Via Electronic Submission

201-14933

December 17, 2003

Hon. Michael O. Leavitt
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Attn: Chemical Right-to-Know Program

ExxonMobil Chemical Company Registration Number

Dear Mr. Leavitt:

ExxonMobil Chemical Company (EMCC) submits for review and public comment the test plan and related robust summaries for Glydexx® N-10, under the U.S. High Production Volume (HPV) Chemical Challenge Program (Program), AR-201. The test plan and robust summaries are provided electronically in the attached zip file in Word format.

Glydexx N-10 is the commercial name for neodecanoic acid, 1,2-epoxypropyl ester (CAS No. 26761-45-5). ExxonMobil Chemical Company manufactures this substance, but is not the sole producer. The test plan identifies adequate existing studies/information to characterize all endpoints in the HPV Program except developmental and reproductive toxicity. Attempts were made requesting participation from the other producer in the development of this test plan, but they declined to participate. At the time of this submission, discovery efforts have not confirmed the lack of a definitive study for this endpoint and ExxonMobil Chemical Company does not support conducting this test without the cooperation of all producers.

We understand that this information will be posted on the internet for a 120-day comment period. Please forward technical comments on this test plan to Laura H. Keller at the address below or you may contact her at (281) 870-6501 (email: laura.h.keller@exxonmobil.com).

Please note that EMCC's corporate contact for questions from the U.S. EPA about the HPV Challenge Program is:

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Sincerely,

Nigel J. Sarginson
Product Stewardship & Regulatory Affairs Manager
ExxonMobil Chemical Company

Enclosure 1: High Production Volume Chemical Challenge Program Test Plan for Glydexx® N10
Enclosure 2: Glydexx® N10 Dossier (IUCLID Data Set)

201-14933B

HIGH PRODUCTION VOLUME (HPV)

CHEMICAL CHALLENGE PROGRAM

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TEST PLAN

For

Glydexx® N10

Prepared by:

ExxonMobil Chemical Company

December 17, 2003

EXECUTIVE SUMMARY

Under the U.S. Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program (Program), ExxonMobil Chemical Company committed to voluntarily compile a Screening Information Data Set (SIDS) that can be used in an initial assessment to characterize the hazard of Glydexx® N-10 (neodecanoic acid, 1,2-epoxypropyl ester; CAS No. 26761-45-5). The data for this assessment include selected physicochemical, environmental fate, and human and environmental effect endpoints identified by the U.S. HPV Program.

A search for existing studies/information and their review identified adequate data to characterize all endpoints except developmental and reproductive toxicity. However, data from the repeated dose toxicity study suggest that Glydexx N-10 may not be developmental or reproductive toxicant. At the time of this submission, discovery efforts have not confirmed the existence of a definitive study for this endpoint.

Data suggest that Glydexx N-10 generally presents a low order of hazard for human health although it has been identified as a skin sensitizer. In the environment, it is expected to rapidly hydrolyze to form the diol, upon which the environmental assessment is based. Glydexx N-10 presents a moderate order of hazard for environmental health. In the environment, Glydexx N-10 is calculated to partition primarily to the aqueous phase, where biological and physical processes can mediate its degradation, which is expected to occur at a slow rate.

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TEST PLAN FOR GLYDEXX® N-10

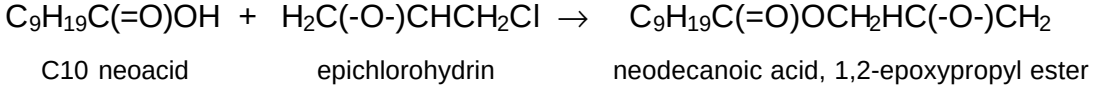
I. INTRODUCTION

Under the U.S. Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program (Program), ExxonMobil Chemical Company committed to voluntarily compile a Screening Information Data Set (SIDS) for Glydexx N-10. This substance is supported by selected screening data needed for an initial assessment of physicochemical properties, environmental fate, and human and environmental effects as defined by the Organization for Economic Cooperation and Development (OECD). Information cited within this test plan comes from existing data.

Procedures to assess the reliability of selected data for inclusion in this test plan were based on guidelines described by Klimisch *et al*. (1997) and identified within the US EPA (1999a) document titled Determining the Adequacy of Existing Data.

II. CHEMICAL PROCESS AND DESCRIPTION

For purposes of the HPV Program, the chemical name for Glydexx N-10 is neodecanoic acid, 1,2-epoxypropyl ester (CAS No. 26761-45-5). The production of Glydexx N-10 includes the reaction of a C10 neoacid with epichlorohydrin to form the corresponding neoacid epoxypropyl ester.



III. TEST PLAN RATIONALE AND DATA SUMMARY

All data identified for Glydexx N-10 (neodecanoic acid, 1,2-epoxypropyl ester) were developed using the parent substance. However, an appropriate assessment for this substance must consider that the parent form has the potential to hydrolyze to form the diol in aqueous conditions. Therefore, for some endpoints, the data were identified for the hydrolysis product. For example, the water solubility is calculated for neodecanoic acid, 1,2-propyldiol ester rather than for neodecanoic acid, 1,2-epoxypropyl ester. Also, the aquatic toxicity data represent the epoxy form, but characterizing toxicity requires caveating that the parent substance hydrolyzes and that results more accurately characterize the hydrolysis product. Note of this reaction should also be included when interpreting human health data.

A. Physicochemical Data

Physicochemical data (Table 1) include measured data from the material safety data sheet (Exxon, 1998). Calculated data are also provided from the EPIWIN© model (EPIWIN, 1999), as discussed in the EPA document titled The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (US EPA, 1999b). The values for two endpoints, water solubility and log Kow, were calculated for the diol form because the epoxide is subject to hydrolysis in aqueous

solution at a sufficiently rapid rate such that the epoxide form would not be found in solution. Hydrolysis of this substance must also be taken into consideration when discussing fate and toxicity in aquatic systems (see relative sections below).

Table 1. Selected Physico-Chemical Properties for Glydexx N-10.

DATA SOURCE	MELTING POINT (º C)	BOILING POINT (º C)	VAPOR PRESSURE (Pa)	WATER SOLUBILITY (mg/L)	LOG K_{ow}
EPIWIN	-	-	-	156.3[a]	2.58[a]
MSDS	<-68	484 - 491	14.67 @ 20º C 74.66 @ 50º C	na	na

a calculated value representing the diol, which is the form that would be present in an aqueous solution; the epoxide would not present because it rapidly hydrolyzes to form the diol

na not applicable

B. Human Health Effects Data

Glydexx N-10 has a low order of acute toxicity by the oral, dermal, and inhalation routes of exposure. It is mildly irritating to the eyes and non-irritating to the skin. Dermal sensitization has been observed in guinea pigs and has been reported in humans following occupational exposure. *In vitro* genotoxicity testing indicated weak mutagenic activity in point mutation assays with metabolic activation using *Salmonella*, but not in *E. coli* or yeast. Mutagenic activity was not observed in an *in vitro* mammalian cell assay. A weak ability to produce chromosomal damage was observed in cultured rat liver cells, but no DNA damage was produced in an *in vivo* rat liver assay. A low order of toxicity was observed in subchronic dietary testing with a No Observed Adverse Effect Level (NOAEL) of 1000 ppm in the diet. At high concentrations of 5000 and 10000 ppm in the diet, kidney effects were observed that were more prominent in males than in females. No effects were noted in reproductive organs of either sex. Further testing to evaluate potential developmental or reproductive effects has not been identified.

Acute Toxicity

Glydexx N-10 has a low order of acute toxicity by the oral, dermal, and inhalation routes of exposure based on testing conducted on the same chemical, but not the ExxonMobil Chemical manufactured substance. In rats, the oral LD_{50} was greater than 10 ml/kg (approximately 10 g/kg) and the dermal LD_{50} was greater than 4 ml/kg (approximately 4 g/kg), (Shell Toxicology Laboratory (Tunstall, 1977). The rat 4-hour inhalation LC_{50} was greater than 0.24 mg/L (approximately 240 mg/m^3), a concentration exceeding the saturated vapor pressure, (Gardiner, 1992). Due to the low vapor pressure resulting in a low level of maximal attainable vapor concentration, inhalation exposure is expected to pose a negligible hazard.

Genotoxicity

Multiple studies have been conducted to evaluate the mutagenic activity of Glydexx N-10 using the same chemical, but not the ExxonMobil Chemical manufactured substance. In point mutation studies without metabolic activation, no mutagenic activity was observed in S*almonella*, *E. coli/ WP2*, or JD1 yeast cells. Testing with S9 activation showed positive results in *Salmonella* strains TA100, TA1535, TA1538, but not in *Salmonella* strains TA97, TA98, TA 1537 or in *E. coli* or yeast (Canter, 1986; Gardiner, 1992; Shell Toxicology Laboratory (Tunstall), 1979a). No significant effects on mutagenic 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.

The clastogenicity of Glydexx N-10 was tested in an *in vitro* chromosomal aberration assay conducted in rat liver cells (RL1 Assay) using the same chemical, but not the ExxonMobil Chemical manufactured substance. A small, but consistent number of chromatid aberrations were seen under test conditions without metabolic activation. The assay was not conducted with S9 activation. Thus, the test material was a weak chromosome-damaging agent in the cultured rat liver cells, (Shell Toxicology Laboratory (Tunstall), 1979a; Gardiner, 1992).

Other genotoxicity assays have been conducted on Glydexx N-10 using the same chemical, but not the ExxonMobil Chemical manufactured substance. In an *in vivo* rat liver DNA integrity assay, no measurable DNA single-strand damage was seen following administration of this test material to rats as a single dose of 5 ml/kg. Additionally, in an *in vitro* mammalian cell gene mutation assay using Syrian hamster BHK cells, no increased frequency of transformed cells was observed at concentrations up to 350 ug/ml, (Shell Toxicology Laboratory (Tunstall), 1982; Shell Toxicology Laboratory (Tunstall), 1979b; Gardiner, 1992).

Repeated Dose Toxicity

A low order of toxicity was observed in rats following five-week dietary testing of Glydexx N-10 using the same chemical, but not the ExxonMobil Chemical manufactured substance. Treatment-related effects were limited to the upper two dietary dose levels of 5,000 and 10,000 ppm (approximately 478 and 888 mg/kg/day body weight, 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 than in females. The Lowest Observed Adverse Effect Level (LOAEL) was 5,000 ppm in the diet (approximately 478 mg/kg/day body weight) and the No Observed Adverse Effect Level (NOAEL) was 1,000 ppm in the diet (approximately 96 mg/kg/day body weight), (Sittingbourne Research Centre, 1981; Gardiner, 1992).

Developmental and Reproductive Toxicity

Data were not identified for the evaluation of developmental and reproductive toxicity of Glydexx N-10. However, in the five week repeated dose toxicity study of the same chemical, but not the ExxonMobil Chemical manufactured substance, reproductive organs were examined and no toxic effects were observed. Testicular organ weights in treated animals showed no significant differences when compared to control animals and microscopic histopathology examinations were unremarkable. No significant differences between treated and control animals were noted for the other reproductive organs that were examined: prostrate, ovaries and uterus.

Non-SIDS Endpoints

Eye Irritation

Glydexx N-10 was non-irritating to the eyes based on rabbit data for the same chemical, but not the ExxonMobil Chemical manufactured substance, (Shell Toxicology Laboratory (Tunstall), 1977; Gardiner, 1992).

Skin Irritation

Glydexx N-10 was a mild irritant to the skin based on rabbit data for the same chemical, but not the ExxonMobil Chemical manufactured substance. 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, (Shell Toxicology Laboratory (Tunstall), 1977; Gardiner, 1992).

Skin Sensitization

Glydexx N-10 has been shown to be skin sensitizer based on guinea pig data for this substance and the same chemical, but not the ExxonMobil Chemical manufactured substance. Two skin sensitization studies have been conducted in guinea pigs using the Magnusson and Kligman procedure. Both studies showed severe sensitization effects, (Shell Toxicology Laboratory (Tunstall), 1977; Gardiner, 1992; Exxon Biomedical Sciences, Inc., 1990). Skin sensitization has been reported in humans from repeated contact in the occupational setting, (Dalquist, 1979).

Table 2. Mammalian Toxicity Studies for Glydexx N-10

ENDPOINT	RESULT
ACUTE	
Oral[1,2] - Rat	LD_{50} >10 ml/kg (approx. 10 g/kg)
Dermal[1,2] - Rat	LD_{50} >4 ml/kg (approx. 4 g/kg)
Inhalation[1] - Rat	LC_{50} >0.24 mg/L (240 mg/m^3) (saturated vapor pressure)
GENOTOXICITY	
Point Mutation[1,2]	▪ Weakly positive with S9, negative w/o (TA100, TA1535, TA1538); ▪ Negative with and w/o S9 (TA97, TA98, TA 1537); ▪ Negative with and w/o S9 (*E. coli* WP2); ▪ Negative with and w/o S9 (JD1 yeast)
Chromosome Aberration[1,2]	Weakly positive w/o S9 (RL1)
REPEATED DOSE	
Oral[1,2] - Rat	NOAEL = 1000 ppm in the diet (approx. 96 mg/kg/day bw) LOAEL = 5000 ppm in the diet (approx. 478 mg/kg/day bw)
REPRODUCTIVE / DEVELOPMENTAL	
Developmental Toxicity	NI
Reproductive Toxicity	NI
IRRITATION / SENSITIZATION	
Ocular Irritation[1,2] -Rabbit	Non-irritant
Dermal Irritation[1,2] -Rabbit (occluded)	Mild irritant
Dermal Sensitization[2] -Guinea Pig	Positive (sensitizer)

[1] Based on data for the same chemical, but not the ExxonMobil Chemical manufactured substance

[2] Robust summary provided

NI - data not identified

C. Aquatic Toxicity Data

Data are available to characterize the fish and invertebrate acute toxicity and alga toxicity of Glydexx N-10. Although the data are associated with the parent substance, neodecanoic acid, 1,2-epoxypropyl ester, the results are interpreted to characterize the

hydrolyzed form of this substance because the parent epoxide rapidly forms the diol in aqueous systems.

Glydexx N-10 demonstrated a 96-hour rainbow trout (*Oncorhynchus mykiss*) LC_{50} toxicity value of 9.61 mg/L (Exxon Biomedical Sciences, Inc., 1998). Data developed for the same chemical, but not the ExxonMobil Chemical manufactured substance, demonstrated a 48-hour invertebrate (*Daphnia magna*) EC_{50} toxicity value of 4.8 mg/L and an alga (*Selenastrum capricornutum*) EC_{50} toxicity value of 3.5 mg/L, based on biomass.

D. Environmental Fate Data

Biodegradation

Biodegradation of an organic substance by bacteria can provide energy and carbon for microbial growth. This process results in a structural change of an organic substance and can lead to the complete degradation of that substance, producing carbon dioxide and water.

The test guideline used to assess the biodegradability of Glydexx N-10 was OECD 301F (Manometric Respirometry Test). The test system applied to this guideline used a continuously stirred, closed system and assessed biodegradability based on oxygen consumption. These procedures are recommended when assessing the biodegradability of poorly water soluble, volatile substances like Glydexx N-10. The source of the microbial inoculum used in this study was a domestic wastewater treatment facility. The inoculum was not acclimated.

Glydexx N-10 biodegraded to 11.6% after 28 days (Exxon Biomedical Sciences, Inc., 1996). Although the data are associated with the parent substance, neodecanoic acid, 1,2-epoxypropyl ester, the results are interpreted to characterize the hydrolyzed form of this substance because the parent epoxide rapidly forms the diol in aqueous systems, which is the case for biodegradation tests.

Additional data were developed for the same chemical, but not the ExxonMobil Chemical manufactured substance, using the OECD 302A (Modified SCAS Test) guideline (Stephenson, 1983). Dissolved organic carbon (DOC) was monitored over a 36-day period. Results between days 22 and 36 of the study (after acclimation may have occurred) showed 68% DOC removal, which suggests that Glydexx N-10 can be removed in a wastewater treatment facility.

Photodegradation – Photolysis

Direct photochemical degradation occurs through the absorbance of solar radiation by a chemical substance in aqueous solution. If the absorbed energy is high enough, then the resultant excited state of the chemical may undergo a transformation. A prerequisite for direct photodegradation is the ability of one or more bonds within a chemical to absorb ultraviolet (UV)/visible light in the 290 to 750 nm range. Light wavelengths longer than 750 nm do not contain sufficient energy to break chemical bonds, and wavelengths

below 290 nm are shielded from the earth by the stratospheric ozone layer (Harris, 1982a).

An approach to assessing the potential for a substance to undergo photochemical degradation is to assume that degradation will occur in proportion to the amount of light wavelengths >290 nm absorbed by constituent molecules (Zepp and Cline, 1977).

Assessing the potential for Glydexx N-10 to photolyze requires consideration of the hydrolyzed form of this substance because this substance has a relatively short hydrolysis half-life and rapidly forms the diol in water. Saturated hydrocarbons and R-OH groups do not absorb light above 290 nm (Harris J, 1982a). Therefore, these moieties are stable in regard to direct photolytic processes. Esters are also stable as this group absorbs UV light in the far UV region, below 220 nm (Mill T, 2000). Consequently, Glydexx N-10 is not subject to photolytic processes in the aqueous environment.

Photodegradation – Atmospheric Oxidation

Photodegradation can be measured (US EPA, 1999a) or estimated using an atmospheric oxidation potential (AOP) model accepted by the EPA (US EPA, 1999b). Atmospheric oxidation as a result of hydroxyl radical attack is not direct photochemical degradation, but rather indirect degradation.

Glydexx N-10 has the potential to volatilize to air, based on a vapor pressure of 14.67 @ 20º C, where it is subject to atmospheric oxidation. In air, Glydexx N-10 can react with photosensitized oxygen in the form of hydroxyl radicals (OH-). The computer program AOPWIN (atmospheric oxidation program for Microsoft Windows) (EPIWIN, 1999) calculates a chemical half-life for a 12-hour day (the 12-hour day half-life value normalizes degradation to a standard day light period during which hydroxyl radicals needed for degradation are generated), based on an OH- reaction rate constant and a defined OH- concentration.

Glydexx N-10 has a calculated half-life in air of 13.3 hours or 1.1 days, based on a rate constant of 23.71E-12 cm^3/molecule*sec and an OH- concentration of 1.5E6 OH-/cm^3.

Stability in Water (Hydrolysis)

Hydrolysis of an organic chemical is the transformation process in which a water molecule or hydroxide ion reacts to form a new carbon-oxygen bond. Chemicals that have a potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Neely, 1985).

Glydexx N-10 is an epoxide, neodecanoic acid, 1,2-epoxypropyl ester, which is subject to hydrolysis to form neodecanoic acid, 1,2-propyldiol ester. Hydrolysis is estimated to occur at a relatively rapid rate for Glydexx N-10, based on data for 14 epoxides (Mabey and Mill, 1978), as summarized by Harris (1982b), that ranged in half-life from approximately 1 minute to 8 days at pH 7.

Chemical Distribution In The Environment (Fugacity Modeling)

Fugacity-based multimedia modeling provides basic information on the relative distribution of a chemical between selected environmental compartments (i.e., air, soil, water, sediment, suspended sediment, and biota). A widely used fugacity model is the EQC (Equilibrium Criterion) Level I model (Mackay, 1996; Mackay, 1998).

The EPA guidance document (US EPA, 1999a) states that EPA accepts Level I fugacity data as an estimate of chemical distribution values. The input data required to run a Level I model include basic physicochemical parameters; distribution is calculated as percent of chemical partitioned to 6 compartments (air, soil, water, suspended sediment, sediment, biota) within a unit world. Level I data are basic partitioning data that allow for comparisons between chemicals and indicate the compartment(s) to which a chemical may to partition, based on selected physical parameters.

Results of the Mackay Level I environmental distribution model (Table 3) suggest that Glydexx N-10 will partition primarily (>99%) to air. These results can be explained by its vapor pressure, 14.67 hPa at 20°C (Exxon, 1998). However, in the environment Glydexx N-10 can undergo hydrolysis to the diol and the distribution of this form is significantly different from the parent. Because hydrolysis for this substance occurs rapidly, it is also appropriate to consider the potential environmental distribution of this form. The data in Table 3 show that the hydrolyzed form would be expected to partition largely to water, 74%, and soil, 25%.

Table 3. Environmental distribution as calculated by the Mackay (1998) Level I fugacity model

Environmental Compartment	Glydexx N-10 Percent Distribution*	Hydrolyzed Form (Diol) Percent Distribution**
Air	99.69	0.00
Water	0.23	74.38
Soil	0.08	25.04
Sediment	0.00	0.56
Suspended Sediment	0.00	0.02
Biota	0.00	0.00

*Distribution is based on the following model input parameters for neodecanoic acid, 1,2-epoxypropyl ester:

Molecular Weight	228.33	
Temperature	20°C	
Log K_{ow}	2.58	
Water Solubility	156.3g/m^3	
Vapor Pressure	1467 Pa	
Melting Point	-68°C	(the EPIWIN value was not used as it was felt the estimated value is incorrect)

**Distribution is based on the following model input parameters for neodecanoic acid, 1,2-propyldiol ester:

Molecular Weight	246.35	
Temperature	20°C	
Log K_{ow}	2.58	
Water Solubility	156.3g/m^3	
Vapor Pressure	9.3E-5 Pa	
Melting Point	-68°C	(the EPIWIN value was not used as it was felt the estimated value is incorrect)

IV. TEST PLAN SUMMARY

A search for existing studies/information and their review identified adequate data to characterize all endpoints for Glydexx N-10 except developmental and reproductive toxicity. At the time of this submission, discovery efforts have not identified the existence of a definitive study for this endpoint. However, testing is not planned until the lack of these data has been confirmed.

A dossier containing the robust summaries of the data presented in this test plan is attached.

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201-14933B

IUCLID

Data Set

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	:	
Printing date	:	16.12.2003
Revision date	:	
Date of last update	:	16.12.2003
Number of pages	:	43
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

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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
Telex	:	
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

Type of use : type
Category : Non dispersive use

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

Type of use : type
Category : Use resulting in inclusion into or onto matrix

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

Type of use : type
Category : Wide dispersive use

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

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

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

Type of use : industrial
Category : Paints, lacquers and varnishes industry

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

Type of use : use
Category : Intermediates

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

Type of use : use
Category : Solvents

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

Type of use : use
Category : other

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

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

Value	:	-68 °C
Sublimation	:	
Method	:	other: no data
Year	:	
GLP	:	
Test substance	:	other TS: Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Test substance	:	Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Conclusion	:	Based on measured data, Glydexx N-10 has a melting point of < -68 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 melting point.
Flag	:	Critical study for SIDS endpoint

09.09.2003 (9)

2.2 BOILING POINT

Value	:	251 -- 278 °C at 1013 hPa
Source	:	Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

18.08.1993

Value	:	484 -- 491 °C at
Decomposition	:	
Method	:	other: no data
Year	:	
GLP	:	
Test substance	:	other TS: Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Result	:	Glydexx N-10 has a boiling point over a narrow temperature range: 484 Degree to 491 Degree C.
Test substance	:	Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Conclusion	:	Based on measured data, Glydexx N-10 has a boiling point of 484 Degree to 491 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 boiling point.
Flag	:	Critical study for SIDS endpoint

09.09.2003 (9)

2.3 DENSITY

Type	:	density
Value	:	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-epoxyproyl 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-epoxyproyl 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)

Method	:	other (calculated): Calculated value using KOWWIN version 1.65, a subroutine of the computer program EPIWIN version 3.04.
Year	:	
GLP	:	
Test substance	:	other TS: Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Remark	:	Estimation Temperature: 25 Degree C
Result	:	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.
Test condition	:	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.
Test substance	:	Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Conclusion	:	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.
Reliability	:	(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.
Flag	:	Critical study for SIDS endpoint

09.09.2003 (5)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Deg. product	:	
Method	:	other: Calculated value using MPBPWIN version 1.40, a subroutine of the computer program EPIWIN version 3.04
Year	:	
GLP	:	
Test substance	:	other TS: Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Remark	:	Estimation Temperature: 25 Degree C
Result	:	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.
Test condition	:	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.
Test substance	:	Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Conclusion	:	Based on calculated data, the hydrolyzed form of Glydexx N-10 has a water solubility of 156.3 mg/L.

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.

Reliability : (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
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	1000000 molecule/cm³
Rate constant	:	= .00000000000944 cm³/(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-epoxyproyl 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-epoxyproyl ester (Glydexx N-10, CAS No. 26761-45-5):

Calculated*	OH- Rate Constant

Substance	half-life (da)	(cm3/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/cm3

Test substance : Neodecanoic acid, 1,2-epoxyproyl 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-epoxyproyl 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 cm3/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-epoxyproyl 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 (17)

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-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)

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

Conclusion : The epoxide group in Glydexx N-10 (neodecanoic acid, 1,2-epoxyproyl 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 Glydexx 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 (H2O) 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-epoxyproyl 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-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10), to undergo hydrolysis to the diol form.

Flag : Critical study for SIDS endpoint

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	volatility
Media	:	water - air
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	:	1982
Remark	:	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
Source	:	Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

01.12.2003 (14)

3.3.2 DISTRIBUTION

Media	:	air - biota - sediment(s) - soil - water
Method	:	Calculation according Mackay, Level I
Year	:	1981
Result	:	Air : 24.02 %m; Water : 75.72 %m; Soil : 0.13 %m; Sediment: 0.12 %m; Biota : 0.00 %m.
Source	:	Shell Nederland Chemie B.V. Hoogvliet-Rotterdam EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

01.12.2003 (15)

Media	:	
Method	:	Calculation according Mackay, Level I
Year	:	
Remark	:	Estimation Temperature: 20 Degree C
Result	:	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

Distribution of the parent substance, neodecanoic acid, 1,2-epoxyproyl ester, and its diol form to compartments not listed above (sediment, suspended sediment, biota) was calculated as less than 1%.

Test condition : 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 expoxide 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 uing 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-epoxyproyl 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-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx 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.

Sample	% Degradation* (day 28)	Mean % Degradation (day 28)
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-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx 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-epoxyproyl 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-epoxyproyl 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

Type	:	semistatic
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC50	:	= 5
Limit test	:	
Analytical monitoring	:	yes
Method	:	OECD Guide-line 203 "Fish, Acute Toxicity 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)

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Type	:	static
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Limit test	:	
Analytical monitoring	:	yes
Method	:	EPA OTS 797.1400
Year	:	1998
GLP	:	no
Test substance	:	other TS: Neodecanoic acid, 1,2-epoxyproyl ester, CAS No. 26761-45-5 (Glydexx N-10)
Method	:	Probit analysis based on: Finney D (1971). Probit analysis. Third Edition. Cambridge University Press, London, England.
Result	:	96-hour LC50 = 9.61 mg/L (95% CI 6.35 to 13.6 mg/L) based upon measured concentrations

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

represents a "key study" for vapor pressure. Flag:Critical study for SIDS endpoint09.09.2003(9)Value:ca. 3.3 IF "3.3" <> "" ".

organic carbon measurements of samples taken from exposure solutions at test initiation and termination. Exposure concentrations are based on the average of analyses.

Test condition	:	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-epoxyproyl 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-epoxyproyl 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

* 30 fish per control and exposure level

Test condition	:	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 CaCO3, and temperature was 20+/-2 Deg C. Organisms age at test initiation = <24 hours old. Undisolved test material was noted in the test vessels. So as to prevent the test organisms from becoming entrained in undisolved 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 undisolved test substance at the surface of the treatment solutions.
Test substance	:	Neodecanoic acid, 1,2-epoxyproyl 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, undisolved 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-epoxyproyl 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 Conc. (mg/L)	Mean Cell Growth - 96 hr (% Inhibition)	Cell Conc. - 96 hr (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 5x102 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+/- 2 Deg C. The test culture was obtained from the American Type Culture

Collection, Maryland, USA.

Test substance	:	Neodecanoic acid, 1,2-epoxyproyl 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, undisolved 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

16.12.2003 (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 indicies 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 Redness	0	0	0	
Conjunctival Swelling (chemosis)	0	0	0	

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 Redness	0	0	0	
Conjunctival Swelling (chemosis)	0	0	0	

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 : 1st: Induction .5 % other: occlusive
2nd: Induction .5 % other: occlusive
3rd: 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 adjuvent (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 : 1st: Induction .5 % other: occlusive
2nd: Induction .5 % other: occlusive
3rd: Challenge 50 % other: occlusive
Number of animals : 40
Vehicle : other: Drakeol 19
Result : sensitizing
Classification :
Method : other: Magnusson and Kligman

Year	:	1990
GLP	:	yes
Test substance	:	other TS
Remark	:	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.
Result	:	Post-Challenge % Response 24hr 48hr Challenge 85 75 Rechallenge
Test condition	:	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 adjuvent (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.
Test substance	:	Glydexx N-10 (CAS No. 26761-45-5)
Conclusion	:	The test material is a severe skin sensitizer in guinea pigs.
Reliability	:	(1) valid without restriction
Flag	:	Critical study for SIDS endpoint

16.12.2003 (6)

5.4 REPEATED DOSE TOXICITY

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

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).

Result : 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 : CAS No. 26761-45-5, Cardura E10

Conclusion : 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 : (1) valid without restriction

Flag : Critical study for SIDS endpoint

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.

Positive with metabolic activation; negative without metabolic activation.

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 : 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

Year	:	1985
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.
Remark	:	Positive ONLY in strains TA 100 and 1535 WITH S9 mix.
Result	:	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. Positive with metabolic activation; negative without metabolic activation.
Test substance	:	Cardura E-10 (CAS No. 26761-45-5)
Conclusion	:	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.
Reliability	:	(1) valid without restriction
Flag	:	Critical study for SIDS endpoint

16.12.2003 (2) (11) (12)

Type	:	other: Mammalian Chromosome Aberration Assay
System of testing	:	Nonbacterial
Test concentration	:	7.5, 15, 12.5, 25, 30, and 50 ug/ml
Cycotoxic concentr.	:	50 ug/ml induced a 50% inhibition of cell growth (w/o activation)
Metabolic activation	:	without
Result	:	positive
Method	:	OECD Guide-line 473
Year	:	1979
GLP	:	yes
Test substance	:	other TS
Remark	:	Chromatid aberrations noted.
Result	:	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.
Test condition	:	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.
Test substance	:	Cardura E-10 (CAS No. 26761-45-5)
Conclusion	:	Test material is a weak chromosome-damaging agent in the cultured rat

liver cells.

Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
16.12.2003 (11) (12) (22)

Type : Mammalian cell gene mutation assay
System of testing : Nonbacterial
Test concentration : 43.75, 87.5, and 350 ug/ml
Cycotoxic concentr. :
Metabolic activation : no data
Result : negative
Method : other
Year : 1980
GLP : yes
Test substance : other TS

Result : 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.
Test substance : Cardura E-10 (CAS No. 26761-45-5)
Conclusion : Negative. No increase in transformed cells was observed.
Reliability : (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'

Type : other: In Vivo Rat Liver DNA Integrity
Species : rat
Sex : male/female
Strain : Wistar
Route of admin. : gavage
Exposure period : once
Doses : 5 ml/kg
Result : negative
Method : other: Rapid screen for measuring DNA single-strand damage in vivo. Petzold and Swenburg, (1978). Cancer Research, 38, 1589-1594.
Year : 1982
GLP : yes
Test substance : other TS

Remark : 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.
Result : NOEL = 5 ml/kg

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.
Test condition : 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

16.12.2003 (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)

16.12.2003 (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