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I. General Information

2002 NOV -4 PM 12: 18

CAS Number: 111-55-7
 Name: 1,2-Diacetoxyethane
 1,2-Ethanediol, Diacetate
 Ethylene Acetate
 Ethylene Diacetate
 Ethylene Diethanoate
 Ethylene Glycol Acetate
 Ethylene Glycol Diacetate
 Ethanediol Diacetate
 Glycol Diacetate

II. Physical-Chemical Data

A. Melting Point

Test Substance	
Test substance:	Ethylene Glycol Diacetate
Remarks:	Purity unknown
Method	
Method:	Not Specified
GLP:	Unknown
Year:	Unknown
Remarks:	
Results	
Melting point value:	-31 °C
Remarks:	
Data Quality	
Remarks:	Data obtained from Hazardous Substances Data Bank Number: 430
References	
	Budavari, S. (Ed.). The Merck Index – Encyclopedia of Chemicals, Drugs and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc 1989, 599.
Other	
	Last revision date: 19980602

B. Boiling Point

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity unknown
Method Method: GLP: Year: Remarks:	Not specified Unknown Unknown
Results Boiling point value: Pressure: Pressure unit: Decomposition: Remarks:	190-191 °C Not specified
Data Quality Remarks:	Data obtained from Hazardous Substances Data Bank Number: 430
References	Budavari, S. (Ed.). The Merck Index – Encyclopedia of Chemicals, Drugs and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc 1989, 599.
Other	Last revision date: 19980602

C. Vapor Pressure

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity unknown
Method Method: GLP: Year: Remarks:	Not specified Unknown Unknown
Results Vapor pressure value: Temperature: Remarks:	0.077 mmHg 25 °C
Data Quality Remarks:	Data obtained from Hazardous Substances Data Bank Number: 430
References	Daubert, T.E. and Danner, R.P. Physical and Thermodynamic Properties of Pure Chemicals Data Compilation; Washington, D.C.: Taylor & Francis, 1989.
Other	Last revision date: 19980602

D. Partition Coefficient

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity unknown
Method Method: GLP: Year: Remarks:	Not specified Unknown Unknown
Results Log Pow: Temperature: Remarks:	0.10-0.38 Unknown
Data Quality Remarks:	Data obtained from Hazardous Substances Data Bank Number: 430
References	Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983. 696
Other	Last revision date: 19980602

E. Water Solubility

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity unknown
Method Method: GLP: Year: Remarks:	Not specified Unknown Unknown
Results Value: Temperature: Description: Remarks:	1.78X10+5 mg/l 24.5 °C Appreciable (>100 g/L)
Data Quality Remarks:	Data obtained from Hazardous Substances Data Bank Number: 430
References	Yalkosky, S.H., Dannenfelser, R.M.; The AQUALSOL dATABASE of Aqueous Solubility. 5 th ed., Tucson, AZ: Univ. Az, College of Pharmacy, 1992.
Other	Last revision date: 19980602

III. Environmental Fate Endpoints

A. Photodegradation

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate
Method Method: Test type: Remarks:	Estimation Atmospheric oxidation
Results Temperature: Hydroxyl radicals reaction OH Rate constant: Half-life Ozone reaction: Remarks:	25 °C 3.7605 x 10 ⁻¹² cm ³ /molecule-sec 2.844 Days (12-hr day; 1.5x10 ⁶ OH/cm ³) No ozone reaction estimation
Conclusions	Material is oxidized by hydroxyl radicals in the atmosphere at a moderate rate.
Data Quality Remarks:	
References	AopWin v1.90; Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210.
Other	

B. Stability in Water

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity was >99%
Method Method: Test type: GLP: Remarks:	OECD-111 and EEC Annex V, Part C.7. Abiotic Degradation: Hydrolysis as a Function of pH Yes A preliminary test was performed at 50 °C in which material was dissolved into a pH solution of 4, 7, or 9 at a concentration of 1500 mg/L and % hydrolyzed was determined over time. The rate constants for pH 4 and 7 were derived through Arrhenius relationships in which the logarithm of rate constants at other temperatures (60, 80, and 90 °C) is plotted against the reciprocal of the absolute temperature (K). All studies monitored pH over time.
Results Half-life: Percent hydrolyzed in 5- days (120 hrs) at 50 °C : Remarks:	pH 4: estimated half life at 25 °C is 3310 hours pH 7: estimated half life at 25 °C is 549 hours pH9: Not determined, greater than 50% hydrolysis occurred in <2.5 hours pH 4: 17% pH 7: 36% pH 9: 100% (an average of 77 and 81% was hydrolyzed after 2.4 hours)
Conclusions	Material is rapidly hydrolyzed under basic conditions.
Data Quality Remarks:	This study followed OECD guidelines and was conducted under GLP assurances.
References	Abiotic Degradation: Hydrolysis as a Function of pH. HAEL Study# 1999-0221, Eastman Kodak Company, Rochester, NY. June 28, 2000.
Other	

C. Biodegradation

<p>Test Substance Test substance: Remarks:</p> <p>References</p>	<p>Ethylene Glycol Data on ethylene glycol (EG) is being submitted as a structural surrogate for ethylene glycol diacetate (EGDA). It is strongly believed that biological processes in the environment would readily cleave the ester bonds in EGDA as occurs in mammalian systems resulting in the glycol parent. The presence of an acetyl moiety attached through an ester linkage has not appeared to adversely impact the ready biodegradability of several simple alcohol (e.g. methyl-, ethyl-, propyl-, butyl-acetate) or glycol ether acetates (e.g. EGBE- and DGBE-acetate).</p> <p>The biodegradability of ethylene glycol was recently reviewed (Staples <i>et al.</i>, 2001) with several studies indicating that ethylene glycol was readily biodegradable using OECD and APHA methods with unacclimated sewage sludge as seed organisms. Please see an assessment of this end point in the Ethylene Glycols category of chemicals under the International Council of Chemical Associations (ICCA) High Production Volume (HPV) Initiative.</p> <p>Staples, C.A., Williams, J.B., Craig, G.R., Roberts, K.M., 2001. Fate, effects and potential environmental risks of ethylene glycol: a review. <i>Chemosphere</i>. 43, 377-383.</p>
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D. Transport between Environmental Compartments (Fugacity)

Test Substance	
Test substance:	Ethylene Glycol Diacetate
Remarks:	
Method	
Test type:	Estimation
Model used:	Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
Remarks:	
Results	
Model data and results:	Concentration (%)
Estimated distribution	Air 1.87
and media concentration	Water 46.8
(levels II/III):	Soil 51.3
	Sediment 0.0797
Remarks:	Physical chemical values utilized in this model were default values obtained from the EPIWIN program.
Conclusions	
Data Quality	
Remarks:	
References	Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay <i>et al.</i> 1996; <i>Environ. Toxicol. Chem.</i> 15(9) , 1618-1626 and 1627-1637.
Other	

IV. Ecotoxicity

A. Acute Toxicity to Fish

<p>Test Substance Test substance: Remarks:</p> <p>Method Method: Test type: GLP: Year: Species/strain: Analytical monitoring: Exposure period: Remarks:</p> <p>Results Nominal concentration: Measured concentration: Endpoint value: Biological observations:</p> <p>Statistical methods:</p> <p>Remarks:</p> <p>Conclusions</p> <p>Data Quality Reliability: Remarks:</p> <p>References</p> <p>Other</p>	<p>Ethylene Glycol Diacetate Purity was 99.2%</p> <p>OECD 203 and EEC/Annex V C.1. Semi-static Yes 2000 Fathead minnow (<i>Pimephales promelas</i>) Yes; Exposure solutions, temperature, pH, dissolved oxygen 96-Hour Biological loading was kept below 1.0 g wet weight per liter of test solution, with 14 fish used per exposure level.</p> <p>7.5, 15, 30, 60, 120 mg/L 6.1, 13.6, 28.5, 57.4, 115.0 mg/L 96-hour LC₅₀ = 40.45 mg/L, 24-hour LC₅₀ = 46.97 At 24-hours, 100% mortality was observed in the 120 mg/L nominal exposure concentration. At 48-hours, 100% mortality was observed in the 60 mg/L nominal concentration. The minnows in the control, and 7.5, 15, and 30 mg/L nominal concentrations exhibited normal behavior and appearance throughout the test and no significant mortality was observed (? 10%). The LC₅₀ values were calculated using the SAS statistical software program EC_LC50.SAS (Ver. 1) The determinations of the LC₅₀ values were based on the arithmetic average (for replicates A and B) of the geometric means of the 0 to 48-hour test substance analytical results and the 48 to 96-hour test substance analytical results. The tests were performed in glass chromatography jars containing 20 L of exposure solution, with glass lids sealed with Parafilm[®]. Exposure temperature ranged from 20-21 °C, pH ranged from 7.4 to 8.4, and dissolved oxygen ranged from 6.5 to 9.1 mg/L. Stability determined by analysis of exposure concentrations by GC/FID.</p> <p>The 96-hour LC₅₀ value indicates that the test substance would be classified as “harmful to aquatic organisms” according to the European Union’s labeling directive and would correspond to a “moderate concern level” according to the U.S. EPA’s assessment criteria.</p> <p>Reliable without restrictions This was a well-documented OECD guideline study conducted under GLP assurances.</p> <p>An Acute Aquatic Effects Test with the Fathead Minnow (<i>Pimephales promelas</i>); Environmental Sciences Section, Health and Environment Laboratories, at Eastman Kodak Company, Rochester, NY; HAEL No. 1999-0221; October 6, 2000.</p> <p>The 96-h LC₅₀ value to <i>P. promelas</i> following exposure to ethylene glycol was 49,000 mg/L. The basis of this difference is unknown.</p>
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B. Acute Toxicity to Aquatic Invertebrates

Test Substance	
Test substance:	Ethylene Glycol Diacetate
Remarks:	Purity was 99.2%
Method	
Method:	OECD 202 and EEC/Annex V C.2.
Test type:	Acute immobilization, Static
GLP:	Yes
Year:	2000
Species/strain:	Daphnid/ <i>Daphnia magna</i>
Analytical monitoring:	Yes; Exposure solutions, temperature, pH, dissolved oxygen
Exposure period:	48-Hour
Remarks:	
Results	
Nominal concentration:	120 mg/L
Measured concentration:	116.3 mg/L
Endpoint value:	48-hour EC ₅₀ >116.3 mg/L
Biological observations:	The daphnids in the dilution water controls and test substance exposure solutions exhibited normal behavior and appearance throughout the test and no significant mortality was observed (? 10%) during the study.
Statistical methods:	NA; No significant differences in immobility were noted between treated and control daphnids.
Remarks:	The test substance exposure concentration was based on the arithmetic average (for replicates A and B) of the geometric means of the test substance analytical results at exposure start (time 0) and the test substance analytical results at exposure end (48-hours). Exposure temperature ranged from 20-21 °C, pH ranged from 7.7 to 8.4, and dissolved oxygen ranged from 7.6 to 9.1 mg/L. Stability determined by analysis of exposure concentrations by GC/FID.
Conclusions	The EC ₅₀ value indicates that the test substance would not be classified according to the European Union's labeling directive and would correspond to a "low concern level" according to the U.S. EPA's assessment criteria.
Data Quality	
Reliability:	Reliable without restrictions
Remarks:	This was a well-documented OECD guideline study conducted under GLP assurances.
References	An Acute Aquatic Effects Limit Test with the Daphnid (<i>Daphnia magna</i>); Environmental Sciences Section, Health and Environment Laboratories, at Eastman Kodak Company, Rochester, NY; HAEL No. 1999-0221, October 9, 2000
Other	

C. Toxicity to Aquatic Plants

Test Substance	
Test substance:	Ethylene Glycol Diacetate
Remarks:	Purity was 99.2%
Method	
Method:	OECD 201 and EEC/Annex V C.3.
Test type:	Growth inhibition of algae
GLP:	Yes
Year:	2001
Species/strain:	<i>Selenastrum capricornutum</i>
Endpoint basis:	Cell concentrations (biomass) and growth rate
Exposure period:	72-hours
Analytical procedures:	Temperature, light intensity, rpm, and test substance concentration were
	assessed at the 0, 24, 48, and 72 hours. The pH was assessed at time 0 and
	after 72 hours.
Remarks:	
Results	
Nominal concentration:	125.0 mg/L
Measured concentration:	119.86 mg/L (geometric mean over all time points)
Endpoint value:	E_bC_{50} and $E_rC_{50} > 119.86$ mg/L; The 72-hour NOEC was determined to be
	119.86 mg/L (highest concentration tested).
Biological observations:	None
Was control response	
satisfactory:	Yes (control culture concentrations increased by a factor of 72-fold)
Statistical methods:	NOEC value was determined through use of SAS statistical software program
	AL_ACUTE (Ver. 2.2). The E_bC_{50} and E_rC_{50} were inestimable as greater than
	50% inhibition in growth and/or biomass was not achieved in this limit test.
Remarks:	A mean illumination of 754 foot-candles was maintained. The mean
	temperature was 24°C and pH ranged from 7.4 to 7.6. Cultures were
	oscillated at 100 rpm. Stability determined by analysis of test substance in the
	test media by GC/FID. No protocol deviations were noted.
Conclusions	
	The 72-hour E_bC_{50} and E_rC_{50} values indicate that, based on this study, the test
	substance would not be classified according to the European Union's labeling
	directive and would correspond to a "low concern level" according to the U.S.
	EPA's assessment criteria.
Data Quality	
Reliability:	Reliable without restrictions
Remarks:	This was a well-documented OECD guideline study conducted under GLP
	assurances.
References	
	A Growth Inhibition Limit Test with the Alga, <i>Selenastrum capricornutum</i> ;
	Health and Environment Laboratories, Eastman Kodak Company, Rochester,
	NY; Study No. EN-512-900134-A; January 30, 2001.
Other	

V. Toxicological Data

A. Acute Toxicity

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity was unknown
Method Method: Test type: GLP: Year: Species/strain: Sex: Animals/sex/dose: Vehicle: Route of exposure: Remarks:	Acute lethality; Other LD ₅₀ estimate No (Pre-GLP) 1941 Rat/Wistar Male 10/dose Water Oral gavage It was noted that there were 10 animals per dose.
Results Value: Deaths at each dose: Remarks:	LD ₅₀ = 6.86 g/kg. Unknown
Conclusions	Material would be considered as practically nontoxic.
Data Quality Reliability: Remarks:	Reliable with restrictions The study was conducted quite some time ago and hence many study details are missing, however basic data are given and results indicate the material is not acutely toxic.
References	Smyth, H.F., Seaton, J., and Fischer, L. (1941). The Single Dose Toxicity of Some Glycols and Derivatives. <i>J. Ind. Hyg. Toxicol.</i> 23(6) : 259-268.
Other	

B. Repeated Dose Toxicity

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity was unknown
Method Method: Test type: GLP: Year: Species/strain: Route of exposure: Duration of test: Dose levels: Sex: Exposure period:	Other Repeated exposure No 1943 Rat Drinking water Up to 131 days 1, 3, and 5 % Both 10 Females received 5% solutions for up to 37 days while 5 males were exposed to a 1% solution for 110 days, then on Day 111 given a 3% drinking water solution for another 20 days.
Post-exposure observation period: Remarks:	None
Results NOAEL (NOEL): Actual doses received: Toxic responses by dose:	1% Unknown Rats receiving the 5% solution soon became ill and ate less. One rat died after a week while the last animal was terminated in a moribund state on Day 37. The kidneys of the rat that died after one week were filled with calcium oxalate crystals and were indistinguishable from other test animals that had received ethylene glycol. Animals exposed to a 1% solution grew and appeared normal out to Day 110. Of the animals consuming a 3% test solution for 20 more days, three had markedly enlarged kidneys. The surface was mottled with masses of crystals that extended deep into the cortex.
Statistical methods: Remarks:	Unknown
Conclusions	It appears that exposure to the diacetate ester of ethylene glycol leads to the formation of calcium oxalate urinary crystals in a manner similar to that of ethylene glycol alone. This strongly suggests the two acetate moieties are cleaved off from the parent glycol.
Data Quality Reliability: Remarks:	Reliable with restrictions While the study report lacked a significant amount of information and overall robustness, it nevertheless still indicates that exposure to the diacetate compound induces renal effects similar to that of ethyleneglycol.
References	Mulinos, M.G., Pomerantz, L., and Lojkin, M. E. (1943). The Metabolism and Toxicology of Ethylene Glycol and Ethylene Glycol Diacetate. <i>Amer. Jour. Pharm.</i> , 115 : 51-63.
Other	Please see an assessment of this end point in the Ethylene Glycols category of chemicals under the International Council of Chemical Associations (ICCA) High Production Volume (HPV) Initiative.

<p>Test Substance Test substance: Remarks:</p>	<p>Ethylene Glycol Diacetate Purity was unknown</p>
<p>Method Method: Test type: GLP: Year: Species/strain: Route of exposure: Duration of test: Dose levels: Sex: Exposure period: Post-exposure observation period: Remarks:</p>	<p>Other Repeated exposure No 1939 Rat Oral 7 - 130 days 1 - 5 % Unknown Daily in drinking water None Eleven animals total were used. The report does not indicate exactly how many animals received each dose level.</p>
<p>Results LOAEL: Actual doses received: Toxic responses by dose: Statistical Methods: Remarks:</p>	<p>The minimal dose required to produce damage in the kidneys was approximately 6 g/kg received in a 5% concentration for 7 days. Unknown It was noted that 4 animals died between 7 and 114 days, all were noted as having lesions present in the kidneys. Kidneys from 4 of the remaining 7 animals also had lesions. These animals were killed at intervals between Day 15 and 130. Lesions were due to the presence of calcium oxalate crystals. There were no histopathological abnormalities noted in the parathyroid glands. None were noted</p>
<p>Conclusions</p>	<p>It appears that exposure to the diacetate ester of ethylene glycol leads to the formation of calcium oxalate urinary crystals in a manner similar to that of ethylene glycol alone. This strongly suggests the two acetate moieties are cleaved off from the parent glycol.</p>
<p>Data Quality Reliability: Remarks:</p>	<p>Reliable with restrictions While the study report lacked a significant amount of information and overall robustness, its primary value lies in its utility showing that an exposure to ethylene glycol diacetate induces renal effects similar to that seen following exposure to ethylene glycol alone.</p>
<p>References</p>	<p>Kesten, H.D., Mulinos, M.G., and Pomerantz, L. (1939). Pathologic Effects of Certain Glycols and Related Compounds. <i>Arch. Path.</i>, 27:447-465.</p>
<p>Other</p>	<p>Please see an assessment of this end point in the Ethylene Glycols category of chemicals under the International Council of Chemical Associations (ICCA) High Production Volume (HPV) Initiative.</p>

C. Genetic Toxicity - Mutation

Test Substance	
Test substance:	Ethylene Glycol Diacetate
Remarks:	Purity was >99%
Method	
Method:	EEC Annex V Guideline number B.14, "Other Effects-Mutagenicity <i>Salmonella typhimurium</i> -Reverse Mutation Assay", and Guideline number B.13, Other Effects-Mutagenicity, <i>Escherichia coli</i> -Reverse Mutation Assay"
Test type:	<i>In vitro</i> mutagenicity
GLP:	Yes
Year:	2000
Species/strain:	<i>Salmonella typhimurium</i> /TA98, 100, 1535, 1537, and <i>Escherichia coli</i> /WP2uvrA(pKM101)
Metabolic activation:	Yes; Aroclor 1254-induced SD rat liver S9
Concentration tested:	Maximum concentration tested was 5000 ug/plate
Remarks:	Positive controls (2-aminoanthracene, 2-nitrofluorene, sodium azide, ICR-191, and 4-nitroquinoline-N-oxide) were run concurrently. Water was used as a vehicle and vehicle control.
Results	
Result:	No positive responses were induced in any of the tester strains
Cytotoxic concentration:	>5000 ug/plate (no evidence of cytotoxicity was seen)
Precipitation concentration:	No precipitate was noted in the report.
Genotoxic effects	
With activation:	Negative
Without activation:	Negative
Statistical methods:	A mean and standard deviation are calculated on the number of revertants.
Remarks:	
Conclusions	Material was not genotoxic under conditions of this assay.
Data Quality	
Reliability:	Reliable without restrictions
Remarks:	This was a well-documented EEC Annex guideline study conducted under GLP assurances at Covance Laboratories Inc., Vienna, VA.
References	Covance study number: 21034-0-409R; February 8, 2000
Other	

D. Genetic Toxicity – Chromosomal Aberrations

Test Substance Test substance: Remarks:	Ethylene Glycol Diacetate Purity was >99%
Method Method: Test type: GLP: Year: Species/strain: Concentrations tested: Metabolic Activation: Remarks:	OECD: TG-473 <i>In vitro</i> mammalian chromosomal aberrations assay Yes 2000 Chinese hamster ovary cells (CHO) 10.2 - 1500 ug/ml (this level meets the 10 mM max. recommended level) Yes; Aroclor 1254-induced SD rat liver S9 The positive controls consisted of mitomycin-C and cyclophosphamide. Negative control was the test vehicle water.
Results Result: Cytotoxic concentration: Precipitation concentration: Genotoxic effects With activation: Without activation: Statistical methods: Remarks:	No significant increases in cells with chromosomal aberrations, polyploidy, or endoreduplication were observed in the analyzed cultures at any concentration. >1500 ug/ml (no signs of toxicity were noted) No precipitate was observed at the maximum concentration tested. Negative Negative Statistical analysis employed a Cochran-Armitage test for linear trends and Fisher's Exact Test to compare the percentage of cells with aberrations.
Conclusions	Material was not genotoxic (did not induce any structural or numerical aberrations) under conditions of this assay.
Data Quality Reliability: Remarks:	Reliable without restrictions This was a well-documented OECD guideline study conducted under GLP assurances.
References	Covance Laboratories Inc., Vienna, VA; Study number: 21034-0-437OECD; March 21, 2000.
Other	

E. Developmental Toxicity

Please see an assessment of this end point in the Ethylene Glycols category of chemicals under the International Council of Chemical Associations (ICCA) High Production Volume (HPV) Initiative.

F. Toxicity to Reproduction

Please see an assessment of this end point in the Ethylene Glycols category of chemicals under the International Council of Chemical Associations (ICCA) High Production Volume (HPV) Initiative.