2-Ethoxyethyl acetate

CAS No: 111-15-9

EINECS No: 203-839-2

SUMMARY RISK ASSESSMENT

Final report, 2008

Germany

FINAL APPROVED VERSION

Rapporteur for the risk assessment of 2-Ethoxyethyl acetate is Germany

Contact point:
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Anmeldestelle Chemikaliengesetz (BauA)
(Federal Institute for Occupational Safety and Health Notification Unit)
Friedrich-Henkel-Weg 1-25
44149 Dortmund (Germany)

fax: +49(231)9071-2679
e-mail**: chemg@baua.bund.de**

Date of Last Literature Search :	**2001**
Review of report by MS Technical Experts finalised:	**2004**
Final report:	**2005**

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance 2-Ethoxyethyl acetate that has been prepared by Germany in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

Note - Human Health Section

With the approval of all Member States and the ECB the Human Health Section of the RAR of 2-Ethoxyethyl acetate was not carried out and thus the risk assessment report is not finalised.

The reason for this decision is mentioned in the following:.

Due to considerable changes in uses during recent years, the production was ceased by all producers in the EU in 2002. There is actually no producer or importer of this substance in the EU. The lead company Dow Europe was the last producer of 2- Ethoxyethyl acetate and discontinued all sales by 01.08.2002. It is not expected that any production or import of the substance will start again in the future.

The substance is classified in Annex I of 67/548 EEC with T, Repro Cat. 2, R10, Xn, R20, R21, R22, R60 and R61. Due to a preliminary human health effect assessment no changes in classification and labelling are expected.

Since the exposure situation does not exist anymore a risk characterisation regarding workers and consumers would lead to conclusion ii. there is at present no need for risk reduction measures beyond those which are being applied already“. For that reason a risk management strategy will not be necessary.

The environmental risk assessment was however performed at a much earlier stage, and in order not to loose these assessment results, the current risk assessment report covering the environmental part is published. The assessment is entirely based on old import figures and on information of a former producer on the use pattern.

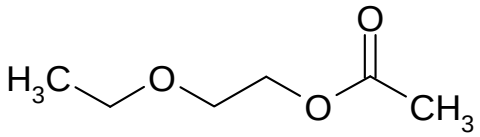
[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

CONTENTS

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS-No.:	111-15-9
EINECS No.	203-839-2
IUPAC Name	2-ethoxyethyl acetate
Synonyms:	ethylglycol acetate, ethylene glycol mono ethyl ether acetate, 2-EEA, acetic acid, 2-ethoxyethyl ester, ethoxyethanol acetate, EGA, Cellosolve Acetate, Ethoxol Acetate, Oxitol Acetate
Molecular weight:	132.1 g/mol
Empirical formula:	$C_6H_{12}O_3$
Structural formula:	



1.2 PURITY/IMPURITIES, ADDITIVES

Purity:	≥ 99 % w/w
Impurities:	< 0.5 % w/w ethyleneglycol diacetate
	< 0.5 % w/w 2-ethoxyethanol
	< 0.1 % w/w 2-ethoxyethanolformate
	< 0.1 % w/w water
	< 0.05 % w/w ethyleneglycol monoacetate
	< 0.01 % w/w 2-(2-ethoxyethoxy)ethyl acetate
Additives:	0.008-0.012 % 2,6-di-tert-butyl-p-cresol (BP-Chemical, UK)
	function: inhibition of peroxide formation

1.3 PHYSICO-CHEMICAL PROPERTIES

2-Ethoxyethyl acetate (2-EEA) is a colourless liquid with a fruity smell at room temperature and normal pressure. Data on the physical and chemical properties are given in Table 1.1.

Table 1.1: Physico-chemical properties

Melting point	< - 62 °C
Boiling point	156 °C
Relative density	0.9730 at 20 °C
Vapour pressure	270 Pa at 20 °C
Surface tension	67.1 mN/m at 25 °C
Water solubility	229 g/l at 20 °C
Partition coefficient	Log Pow 0.24 (experimental)
Flash point	51 °C (closed cup)
Flammability	flammable
Ignition temperature	380 °C (DIN 51794)
Explosive properties	not explosive
Oxidizing properties	no oxidizing properties
Henry's law constant	0.16 Pa x m^3 x mol^{-1}

1.4 CLASSIFICATION

- Classification according to Annex I of directive 67/548/EEC (31st ATP)::

R 10 flammable

Reprotox. Cat. 2

T toxic

R 60 may impair fertility

R 61 may cause harm to unborn child

Xn Harmful R 20 harmful by inhalation

R 21 harmful in contact with skin

R 22 harmful if swallowed

- Proposal of the rapporteur (only environmental part)

  According to the data presented below and the criteria of Directive 67/548/EEC 2-ethoxyethyl acetate has not to be classified as dangerous for the environment.

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION AND IMPORT

2-Ethoxyethyl acetate (hereafter referred to as 2-EEA) belongs to the group of glycol ethers which are mainly used as solvents. 2-EEA is produced by standard esterification techniques using 2-Ethoxyethanol, the acid anhydride or chloride and an acid catalyst.

No production of 2-EEA takes place within the EU at present. The last European production site ceased production in 1996. According to IND estimated sales in the year 2000 were less than 5,000 tonnes. In August 2002 the last importer announced that it discontinued all sales of 2-EEA. With this withdrawal from the market it was predicted "*that the amount of product onto the EU market may rapidly drop even below 1,000 tonnes per year in the near future*".

About 5,000 t 2-EEA were onto the EU market in the year 2000. Although no import/production takes place at present in the EU the amount estimated to be at the European market might be somewhere under 5,000 t/a, maybe even below 1,000 t/a. As the Rapporteur has no current import figures all exposure scenarios where both calculated with 1,000 t/a and with 5,000 t/a in order to get an idea of the possible risk 2-EEA might pose to the environment.

2.2 USE

According to former industry information 2-EEA was mainly used as a solvent in the chemical industry and for the formulation of paints, lacquers and varnishes for industrial use. 2-EEA was also used as an intermediate in the chemical industry (see Table 2.1). This information is based on historic information and seems to have no relevance at present. No information is available on the current use pattern and no information is available as to which products 2-EAA is further processed to.

The Rapporteur has no indication that the applications described above are still in use. No production in and no import into the EU takes place. Neither detailed information on the use pattern nor detailed monitoring data are available.

Table 2.1 shows the industrial and use categories of 2-EEA for the European Market used in the risk assessment

Table 2.1 Industrial and use categories of 2-EEA

Main category (MC)	**Industrial category (IC)**	**Use category (UC)**	**Mass balance [%]**	**1,000 t import [t/a]**	**5,000 t import [t/a]**
Non-dispersive use (**3**)	Chemical industry (**3**)	Intermediate (**33**)	**< 15**	**150**	**750**
Non-dispersive use (**3**)	Chemical industry (**2**)	Solvent (**48**)	**< 10**	**100**	**500**
Wide dispersive use (**4**)	Paint, lacquers and varnishes industry (**14**)	Solvent (**48**)	**~ 75**	**750**	**3,750**

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

Releases of 2-EEA into the environment are to be expected during processing as well as formulation and industrial use of solvents. Specific release data were not submitted by Industry and all calculations are based on default values of the TGD.

2-EEA has not been reported to occur as a natural substance.

The entire exposure assessment is based on old import figures and on information of a former producer on the use pattern. No information is available of how much 2-EEA might be onto the European Market and whether the use pattern has any relevance at present. According to the latest information there has been no production and import of the substance into the EU since 2002. The exposure assessment was calculated with 1,000 t/a and 5,000 t/a in order to get an idea of the possible risk that 2-EEA might pose to the environment.

2-EEA is readily biodegradable. An estimation of the half life for the atmospheric reaction of 2-EEA with hydroxyl radicals with the programme AOP 1.87 results in a half-life of 25.6 h (24-h day, $5x10^5$ OH/cm^3). This leads to a k_{deg_air} of 0.65 d^{-1}.

Considering the chemical structure hydrolysis is not to be expected. Also no direct photolysis in water takes place as there is no relevant absorption above a wavelength of 290 nm.

With a Henry's law constant of 0.16 Pa m^3 mol^{-1} 2-EEA is considered moderately volatile.

There are no experimental results on the adsorption of 2-EEA to soil available. A K_{OC} of 13.9 l/kg was calculated using a log K_{ow} of 0.24. 2-EEA does not meet the PBT criteria.

According to Mackay model (level 1) the hydrosphere is the target compartment for 2-EEA (94.8 %), followed by the atmosphere (5.2 %). However, 2-EEA has a high vapour pressure as well as a high water solubility. If 2-EEA is used in aqueous applications the hydrosphere is likely to be the target compartment, whereas the use of 2-EEA as an evaporative solvent results in the highest atmospheric emissions.

Based on physico-chemical properties (log H = -0.81; log K_{ow} = 0.24), as well as the biodegradation rate of 1 h^{-1} in the STP, an elimination rate of 87.4 % (SimpleTreat 3.0) in STP can be estimated.

The measured log K_{ow} of 0.24 does not indicate a potential for bioaccumulation. Based on this value a BCF of 0.32 l kg^{-1} can be calculated for fish. 2-EEA is expected to be highly mobile in soil and may leach to the groundwater.

Predicted environmental concentrations (PECs)

Concentrations in water, air and soil are estimated according to the methods in the TGD, and these are summarised in Table 3.1 (for water and air). No monitoring data relating to the occurrence of 2-EEA in the environment are available.

Table 3.1: Summary of PECs for 2-EEA

Scenario IC/UC	**PEC_{water} (mg/l) (1000 t/a)**	**PEC_{water} (mg/l) (5000 t/a)**	**PEC_{air} (mg/m^3) (1000 t/a)**	**PEC_{air} (mg/m^3) (5000 t/a)**
14/48 formulation	0.25	0.14	$4.6x10^{-3}$	0.02
14/48 industrial use	0.02	0.12	$7.7x10^{-3}$	0.04
2/48	12.6	20.2	$3.8x10^{-3}$	0.02
3/33	0.02	0.03	$5.7x10^{-4}$	$2.3x10^{-3}$
Regional	$3x10^{-5}$	$1.5x10^{-4}$	$3.3x10^{-7}$	$1.7x10^{-6}$

The PECs for sewage treatment plants are calculated as 0.24 mg/l to 126 mg/l (1000 t/a), and 1.01 mg/l to 202 mg/l (5000 t/a), respectively. Data on occurrence in the sediment do not exist for 2-EEA. According to the known physico-chemical properties, there is no indication that 2-EEA accumulates in the sediment. No $PEC_{sediment}$ was derived.

2-EEA is expected to enter the soil as result of deposition from the atmosphere. Considering this route of exposure, the highest local concentration in soil (PEC) can be expected as 1.2 µg/kg (1000 t/a), and 5.9 µg/kg (5000 t/a), respectively (PECregional$_{soil}$ is $2.1x10^{-3}$ µg/kg$_{ww}$ (1000 t/a) and 0.01 µg/kg$_{ww}$ (5000 t/a)).

Since there is no indication of 2-EEA possessing a bioaccumulation potential, a risk characterization for exposure via the food chain is not necessary.

3.2 EFFECTS ASSESSMENT

Aquatic compartment (incl. sediment)

Short-term effect data for algae, invertebrates and fish are available. The lowest valid LC_{50} of 41.0 mg/l (96h, *Lepomis macrochirus*) is reported for fish. In addition, there is a long-term value for the inhibition of reproduction in *Daphnia magna* as well as a 72h EC_{10} for *Scenedesmus subspicatus* (growth inhibition) available.

Fish is the acutely most sensitive species. The $PNEC_{water}$ of 0.30 mg/l is therefore based on the NOEC of 30 mg/l (21d, *Daphnia magna*) applying an assessment factor of 100.

A PNEC for sediment was not calculated as 2-EEA does not adsorb to organic matter and there are no tests with benthic organisms available.

STP

A $PNEC_{microorganisms}$ of 435 mg/l is derived using an assessment factor of 1 on the EC_{10} of 435 mg/l for *Pseudomonas putida*.

Atmosphere

No ecotoxicological data are available for this environmental compartment.

Due to the low tonnage and the atmospheric half-life ($t_{1/2}$ = 25.6 h) abiotic effects on the atmosphere, such as contribution to global warming and ozone depletion are not to be expected in connection with 2-EEA.

Terrestrial compartment

As there are no studies with terrestrial species available the equilibrium partition method was used to calculate a $PNEC_{soil}$ of 0.11 mg/kg.

3.3 RISK CHARACTERISATION

Aquatic compartment (incl. sediment)

Based on the scenarios "Paints, lacquers and varnishes industry/solvents" (IC/UC 14/48) and "Chemical industry: chemicals used in synthesis/intermediates" (IC/UC 3/33) no risk has been identified to surface water.

Concerning the scenario "Chemical Industry: basic chemicals/solvents" (IC/UC 2/48) a risk to the aquatic environment was identified. Using default values from the TGD the risk was identified for both the 1,000 t and the 5,000 t import per year.

However, **at present** there is no need for further information and/or testing nor for risk reduction measures beyond those which are being applied already because at present there is no production within the EU, nor is there any import into the EU and presumably therefore no use. Based on this information conclusion (ii) is drawn.

The risk assessment is based solely on historical data and can currently be considered of historical value only. Thus the identified risk should be regarded as hypothetical.

If production, importation and/or use in the EU are restarted the conclusion would need to be reassessed and any manufacturer or importer would then be asked to provide current import figures and site specific exposure data. **Conclusion (ii)**

STP

The PEC/PNEC ratios for STPs are below 1 for all scenarios. **Conclusion (ii)**

Atmosphere

Due to the atmospheric half-life ($t_{1/2}$ = 25.6 h), abiotic effects on the atmosphere, such as global warming and ozone depletion, are not to be expected in connection with 2-EEA. The highest calculated air concentration are 7.7×10^{-3} mg/m^3 (1000 t/a) and 0.04 mg/m^3 (5000 t/a), respectively, for industrial use as solvent in paint and varnishes industry. Since no data are available on the ecotoxicological effect of the substance in connection with the atmosphere, it is not possible to perform a quantitative assessment of this environmental compartment. On the basis of the available information on the substance, further testing seems not necessary. **Conclusion (ii)**

Terrestrial compartment

The PECs for the terrestrial compartment are 1.2×10^{-3} mg/kg$_{ww}$ (1,000 t/a) and 5.9×10^{-3} mg/kg$_{ww}$ (5,000 t/a). Comparison with the PNEC$_{soil}$ of 0.11 mg/kg indicates no risk for the terrestrial compartment. **Conclusion (ii)**

4 HUMAN HEALTH

The Human Health part of the Risk Assessment will not be performed.

5 CONCLUSIONS / RESULTS

5.1 ENVIRONMENT

(ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Based on the scenarios “Paints, lacquers and varnishes industry, solvents” (IC/UC 14/48) and “Chemical industry: chemicals used in synthesis/intermediates” (IC/UC 3/33) no risk was identified to surface water. Conclusion (ii) also applies to waste water treatment plants for all scenarios and to the terrestrial compartment.

Concerning the scenario “Chemical Industry: basic chemicals/solvents” (IC/UC 2/48) a risk to the aquatic environment was identified. Using default values from the TGD the risk was identified for both the 1,000 t and the 5,000 t import per year.

However, **at present** there is no need for further information and/or testing nor for risk reduction measures beyond those which are being applied already because at present there is no production within the EU, nor is there any import into the EU and presumably therefore no use. **Based on this information conclusion (ii) is drawn.**

The risk assessment is based solely on historical data and can currently be considered of historical value only. Thus the identified risk should be regarded as hypothetical.

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