aerobic  
**Inoculum** : activated sludge, domestic, non-adapted  
**Concentration** : 20 mg/l related to Test substance  
related to

**Contact time** :  
**Degradation** : = 7 - 8 (±) % after 28 day(s)  
**Result** : under test conditions no biodegradation observed

**Deg. product** :  
**Method** : OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test"  
**Year** :  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
01.12.2003 (26)

**Type** : aerobic  
**Inoculum** : activated sludge, domestic  
**Concentration** : 20 mg/l related to Test substance  
related to

**Contact time** :  
**Degradation** : = 68 (±) % after 14 day(s)  
**Result** : inherently biodegradable

**Deg. product** :  
**Method** : OECD Guide-line 302 A "Inherent Biodegradability: Modified SCAS Test"  
**Year** :  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
01.12.2003 (27)

**Type** :  
**Inoculum** : activated sludge, domestic  
**Contact time** : 28 day(s)  
**Degradation** : (±) % after  
**Result** :  
**Deg. product** :



**Method** : OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"  
**Year** : 1996  
**GLP** : no  
**Test substance** : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydext N-10)

**Remark** : Ready Biodegradability, Manometric Respirometry Test  
**Result** : By day 28, 11.6% degradation of the test substance was observed.

By day 14, >60% biodegradation of positive control was observed, which meets the guideline requirement. No significant excursions from the protocol were noted.

Biodegradation was based on oxygen consumption and the theoretical oxygen demand of the test material as calculated using results of an elemental analysis of the test material.

	% Degradation* (day 28)	Mean % Degradation (day 28)
Sample		
Test Substance	12.5, 11.5, 10.7	11.6
Na Benzoate	95.5, 98.9	97.2

\* replicate data

**Test condition** : Activated sludge and test substance were combined prior to test material addition. Test medium consisted of glass distilled water and mineral salts (phosphate buffer, ferric chloride, magnesium sulfate, calcium chloride).

Test vessels were 1L glass flasks placed in a waterbath and electronically monitored for oxygen consumption. Test substance was tested in triplicate, controls and blanks were tested in duplicate.

Test substance concentration was between 31 to 50 mg/L. Sodium benzoate (positive control) concentration was approximately 44 mg/L.

Test temperature was 22 +/- 1 Deg C. All test vessels were stirred constantly for 28 days using magnetic stir bars and plates.

**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydext N-10)

**Conclusion** : The test substance is not readily biodegradable.

**Reliability** : (1) valid without restriction

This summary represents a key study because the testing procedure followed an OECD standard guideline, which describes a procedure specifically designed to evaluate this endpoint, and the results were reviewed for reliability and assessed as valid.

**Flag** : Critical study for SIDS endpoint  
01.12.2003

(7)

**Type** :  
**Inoculum** : activated sludge  
**Contact time** : 36 day(s)  
**Degradation** : (±) % after

**Result** :

**Deg. product** :

**Method** : OECD Guide-line 302 A "Inherent Biodegradability: Modified SCAS Test"

**Year** : 1989

**GLP** : yes

**Test substance** : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)

**Remark** : Inherent Biodegradability: Modified SCAS Test

**Result** : After 22 days acclimation, continuing to day 36 (test termination), DOC

removal remained at 68 +/- 5%. Removal was based on DOC reduction in replicate SCAS systems.

Mean effluent DOC concentration in the test substance SCAS systems on day 22 was 7.22 +/- 0.63 ppm. The control systems DOC concentration was 2.88 +/- 0.29 ppm. The influent DOC value, 13.68 ppm, used to calculate test substance removal was based on the theoretical percent carbon content of the test substance.

No excursions from the protocol were noted.

% DOC Removal\*  
(between days 22 and 36)

Test Substance 68 +/- 5

\* average of duplicate data

**Test condition** : Activated sludge and test substance were combined prior to test material addition. Test substance removal was based on loss of dissolved organic carbon

Test temperature was 20 +/- 1 Deg C. Through the test, dissolved oxygen ranged from 3.5 to 6.7 mg/L, pH ranged from 7.0 to 7.4, and mixed liquor suspended solids ranged from 2.3 to 3.3 g/L.

**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)

**Conclusion** : The test substance is inherently biodegradable.

**Reliability** : (1) valid without restriction

The test procedure followed an OECD standard guideline, which describes a procedure specifically designed to evaluate this endpoint, and the results were reviewed for reliability and assessed as valid.

08.09.2003

(1)

### 3.6 BOD5, COD OR BOD5/COD RATIO

### 3.7 BIOACCUMULATION

### 3.8 ADDITIONAL REMARKS

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

<b>Type</b>	: semistatic								
<b>Species</b>	: <i>Oncorhynchus mykiss</i> (Fish, fresh water)								
<b>Exposure period</b>	: 96 hour(s)								
<b>Unit</b>	: mg/l								
<b>LC50</b>	: = 5								
<b>Limit test</b>	:								
<b>Analytical monitoring</b>	: yes								
<b>Method</b>	: OECD Guide-line 203 "Fish, Acute Toxicity Test"								
<b>Year</b>	: 1981								
<b>GLP</b>	: yes								
<b>Test substance</b>	: as prescribed by 1.1 - 1.4								
<b>Source</b>	: Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)								
01.12.2003	(24)								
<b>Type</b>	: static								
<b>Species</b>	: <i>Oncorhynchus mykiss</i> (Fish, fresh water)								
<b>Exposure period</b>	: 96 hour(s)								
<b>Unit</b>	: mg/l								
<b>Limit test</b>	:								
<b>Analytical monitoring</b>	: yes								
<b>Method</b>	: EPA OTS 797.1400								
<b>Year</b>	: 1998								
<b>GLP</b>	: no								
<b>Test substance</b>	: other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)								
<b>Method</b>	: Probit analysis based on: Finney D (1971). Probit analysis. Third Edition. Cambridge University Press, London, England.								
<b>Result</b>	: 96-hour LC50 = 9.61 mg/L (95% CI 6.35 to 13.6 mg/L) based upon measured concentrations								
	<table> <tr> <th>Measured Conc. (mg/L)</th><th>Fish Total Mortality (@ 24, 48, 72, 96 hrs)*</th></tr> <tr> <td>Control</td><td>0, 0, 0, 0</td></tr> <tr> <td>1.32</td><td>0, 0, 0, 0</td></tr> <tr> <td>5.56</td><td>0, 5, 5, 5</td></tr> </table> <p>represents a "key study" for vapor pressure. Flag: Critical study for SIDS endpoint 09.09.2003(9) Value: ca. 3.3 IF "3.3" &lt;&gt; ""</p> <p>organic carbon measurements of samples taken from exposure solutions at test initiation and termination. Exposure concentrations are based on the average of analyses.</p>	Measured Conc. (mg/L)	Fish Total Mortality (@ 24, 48, 72, 96 hrs)*	Control	0, 0, 0, 0	1.32	0, 0, 0, 0	5.56	0, 5, 5, 5
Measured Conc. (mg/L)	Fish Total Mortality (@ 24, 48, 72, 96 hrs)*								
Control	0, 0, 0, 0								
1.32	0, 0, 0, 0								
5.56	0, 5, 5, 5								
<b>Test condition</b>	: Individual treatments of each test substance concentration were prepared. Each treatment was prepared by adding the appropriate amount of test substance to dilution medium in glass vessels. The treatment solutions were mixed at a vortex of <=10% of the static medium depth of solution. The treatment solutions were mixed for approximately 24 hours on magnetic stirplates with teflon coated stirbars. After mixing, the solutions were allowed to settle for approximately 1 hour before the aqueous phase was removed and added to 19 L glass aquaria, each containing 9 L of								

treatment solution.

Nominal test substance treatment levels were 62.5, 125, 250, 500, and 1000 mg/L. Measured treatment levels were 1.32, 5.56, 8.72, 13.6, and 18.9 mg/L, based on the mean of test material in samples taken from treatment solutions at test initiation and termination, as determined using total organic carbon measurements.

Lighting was 63.01 to 71.28 foot-candles with 16 hours light and 8 hours dark. Treatment solution parameters are as follows:

Treatment Level (mg/L)	Dissolved Oxygen (mg/L)	pH	Temperature (Deg. C)
Control	9.3 - 10.4	7.0 - 7.8	11.1 - 12.5
1.32	8.8 - 9.7	6.9 - 7.7	11.1 - 12.3
5.56	8.1 - 10.6	6.8 - 7.7	11.0 - 12.0
8.72	8.3 - 10.4	6.9 - 7.6	11.0 - 12.6
13.60	9.4 - 10.6	7.0 - 7.6	11.0 - 12.1
18.90	9.5 - 10.4	7.5 - 7.7	11.1 - 12.3

Fish supplied by Thomas Fish Co., Anderson, CA, USA: age = approx. 6 weeks old; mean wt. = 0.429 g; mean total length = 4.0 cm; test loading = 0.477 g fish/L.

- Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Glydexx N-10)
- Conclusion** : 96-hour LC50 = 9.61 mg/L (95% CI 6.35 to 13.6 mg/L) based upon measured concentrations
- Reliability** : (1) valid without restriction  
The study was conducted according to the test guideline and there were no significant deviations from the guideline that would suggest the results were questionable. Therefore the study was assessed as valid.
- Flag** : Critical study for SIDS endpoint

01.12.2003

(8)

#### 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

- Type** :
- Species** : Daphnia magna (Crustacea)
- Exposure period** : 48 hour(s)
- Unit** : mg/l
- EC50** : = 4.8
- Analytical monitoring** : yes
- Method** : OECD Guide-line 202
- Year** : 1981
- GLP** : yes
- Test substance** : as prescribed by 1.1 - 1.4

- Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

01.12.2003

(24)

- Type** : static
- Species** : Daphnia magna (Crustacea)
- Exposure period** : 48 hour(s)
- Unit** : mg/l
- Analytical monitoring** : no
- Method** : other: no data
- Year** : 1983
- GLP** : no data

- Test substance** : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)
- Method** : Probit analysis using log transformed concentration values based on: Finney D (1971). Probit analysis. Third Edition. Cambridge University Press, London, England.
- Result** : 48-hour EC50 = 4.8 mg/L (95% CI = 4.0 to 5.7 mg/L) based upon nominal values

Nominal Conc. (mg/L)	D. magna Total Immobilization (@ 24, 48 hrs)*
Control	0, 0
2.0	0, 2
4.3	0, 9
9.3	11, 29
20	30, 30
43	30, 30
93	30, 30
200	30, 30

- Test condition** : \* 30 fish per control and exposure level
- Individual treatment solutions were prepared by adding test substance with acetone as a co-solvent to glass flasks containing 140 ml of solution. The concentration of acetone in each treatment solution and control was adjusted to 0.1 ml/L. Triplicate test systems were used for each treatment level and control. Ten organisms were added per replicate. Nominal treatment levels ranged from 2 to 200 mg/L.

In the test chambers, dissolved oxygen ranged from 8.8 to 9.2 mg/L, pH ranged from 8.1 to 8.3, water total hardness was 190 mg/L as CaCO<sub>3</sub>, and temperature was 20+/-2 Deg C.

Organisms age at test initiation = <24 hours old.

Undissolved test material was noted in the test vessels. So as to prevent the test organisms from becoming entrained in undissolved test material, treatment solution surfaces were kept dark with black caps. The test organisms then avoided the surface areas. It was noted that none of the immobilized organisms were trapped in undissolved test substance at the surface of the treatment solutions.

- Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)
- Conclusion** : 48-hour EC50 = 4.8 mg/L (95% CI = 4.0 to 5.7 mg/L) based upon nominal values
- Reliability** : (2) valid with restrictions
- There is less raw data and information on the testing procedure than desirable in order to rate this study for reliability at a level higher than 2 (reliable with restrictions). However, there is sufficient information in the report to suggest that the testing procedure generally followed an acceptable test guideline, OECD 202, and used acceptable methods to prepare exposure solutions. However, undissolved test material was noted in some of the test vessels.
- Flag** : Critical study for SIDS endpoint

08.09.2003

(25)

#### 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

- Species** : Selenastrum capricornutum (Algae)
- Endpoint** : biomass
- Exposure period** : 96 hour(s)

Unit : mg/l  
 NOEC : = 1  
 LOEC : = 1.9  
 EC50 : = 3.5  
 Limit test :  
 Analytical monitoring : yes  
 Method : OECD Guide-line 201 "Algae, Growth Inhibition Test"  
 Year : 1981  
 GLP : yes  
 Test substance : as prescribed by 1.1 - 1.4  
  
 Source : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
 EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
 01.12.2003 (24)  
  
 Species : Selenastrum capricornutum (Algae)  
 Endpoint :  
 Exposure period : 96 hour(s)  
 Unit :  
 Limit test :  
 Analytical monitoring : no  
 Method : other: no data  
 Year : 1983  
 GLP : no data  
 Test substance : other TS: Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)  
  
 Method : Probit analysis using log transformed concentration values based on: Finney D (1971). Probit analysis. Third Edition. Cambridge University Press, London, England.  
  
 Remark : Species/Strain: Fresh-Water Green Algae (Selenastrum capricornutum, now known as Pseudokirchneriella subcapitata)  
 Result : 72-hour EbC50 = 3.5 mg/L (biomass)

Nominal	Mean Cell	Cell
Conc. (mg/L)	Growth - 96 hr	Conc. - 96 hr
	(% Inhibition)	(cells/ml)
Control	n/a	1.1E5
1.0	0	1.1E6
1.9	20	8.4E5
3.5	50	5.3E5
6.6	85	1.6E5
12	97	2.9E4
23	100	4.5E3
43	100	3.7E3
81	99	5.6E3
150	99	7.2E3
280	100	2.8E3
530	99	7.3E3
1000	100	4.7E3

Test condition : Individual treatment solutions were prepared by adding test substance with acetone as a co-solvent to glass flasks containing 50 ml of culture medium. The concentration of acetone in each treatment solution and control was adjusted to 0.05 ml/L. One replicate per treatment level and six control flasks were used in this study. Each flask was inoculated with *S. capricornutum* to give an initial concentration of  $5 \times 10^2$  cell/ml. Nominal treatment levels ranged from 1 to 1000 mg/L. Flasks were incubated in a cooled, orbital incubator set at 100 cycles/min under constant illumination. Cell counts were made using a Coulter Counter.

The incubator light was approximately 3000 lux and temperature was  $24 \pm 2$  Deg C. The test culture was obtained from the American Type Culture

Collection, Maryland, USA.

**Test substance** : Neodecanoic acid, 1,2-epoxypropyl ester, CAS No. 26761-45-5 (Cardura E10)

**Conclusion** : 96-hour EbC50 = 3.5 mg/L (biomass) (95% CI = 3.1 to 3.8 mg/L) based upon nominal values

**Reliability** : (2) valid with restrictions  
 There is less raw data, information on the testing procedure, and replication than desirable in order to rate this study for reliability at a level higher than 2 (reliable with restrictions). Although only one replicate per treatment level was included in the study design, there were sufficient treatment levels to show a distinct trend. Also, there is sufficient information in the report to suggest that the testing procedure generally followed an acceptable test guideline, OECD 202, and used acceptable methods to prepare exposure solutions. However, undissolved test material was noted in some of the test vessels.

**Flag** : Critical study for SIDS endpoint  
 08.09.2003 (25)

#### 4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

**Type** : aquatic

**Species** : *Pseudomonas fluorescens* (Bacteria)

**Exposure period** : 6 hour(s)

**Unit** : mg/l

**EC0** : > 100

**Analytical monitoring** : yes

**Method** : other

**Year** : 1977

**GLP** : yes

**Test substance** : as prescribed by 1.1 - 1.4

**Remark** : Test method in : TNO, Degradability, Ecotoxicity and Bioaccumulation, Delft NL, 1977.

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
 EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)  
 01.12.2003 (26)

#### 4.5.1 CHRONIC TOXICITY TO FISH

#### 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

#### 4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

#### 4.6.2 TOXICITY TO TERRESTRIAL PLANTS

#### 4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

#### 4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

**4.7 BIOLOGICAL EFFECTS MONITORING****4.8 BIOTRANSFORMATION AND KINETICS****4.9 ADDITIONAL REMARKS**



## 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

## 5.1.1 ACUTE ORAL TOXICITY

Type	: LD50
Value	: > 10 ml/kg bw
Species	: rat
Strain	: Wistar
Sex	: male/female
Number of animals	: 4
Vehicle	: other: none
Doses	: 1.25, 2.5, 5.0, 10.0 ml/kg (approx. 1.25, 2.5, 5.0, 10.0 g/kg)
Method	: other: Similar to original OECD 401
Year	: 1977
GLP	: yes
Test substance	: other TS
Remark	: One female rat at 10.0 ml/kg died on day 2, otherwise there was no mortality in the study. Rats showed signs of lethargy and ataxia at the higher doses, and the animal that died did so following a period of coma. Body weight gain was low in the two high dose groups (5 and 10 ml/kg). No other study details were available.
Test condition	: Male and female Wistar rats approximately 12 weeks old were used at each dose level. Animals were housed four animals/sex/ cage. Rats were weighed, fasted overnight and the test material was administered by intra-esophageal intubation using a ball point needle fitted to a syringe. After dosing, food and water were freely available throughout the 9-day observation period.
Test substance	: CAS No. 26761-45-5, Cardura E10
Conclusion	: Rat Oral LD50 >10 ml/kg (approx. 10 g/kg)
Reliability	: (2) valid with restrictions Study conducted under conditions comparable to GLP and OECD guidelines.
Flag	: Critical study for SIDS endpoint
16.12.2003	(12) (18)

## 5.1.2 ACUTE INHALATION TOXICITY

Type	: LC50
Value	: > .25 mg/l
Species	: rat
Strain	:
Sex	:
Number of animals	:
Vehicle	: no data
Doses	: 0.25 mg/l (240 mg/m3) (saturated vapor concentration)
Exposure time	: 4 hour(s)
Method	: other: not specified
Year	: 1982
GLP	: yes
Test substance	: other TS
Remark	: LD50 is greater than saturated vapour concentration. No signs of intoxication were observed after exposure.
Test substance	: CAS No. 26761-45-5, Carcura E10
Conclusion	: LC50 >0.25 mg/l (240 mg/m3)

**Reliability** : (4) not assignable  
This robust summary has a reliability rating of 4 because the data were not retrieved and reviewed for quality.

**Flag** : Critical study for SIDS endpoint  
16.12.2003 (11) (12)

### 5.1.3 ACUTE DERMAL TOXICITY

**Type** : LD50  
**Value** : > 4 ml/kg bw  
**Species** : rat  
**Strain** : Wistar  
**Sex** : male/female  
**Number of animals** : 4  
**Vehicle** : other: none  
**Doses** : 2.0 and 4.0 ml/kg (approx. 2.0 and 4.0 g/kg)  
**Method** : other: Noakes, D. N. and Sanderson, D.M., 1969. A method for determining toxicity of pesticides. Br. J. Industr. Med., 26, 59-64. Similar to OECD 402  
**Year** : 1977  
**GLP** : yes  
**Test substance** : other TS

**Remark** : No deaths resulted from exposure to the test material. The body weight gains were reduced at the top dose level and the animals showed signs of skin irritation.

**Test condition** : Groups of 12-13 weeks old rats were used at each dose level. Undiluted chemical was placed onto the shorn dorso-lumbar skin and bandaged into contact with the skin using an impermeable dressing of aluminum foil and waterproof plaster. Rats were individually housed over the 24-hour exposure period. Rats were fasted, but provided water ad libitum during the exposure period. After 24-hours, dressings were removed and the exposed area was washed. Animals were observed for signs of toxicity during the following 9 days.

**Test substance** : CAS No. 26761-45-5, Cardura E10  
**Conclusion** : Dermal LD50 >4 ml/kg (approx. 4 g/kg)  
**Reliability** : (2) valid with restrictions  
Study conducted under conditions comparable to GLP and OECD guidelines.

**Flag** : Critical study for SIDS endpoint  
16.12.2003 (12) (18)

### 5.1.4 ACUTE TOXICITY, OTHER ROUTES

#### 5.2.1 SKIN IRRITATION

**Species** : rabbit  
**Concentration** : undiluted  
**Exposure** : Occlusive  
**Exposure time** :  
**Number of animals** : 8  
**Vehicle** : other: none  
**PDII** : 1.95  
**Result** : moderately irritating  
**Classification** :  
**Method** : Draize Test  
**Year** : 1977

GLP : yes  
 Test substance : other TS

Remark : Not expected to be irritating in the EEC/OECD 4 hour semi-occluded as opposed to this 24 hour occluded. No additional effects were reported.

Result : A single 24-hour application of the test material to intact, occluded rabbit skin was mildly irritating. The test material is not expected to be irritating when applied to intact skin in the EEC/OECD 4-hour semi-occluded test.

#### Irritation Scores

Mean Scores: 24hr 48hr 72hr

Erythema 2.1 Not reported 1.8

Edema 1.0 Not reported 1.1

Test condition : The dorsal skin of 4 male and 4 female rabbits was shaved and 0.5 ml test material was applied to a patch, placed on the intact skin, and covered with an occlusive polyethylene film, held in place with an elastic bandage for 24 hours. Following patch removal, visual examinations were conducted for the degree of erythema and edema (scale of 0-4 for each) at 24 and 72 hours and at 7 days. The test was conducted under occluded conditions for 24 hours rather than semi-occluded conditions for 4 hours as required by current guidelines.

Conclusion : A single 24-hour application of the test material to intact, occluded rabbit skin was mildly irritating.

Reliability : (1) valid without restriction

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(11) (12) (18)

Species : rabbit  
 Concentration : undiluted  
 Exposure : Occlusive  
 Exposure time :  
 Number of animals : 8  
 Vehicle : other: none  
 PDII : 1.85  
 Result : moderately irritating  
 Classification :  
 Method : Draize Test  
 Year : 1977  
 GLP : yes  
 Test substance : other TS

Remark : No other effects were reported.

Result : A single 24-hour application of the test material to abraded, occluded rabbit skin was mildly irritating. The test material is not expected to be irritating when applied to intact skin in the EEC/OECD 4-hour semi-occluded test.

#### Irritation Scores

Mean Scores: 24hr 48hr 72hr

Erythema 2.1 Not reported 1.6

Edema 0.6 Not reported 0.9

Test condition : The dorsal skin of 4 male and 4 female rabbits was shaved and abraded. 0.5 ml test material was applied to a patch, placed on the abraded skin, and covered with an occlusive polyethylene film, held in place with an elastic bandage for 24 hours. Following patch removal, visual examinations were conducted for the degree of erythema and edema (scale of 0-4 for each) at 24 and 72 hours and at 7 days. The test was conducted under occluded conditions for 24 hours rather than semi-occluded conditions for 4 hours as required by current guidelines. The test was conducted under abraded, occluded conditions for 24 hours rather than non-abraded, semi-occluded conditions for 4 hours as required by current guidelines.

**Test substance** : CAS No. 26761-45-5  
**Conclusion** : A single 24 hour application of the test material to abraded, occluded rabbit skin was mildly irritating.  
**Reliability** : (1) valid without restriction  
 16.12.2003 (11) (12) (18)

### 5.2.2 EYE IRRITATION

**Species** : rabbit  
**Concentration** : undiluted  
**Dose** : .2 ml  
**Exposure time** :  
**Comment** : not rinsed  
**Number of animals** : 4  
**Vehicle** : other: none  
**Result** : not irritating  
**Classification** :  
**Method** : other: Draize, 1963; Directive 84/449/EEC, B.5  
**Year** : 1977  
**GLP** : yes  
**Test substance** : other TS

**Remark** : Larger volume (0.2 ml) used than required by guidelines (0.1 ml).  
 The test material was non-irritating to rabbit eyes. The maximum mean score was 0.6 on a Draize scale of 0-110 for conjunctival redness only at the 1-2 hour evaluation period. Mean scores were 0 for corneal and iridal responses at 1-2 hours, and for all indices on days 1, 2, 3, and 7.

**Result** : Irritation Scores for EU

Group Mean Scores:  
N =4            24 Hr    48 Hr    72 Hr

Cornea		0	0	0
Iris	0	0	0	
Conjunctival	0	0	0	
Redness				
Conjunctival	0	0	0	
Swelling (chemosis)				

Irritation Scores for OSHA

Maximum group  
mean Score:            24 Hr    48 Hr    72 Hr

(4 rabbits)

0.6 at 1-2 hours for  
conjunctival redness

Cornea		0	0	0
Iris	0	0	0	
Conjunctival	0	0	0	
Redness				
Conjunctival	0	0	0	
Swelling (chemosis)				

**Test condition** : Each of 4 rabbits received 0.2 ml of undiluted test material into the conjunctival sac of one eye. The contra-lateral eye served as the control. The eyes were evaluated and scored at 1 or 2 hours and on days 1, 2, 3,

and 7. A larger volume (0.2 ml) was administered than required by current guidelines (0.1 ml).

**Test substance** : CAS No. 26761-45-5

**Conclusion** : Test material was non-irritating to rabbit eyes.

**Reliability** : (1) valid without restriction

16.12.2003

(11) (12) (18)

### 5.3 SENSITIZATION

**Type** : Guinea pig maximization test

**Species** : guinea pig

**Concentration** : 1<sup>st</sup>: Induction .5 % other: occlusive  
2<sup>nd</sup>: Induction .5 % other: occlusive  
3<sup>rd</sup>: Challenge 50 % other: occlusive

**Number of animals** : 20

**Vehicle** : other: corn oil

**Result** : sensitizing

**Classification** :

**Method** : other: Magnusson and Kligman

**Year** : 1977

**GLP** : yes

**Test substance** : other TS

**Remark** : All males and all but one female showed positive sensitization effects immediately after removal of the challenge patch and at 24 and 48 hours with scores of + and ++. One female was negative at all three time-points.

**Result** : Post-Challenge

% Response	24hr	48hr
Challenge	95	95
Rechallenge		

**Test condition** : Ten male and 10 female guinea pigs were used for the test group and 5 of each sex were used for the control group. Induction was accomplished in two stages. Two rows of three intradermal injections were made to the shaved dorsal skin using: 0.1 ml. Freund's complete adjuvant (FCA), test material in corn oil, and 0.1 ml test material in 50:50 FCA/corn oil. One week later the same area was clipped and filter paper soaked in test material was placed on the injection sites, secured with elastic adhesive bandage and left in place for 48 hours. The challenge was carried out 2 weeks after the topical induction. Topical application of the test material was made to the shaved flank of both test and control animals. Filter paper was soaked with test material and applied under adhesive tape, then secured with an elastic bandage for 24 hours. Visual examinations were made immediately after removal of the patch, and at 24 and 48 hours later. A four point scoring system was used: -, trace, +, and ++.

**Test substance** : CAS No. 26761-45-5

**Conclusion** : The test material is a severe skin sensitizer in guinea pigs.

**Reliability** : (1) valid without restriction

16.12.2003

(11) (12) (18)

**Type** : Guinea pig maximization test

**Species** : guinea pig

**Concentration** : 1<sup>st</sup>: Induction .5 % other: occlusive  
2<sup>nd</sup>: Induction .5 % other: occlusive  
3<sup>rd</sup>: Challenge 50 % other: occlusive

**Number of animals** : 40

**Vehicle** : other: Drakeol 19

**Result** : sensitizing

**Classification** :

**Method** : other: Magnusson and Kligman

<b>Year</b>	:	1990									
<b>GLP</b>	:	yes									
<b>Test substance</b>	:	other TS									
<b>Remark</b>	:	The results in the animals treated with the test material showed erythema ranging from very slight to severe (scores of 1-4) along with edema ranging from very slight to slight (scores of 1-2) at 24 and 48 hours post-challenge. The overall response rates at 24 hours were 85% for erythema and 40% for edema. The overall response rates at 48 hours were 75% for erythema and 20% for edema. The results in vehicle control treated animals were limited to very slight erythema in 2 animals at 24 hours.									
<b>Result</b>	:	Post-Challenge <table> <tr> <td>% Response</td><td>24hr</td><td>48hr</td></tr> <tr> <td>Challenge</td><td>85</td><td>75</td></tr> <tr> <td>Rechallenge</td><td></td><td></td></tr> </table>	% Response	24hr	48hr	Challenge	85	75	Rechallenge		
% Response	24hr	48hr									
Challenge	85	75									
Rechallenge											
<b>Test condition</b>	:	Two groups of 20 females each were used for the treated and irritation controls. Induction was accomplished in two stages. Two rows of three intradermal injections were made to the shaved mid-dorsal skin using: 0.1 ml. Freund's complete adjuvant (FCA) in water for test and controls; 5% test material in Drakeol 19 (vehicle only for controls); and 0.1 ml 5% test material in FCA/water (5% Drakeol in FCA/water for controls). One week later the same area was clipped and 0.5 ml of undiluted test material (undiluted vehicle for controls) was placed on the injection sites beneath Webril pads, secured with elastic adhesive bandage and left in place for 48 hours. The challenge was carried out 21 days after the initial intradermal induction. Topical application of the test material was made to the shaved flank of both test and control animals using 0.5 ml of 5% test material or vehicle for controls. A pad was placed on top of the test material, covered with plastic tape, then secured with an elastic bandage for 24 hours. Visual examinations were made 24 hours after the intradermal induction, 24 hours after removal of the topical induction pad, and at 24 and 48 hours after removal of the challenge pad. Scoring was conducted using the Draize scale of 0-4.									
<b>Test substance</b>	:	Glydexx N-10 (CAS No. 26761-45-5)									
<b>Conclusion</b>	:	The test material is a severe skin sensitizer in guinea pigs.									
<b>Reliability</b>	:	(1) valid without restriction									
<b>Flag</b>	:	Critical study for SIDS endpoint									
16.12.2003											

(6)

#### 5.4 REPEATED DOSE TOXICITY

<b>Type</b>	:	Sub-chronic
<b>Species</b>	:	rat
<b>Sex</b>	:	male/female
<b>Strain</b>	:	Wistar
<b>Route of admin.</b>	:	oral feed
<b>Exposure period</b>	:	5 weeks
<b>Frequency of treatm.</b>	:	continuous
<b>Post exposure period</b>	:	none; animals euthanized at end of 5 weeks (36 days)
<b>Doses</b>	:	0, 100, 500, 1,000 and 10,000 ppm in the diet
<b>Control group</b>	:	yes
<b>NOAEL</b>	:	1000 ppm
<b>LOAEL</b>	:	5000 ppm
<b>Method</b>	:	OECD Guide-line 407 "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-d Study"
<b>Year</b>	:	1981
<b>GLP</b>	:	yes
<b>Test substance</b>	:	other TS

**Method** : Body and organ weights were analyzed by covariance analysis; food intake, clinical chemical and hematological parameters were examined by a two-way analysis of variance. The significance tests used were: Williams, DA, 1971. Biometrics, 27, 103-117; Williams, DA, 1972. Biometrics, 28, 519-531; Dunnet, CW, 1964. Biometrics, 20, 482-491. Wilcoxon, F, 1971. Applied Statistics, 20 was used for pairwise comparisons.

**Remark** : No deaths occurred in the study and no effects were observed in either males or females at dietary levels of 100, 500, or 1,000 ppm (approx. 10, 48, or 96 mg/kg/day, respectively). Treatment related effects were limited to male and female rats at 5,000 and 10,000 ppm (approx. 478 and 888 mg/kg/day, respectively) in the diet. Food intake was decreased throughout the study in males and females at the highest dose and in males only at 5,000 ppm in the diet. Body weights were decreased in females at the highest dose level and in males at 5,000 and 10,000 ppm in the diet during the latter weeks of the study.

Hematology effects were limited to decreased erythrocytes and hematocrit in males at the 10,000 ppm dietary level. Clinical chemistry effects included increased plasma urea in males at the upper 2 dose levels and decreased alkaline phosphatase activity in females at the same two levels. At 10,000 ppm, females had increased plasma protein and males had increased sodium concentrations. Males at 5,000 ppm had increased potassium concentrations. Urine analyses showed increases in ketone levels in males at the 10,000 ppm dietary level and increases in total tubular epithelial cells were found in males at the upper two dose levels.

Increased liver and kidney weights were observed in males and females at the upper two dietary dose levels of 5,000 and 10,000 ppm. Treatment induced effects were identified in the proximal tubules of the kidneys of male rats fed 5,000 and 10,000 ppm. The degenerative, occlusive and regenerative lesions in the males represent a significant nephrotoxic injury. Very mild lesions in the renal tubule were seen in female rats fed 5,000 and 10,000 ppm.

**Result** : The No Observed Adverse Effect Level (NOAEL) for the study was 1,000 ppm in the diet (approx. 96 mg/kg bw) and the Lowest Observed Adverse Effect Level (LOAEL) was 5,000 ppm in the diet (approx. 478 mg/kg bw).  
: NOAEL: 1000 ppm in the diet (approx. 96 mg/kg/day bw); LOAEL: 5000 ppm in the diet (approx. 478 mg/kg/day bw)

Actual dose received by dose level by sex:

100 ppm in the diet = males approximately 8 mg/kg/day bw; females 11 mg/kg/day bw (ave 10 mg/kg/day bw)

500 ppm in the diet = males approximately 41 mg/kg/day bw; females 55 mg/kg/day bw (ave. 48 mg/kg/day bw)

1000 ppm in the diet = males approximately 82 mg/kg/day bw; females 110 mg/kg/day bw (ave. 96 mg/kg/day bw)

5000 ppm in the diet = males approximately 408 mg/kg/day bw; females 548 mg/kg/day bw (ave. 478 mg/kg/day bw)

10,000 ppm in the diet = males approximately 758 mg/kg/day bw; females 1018 mg/kg/day bw (ave = 888 mg/kg/day bw)

Toxic response/effects by dose level:

All rats survived to the scheduled necropsy and the general health and behavior of the control and treated rats were similar throughout the study. Statistically significant decreases in mean food intake and mean body

weights as compared to controls were observed during the later weeks of the study in male rats fed 5,000 ppm in the diet. The mean food intake and mean bodyweight of male rats fed 10,000 ppm also had statistically significant decreases as compared to controls through out the study. Similarly, for females fed 10,000 ppm the mean bodyweight for the last three weeks of the study and mean food intake throughout the study had statistically significant decreases compared to the controls.

The hematological results showed a statistically significant reduction in erythrocytes count and hematocrit in male rats fed 10,000 ppm. No other dose-related effects were seen in either sex.

Statistically significant changes in the results of the clinical chemical analyses were confined to the 5,000 and 10,000 ppm treatment groups. At 5,000 and 10,000 ppm, plasma urea was increased and blood glucose decreased in males while plasma alkaline phosphatase activity was decreased in females. At 10,000 ppm, there were also increases in plasma protein in females and in plasma sodium ion concentration in males. In males at 5,000 ppm, there was an increase in plasma potassium ion concentration.

In male rats fed 10,000 ppm there were increases in urinary ketones and total tubular epithelial cells. The latter were also increased in the urine of the 5,000 ppm males. No other urinary changes were seen.

Statistically significant increases in the relative liver and kidney weights were observed in males and females at 5,000 and 10,000 ppm.

Treatment induced effects were identified in the proximal tubules of the kidneys of male rats fed 5,000 and 10,000 ppm. The degenerative, occlusive and regenerative lesions in the males represent a significant nephrotoxic injury. Very mild lesions in the renal tubule were seen in female rats fed 5,000 and 10,000 ppm. The pathological examinations of the kidneys of male and female rats fed 100, 500, or 1,000 ppm did not reveal compound related effects.

**Test condition**

- : Wistar rats of both sexes (20/sex for controls or 10/sex/dose for test) were fed diets containing either 0 (controls), 100, 500, 1000, 5000, or 10,000 ppm Cardura E10. During the study daily observations were made on individual animal health and behavior. Body weights and food consumption of each rat were measured at weekly intervals. In the week prior to killing, tail blood was collected from each rat and blood glucose measured urine analysis was performed on urine samples obtained from half of the rats on the study. Animals were killed after five weeks feeding and terminal blood samples were taken for hematological and clinical chemical estimations. Full necropsies were conducted on all animals, major organs were weighed, and all macroscopic observations recorded. Histological examination was also performed on the major organs of all animals.

**Test substance  
Conclusion**

- : CAS No. 26761-45-5, Cardura E10
- : Treatment related effects were limited to the upper two dietary dose levels of 5,000 and 10,000 ppm (approx. 478 and 888 mg/kg/day, respectively). Dose-related effects at these two dietary levels included: decreased food intake and body weights, minor changes in hematology and clinical chemistry, increased liver and kidney weights and nephrotoxicity to the proximal tubules of the kidneys that was more pronounced in males. The LOAEL was 5,000 ppm in the diet (approx. 478 mg/kg bw) and the NOAEL was 1,000 ppm in the diet (approx. 96 mg/kg bw).

**Reliability  
Flag**

- : (1) valid without restriction
- : Critical study for SIDS endpoint

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(11) (12) (23)



## 5.5 GENETIC TOXICITY 'IN VITRO'

**Type** : Bacterial reverse mutation assay  
**System of testing** : Bacterial  
**Test concentration** : 0.2 - 2000 ug/plate  
**Cycotoxic concentr.** : >2000 ug/plate  
**Metabolic activation** : with and without  
**Result** :  
**Method** : OECD Guide-line 471  
**Year** : 1979  
**GLP** : no data  
**Test substance** : other TS

**Method** : A mutagenic response was defined as a reproducible, dose-related increase in the number of histidine-independent colonies over the spontaneous incidence. There was no requirement for a specific magnitude of increase.

**Result** : Mutagenic only with metabolic activation in strains TA100 and TA1535, and TA 1538. Not mutagenic without metabolic activation in strains TA100, TA1535, and TA1538. Not mutagenic in strain TA98 with or without metabolic activation. This class of glycidyl esters was considered mutagenic based on their ability to induce base-pair substitutions. In general, no significant effects on mutation frequency were detected below 100 ug of material per plate suggesting that the mutagenic activity in bacteria was relatively weak. The range of bacterial strains in which activity was demonstrated indicates the mutagenicity was expressed both by base-pair substitution and frameshift mechanisms.  
 Studies in which the complete S9 homogenate was replaced by washed microsomes from uninduced rat liver showed that the inclusion of a NADP generating system had no significant effect on the frequency of mutation.

**Test condition** : Positive with metabolic activation; negative without metabolic activation.  
 20 ul volumes of appropriate DMSO solutions of test material (i.e., 0.01, 0.1, 1.0, 25, and 100 mg/ml) were added to the top agar mix to give final concentrations of 0, 0.2, 2, 500, and 2000 ug/plate both in the presence and absence of S9 liver fractions. The cultures were then incubated at 37C for 48 hours before the revertant colonies were counted. Further studies were performed with appropriate concentrations of test material to produce dose response curves. All tests are carried out in quadruplicate and the mean number of colonies on the test plates are compared with the control means. At least two replicate studies are carried out on different days in order to confirm the reproducibility of the results. Positive controls were 3,4-Benzo[a] pyrene and 4-Nitroquinoline oxide.

**Test substance** : Cardura E-10 (CAS No. 26761-45-5)

**Conclusion** : Positive with metabolic activation; negative without metabolic activation.  
 This material was considered mutagenic in this report based on the ability to induce base-pair substitutions and the frameshift mechanism.

**Reliability** : (1) valid without restriction

16.12.2003

(11) (12) (19)

**Type** : Bacterial reverse mutation assay  
**System of testing** : Bacterial  
**Test concentration** : 0.2 - 2000 ug/plate  
**Cycotoxic concentr.** : >2000 ug/plate  
**Metabolic activation** : with and without  
**Result** : negative  
**Method** : OECD Guide-line 471  
**Year** : 1979  
**GLP** : yes  
**Test substance** : other TS

- Result** : The test material did not induce a significant increase in mutation frequency in the Escherichia coli WP2 strain. In one experiment, an increased number of revertant colonies was recorded in E. coli WP2. This was not reproducible and is considered to be an isolated finding of no biological significance.
- Test condition** : 20 ul volumes of appropriate DMSO solutions of test material (i.e., 0.01, 0.1, 1.0, 25, and 100 mg/ml) were added to the top agar mix to give final concentrations of 0, 0.2, 2, 500, and 2000 ug/plate both in the presence and absence of S9 liver fractions. The cultures were then incubated at 37C for 48 hours before the revertant colonies were counted. Further studies were performed with appropriate concentrations of test material to produce dose response curves. All tests are carried out in quadruplicate and the mean number of colonies on the test plates are compared with the control means. At least two replicate studies are carried out on different days in order to confirm the reproducibility of the results. Positive controls were 3,4-Benzo[a] pyrene and 4-Nitroquinoline oxide.
- Test substance** : Cardura E-10 (CAS No. 26761-45-5)
- Conclusion** : There was no increase in mutation frequency in either of the E coli strains in the presence or absence of S9 activation.
- Reliability** : (1) valid without restriction
- Flag** : Critical study for SIDS endpoint

16.12.2003

(11) (12) (19)

- Type** : Gene mutation in Saccharomyces cerevisiae
- System of testing** : Nonbacterial
- Test concentration** : 0.01, 0.1, 0.5, 1.0 and 5.0 mg/ml
- Cycotoxic concentr.** : unspecified
- Metabolic activation** :
- Result** : negative
- Method** : other
- Year** : 1979
- GLP** : yes
- Test substance** : other TS

- Result** : A total of 10 experiments were performed in which the test material was incorporated in liquid cultures of Saccharomyces cerevisiae JD1. Although there were isolated increases in gene conversion, these were not consistent with dose or gene locus or with the presence of S9, and were not reproducible. They are considered to be due to experimental variation and are not of biological significance.

- Test condition** : Liquid suspension cultures were dosed with 20 ul of appropriate DMSO solutions of test material (i.e., 1, 10, 100, and 500 mg/ml) to give final concentrations of 0.01, 0.1, 0.5, 1.0, and 5.0 mg/ml broth with and without the incorporation of S9 microsomal fraction. After 1 hour incubation, the cultures were seeded in appropriate culture medium for the selection of revertant colonies. After 3 days at 30C, the number of revertant colonies were counted. Ten experiments were carried-out: 5 in the absence and 5 in the presence of S9 liver fractions.

- Test substance** : Cardura E-10 (CAS No. 26761-45-5)
- Conclusion** : The test material was negative in the Saccharomyces cerevisiae gene mutation assay either in the presence or absence of S9 .

- Reliability** : (1) valid without restriction
- Flag** : Critical study for SIDS endpoint

16.12.2003

(11) (12) (19)

- Type** : Bacterial reverse mutation assay
- System of testing** : Bacterial
- Test concentration** : 1 - 1000 ug/plate
- Cycotoxic concentr.** : not specified
- Metabolic activation** : with and without
- Result** :
- Method** : OECD Guide-line 471

<b>Year</b>	: 1985
<b>GLP</b>	: no data
<b>Test substance</b>	: other TS
<b>Method</b>	: A mutagenic response was defined as a reproducible, dose-related increase in the number of histidine-independent colonies over the spontaneous incidence. There was no requirement for a specific magnitude of increase.
<b>Remark</b>	: Positive ONLY in strains TA 100 and 1535 WITH S9 mix.
<b>Result</b>	: Mutagenic with metabolic activation in strains TA100 and TA1535. Not mutagenic without metabolic activation in strains TA100 and TA1535. Not mutagenic in strains TA97, TA98, or TA1537 with or without metabolic activation. This class of glycidyl esters was considered mutagenic based on their ability to induce base-pair substitutions.
<b>Test substance</b>	Positive with metabolic activation; negative without metabolic activation.
<b>Conclusion</b>	: Cardura E-10 (CAS No. 26761-45-5) : Positive with metabolic activation; negative without metabolic activation. This class of glycidyl esters was considered mutagenic in this publication based on their ability to induce base-pair substitutions.
<b>Reliability</b>	: (1) valid without restriction
<b>Flag</b>	: Critical study for SIDS endpoint
16.12.2003	(2) (11) (12)
<b>Type</b>	: other: Mammalian Chromosome Aberration Assay
<b>System of testing</b>	: Nonbacterial
<b>Test concentration</b>	: 7.5, 15, 12.5, 25, 30, and 50 ug/ml
<b>Cycotoxic concentr.</b>	: 50 ug/ml induced a 50% inhibition of cell growth (w/o activation)
<b>Metabolic activation</b>	: without
<b>Result</b>	: positive
<b>Method</b>	: OECD Guide-line 473
<b>Year</b>	: 1979
<b>GLP</b>	: yes
<b>Test substance</b>	: other TS
<b>Remark</b>	: Chromatid aberrations noted.
<b>Result</b>	: Few metaphase cells were obtained from cultures exposed to 50 ug/ml of material, though at concentrations below this, an adequate number of metaphases was present. Occasional chromatid exchange figures were observed in cultures treated with test material. A second study was carried out at lower concentrations of 7.5, 15, and 30 ug/ml. At 6 hours, occasional chromatid aberrations were observed at 15 and 30 ug/ml. At 24 hours, occasional chromatid aberrations were seen at all dose levels. Although the incidence of chromatid aberrations was very small, they occurred consistently in both experiments. It was concluded that the test material induced a low frequency of chromatid aberrations at concentrations just below the cytotoxic dose. The results indicate the test material is a weak chromosome-damaging agent in the cultured rat liver cells.
<b>Test condition</b>	: Rat liver (RL1) monolayer slide cultures were exposed to culture medium containing test material at final concentrations of 12.5, 25, and 50 ug/ml for 24 hours. Afterwards, cultures were processed (Colcemid added to arrest metaphase) for metaphase chromosome analysis and 100 cells were analysed from each culture per dose group. A second set of experiments was conducted at concentrations of 7.5, 15, and 30 ug/ml with incubation times of 6 hours or 24 hours. The percentage of cells showing polyploidy, chromatid gaps, chromatid breaks, multiple chromatid breaks, acentric fragments and exchange figures was determined. The percentage of cells showing chromatid aberrations was determined by summing chromatid breaks, multiple chromatid breaks, and exchange figures. The positive control was methyl methanesulphonate.
<b>Test substance</b>	: Cardura E-10 (CAS No. 26761-45-5)
<b>Conclusion</b>	: Test material is a weak chromosome-damaging agent in the cultured rat

<b>Reliability Flag</b>	: liver cells. (1) valid without restriction Critical study for SIDS endpoint	(11) (12) (22)
16.12.2003		
<b>Type</b>	: Mammalian cell gene mutation assay	
<b>System of testing</b>	: Nonbacterial	
<b>Test concentration</b>	: 43.75, 87.5, and 350 ug/ml	
<b>Cycotoxic concentr.</b>	:	
<b>Metabolic activation</b>	: no data	
<b>Result</b>	: negative	
<b>Method</b>	: other	
<b>Year</b>	: 1980	
<b>GLP</b>	: yes	
<b>Test substance</b>	: other TS	
<b>Result</b>	: When suspension cultures of BHK cells were exposed to the test material at concentrations of 43.75, 87.5, and 350 ug/ml, no increased frequency of transformed cells was observed.	
<b>Test substance</b>	: Cardura E-10 (CAS No. 26761-45-5)	
<b>Conclusion</b>	: Negative. No increase in transformed cells was observed.	
<b>Reliability</b>	: (4) not assignable This robust summary has a reliability rating of 4 because the data were not retrieved and reviewed for quality.	
16.12.2003		(11) (12) (20)

## 5.6 GENETIC TOXICITY 'IN VIVO'

<b>Type</b>	: other: In Vivo Rat Liver DNA Integrity	
<b>Species</b>	: rat	
<b>Sex</b>	: male/female	
<b>Strain</b>	: Wistar	
<b>Route of admin.</b>	: gavage	
<b>Exposure period</b>	: once	
<b>Doses</b>	: 5 ml/kg	
<b>Result</b>	: negative	
<b>Method</b>	: other: Rapid screen for measuring DNA single-strand damage in vivo. Petzold and Swenburg, (1978). Cancer Research, 38, 1589-1594.	
<b>Year</b>	: 1982	
<b>GLP</b>	: yes	
<b>Test substance</b>	: other TS	
<b>Remark</b>	: Partially hepatectomised rats used to examine effect on liver DNA. There was no effect on liver DNA. The results indicate that neither the test material nor its in situ generated metabolites have any effect on the integrity of rat liver DNA in vivo following a single oral dose of 5 ml/kg and 6 hour exposure.	
<b>Result</b>	: NOEL = 5 ml/kg	
<b>Test condition</b>	: Effects on mitotic index or PCE/NCE ratios by dose level by sex: No measurable DNA single-strand damage was found after administration of 5 ml/kg test material to Wistar rats for an exposure period of 6 hours. In the pre-treatment stage, partial hepatectomy was performed on Wistar rats and the liver was labelled with thymidine-(methyl-3H) during the peak of restorative DNA synthesis (18-36 hrs). Animals were used in the experiment after a minimum recovery period of 2 weeks when the liver had returned to its quiescent state.  Pairs of male and female Wistar rats were given the test material by oral gavage at 5 l/kg in DMSO, the positive control (methyl methanesulphonate	

in DMSO), or the solvent control (DMSO). After 6 hours, the livers were removed and processed using alkaline elution analysis prior to determination of radioactivity by scintillation counting techniques. The results from test animals were compared to the positive control for indications of single-strand damage to the DNA.

**Test substance** : CAS No. 26761-45-5, Cardura E10

**Conclusion** : The test material produced no measurable DNA single-strand damage when administered to Wistar rats as a single dose (5 ml/kg) when measured 6 hours post-dosing.

**Reliability** : (1) valid without restriction

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(11) (12) (21)

## 5.7 CARCINOGENICITY

### 5.8.1 TOXICITY TO FERTILITY

### 5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### 5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

## 5.9 SPECIFIC INVESTIGATIONS

### 5.10 EXPOSURE EXPERIENCE

**Remark** : An isolated case of Cardura E10 sensitivity in an epoxy resin worker has been reported.

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

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(13)

**Remark** : An isolated case of occupational sensitivity to Cardura E10 has been reported using patch concentrations of resin down to 0.001% and Cardura E down to 0.01%.

**Source** : Shell Nederland Chemie B.V. Hoogvliet-Rotterdam  
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

16.12.2003

(3)

### 5.11 ADDITIONAL REMARKS

**6.1 ANALYTICAL METHODS**

**6.2 DETECTION AND IDENTIFICATION**

**7.1 FUNCTION**

**7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED**

**7.3 ORGANISMS TO BE PROTECTED**

**7.4 USER**

**7.5 RESISTANCE**

**8.1 METHODS HANDLING AND STORING**

**8.2 FIRE GUIDANCE**

**8.3 EMERGENCY MEASURES**

**8.4 POSSIB. OF RENDERING SUBST. HARMLESS**

**8.5 WASTE MANAGEMENT**

**8.6 SIDE-EFFECTS DETECTION**

**8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER**

**8.8 REACTIVITY TOWARDS CONTAINER MATERIAL**



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**10.1 END POINT SUMMARY**

**10.2 HAZARD SUMMARY**

**10.3 RISK ASSESSMENT**