EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

Institute for Health and Consumer Protection
European Chemicals Bureau
I-21020 Ispra (VA) Italy

1-METHOXYPROPAN-2-OL (PGME)
Part I – Environment

CAS No: 107-98-2

EINECS No: 203-539-1

Summary Risk Assessment Report

2006 **EUR 22479 EN**

The mission of the IHCP is to provide scientific support to the development and implementation of EU polices related to health and consumer protection. The IHCP carries out research to improve the understanding of potential health risks posed by chemical, physical and biological agents from various sources to which consumers are exposed.

The Toxicology and Chemical Substances Unit (TCS), commonly known as the European Chemicals Bureau (ECB), provides scientific and technical input and know-how to the conception, development, implementation and monitoring of EU policies on dangerous chemicals including the co-ordination of EU Risk Assessments. The aim of the legislative activity of the ECB is to ensure a high level of protection for workers, consumers and the environment against dangerous chemicals and to ensure the efficient functioning of the internal market on chemicals under the current Community legislation. It plays a major role in the implementation of REACH through development of technical guidance for industry and new chemicals agency and tools for chemical dossier registration (IUCLID5). The TCS Unit ensures the development of methodologies and software tools to support a systematic and harmonised assessment of chemicals addressed in a number of European directives and regulation on chemicals. The research and support activities of the TCS are executed in close co-operation with the relevant authorities of the EU MS, Commission services (such as DG Environment and DG Enterprise), the chemical industry, the OECD and other international organisations.

European Commission
Directorate-General Joint Research Centre
Institute of Health and Consumer Protection (IHCP)
European Chemicals Bureau (ECB)

Contact information:

Institute of Health and Consumer Protection (IHCP)
Address: Via E. Fermi 1 – 21020 Ispra (Varese) – Italy
E-mail: ihcp-contact@jrc.it
Tel.: +39 0332 785959
Fax: +39 0332 785730
http://ihcp.jrc.cec.eu.int/

European Chemicals Bureau (ECB)
E-mail:esr.tm@jrc.it
http://ecb.jrc.it/

Directorate-General Joint Research Centre
http://www.jrc.cec.eu.int

EUR 22479 EN
ISSN 1018-5593
Luxembourg: Office for Official Publications of the European Communities, 2006

Printed in Italy

1-METHOXYPROPAN-2-OL (PGME)

Part I - Environment

CAS No: 107-98-2

EINECS No: 203-539-1

SUMMARY RISK ASSESSMENT REPORT

Final report, 2006

France

The summary of the environmental risk assessment of 1-methoxypropan-2-ol (PGME) has been prepared by the Ministry of the Environment (MEDD) on behalf of the European Union.

The scientific work on this report has been prepared by:

Institut National de l'Environnement Industriel et des Risques (INERIS)
Direction des Risques Chroniques
Unité Evaluation des Risques Ecotoxicologiques
Parc Technologique ALATA
BP n°2
60550 Verneuil-en-Halatte
France

Date of Last Literature Search:	**2004**
Review of report by MS Technical Experts finalised:	**2005**
Final report:	**2006**

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance 1-methoxypropan-2-ol (PGME) that has been prepared by France 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.

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

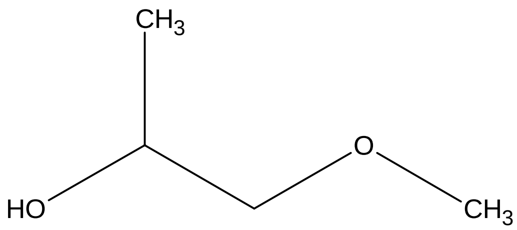
CONTENTS

TABLES

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS No: 107-98-2
EINECS No: 203-539-1
IUPAC Name: 1-methoxypropan-2-ol
Synonyms: 1-methoxy-2-hydroxypropane; 1-methoxy-2-propanol; 1-methoxypropanol-2; 1-methoxypropane-2-ol; 2-methoxy-1-methylethanol; 2-propanol-1-methoxy; methoxy Propanol; methoxypropanol; monomethyl ether of propylene glycol; monopropylene glycol methyl ether; PGME; propylene glycol methyl ether; propylene glycol monomethyl ether; éther 1-méthylique d'alpha-propylèneglycol; éther monométhylique du propylène-glycol
Molecular formula: $C_4H_{10}O_2$
Molecular weight: 90.1 g/mol
Structural formula:



In this assessment, the name PGME will be used for the substance, as this is the more common name.

1.2 PHYSICO-CHEMICAL PROPERTIES

Table 1.1 Physico-chemical properties

Property	Value
Physical state	Liquid
Melting point	-96°C
Boiling point	120°C
Relative density	0.921 g/cm^3
Vapour pressure	16.4 hPa at 25°C
Water solubility	Fully miscible, 500 g/l
Partition coefficient n-octanol/water (log value)	-0.49
Flash point	32°C
Autoflammability	278°C
Henry's constant	0.12 Pa.m3/mol

1.3 CLASSIFICATION

According to the data presented and the criteria of Directive 67/548/EEC, PGME is not classified as dangerous for the environment.

2 GENERAL INFORMATION ON EXPOSURE

The figures presented above show that there is a trend for an increase in production year-by-year: 171, 185.4 and 188 kt for years 2001, 2002 and 2003 respectively. However this is almost entirely due to increased demand for exports: 29.5, 42.5 and 50 kt each year between 2001 and 2003. The overall demand within the EU remains flat.

PGME is currently manufactured with volumes exceeding 1,000 tonnes/year by four producers in the EU.

The industrial and use categories of PGME are summarised in **Table 2.1**. PGME is mainly used as solvent. A breakdown of the uses of PGME in Europe has been established based on the data collected for years 2001 to 2003. The total used tonnage recorded is 142,000 tonnes taking into account the captive use.

Table 2.1 Use of PGME in the EU

End use	Quantity used (tonnes)	Percentage of total use
Chemical industry: chemicals used in synthesis	3,500	2.5%
	58,500 (Captive use)	41.7% (Captive use)
Paints and coating*	54,000	38.5%
Printing inks*	12,000	8.5%
Detergents, cleaners	7,500	5.3%
Leather finishing agent	1,900	1.3%
Electronic industry	1,500	1%
Agriculture	1,150	0.8%
Cosmetics/Personal care	1,000	0.7%
Adhesive	400	0.2%
Metal cleaning	400	0.2%
Oil spill dispersant/Oilfield chemicals	150	0.1%
Total	142,000	100%

* For these end uses there is a possibility that formulation and processing steps take place at a same site. These cases will be treated during risk characterisation.

According to the other glycol ethers, 10% of paints and coating are used at private level and 90% are used at industrial level

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 Environmental fate

The level of exposure of the environment to a chemical depends on the quantities and compartments of release and subsequent degradation, distribution and accumulation in the environment. This section presents the major characteristics of PGME relevant for the exposure assessment.

- No experimental data on hydrolyse is available. Based on the structure of the substance, hydrolysis is not expected to be an important removal process in the environment.
- An estimated atmospheric half-life value of ~18 hours has been derived for PGME.
- According to standard tests on ready biodegradation and further experimental data which confirmed high biodegradation rates, PGME can be regarded as readily biodegradable (half-lives in surface water, soil and sediment can be estimated for EGBE, respectively 15, 30 and 300 days).
- $K_{air\text{-}water}$ of $5.06.10^{-5}$ indicates that volatilisation of PGME from surface water and moist soil is expected to be very low.
- In view of the estimated BCF (3.16) calculated based on the log Kow, PGME is expected to have a low bioaccumulation potential.
- Based on the results from a multimedia fugacity model and the physico-chemical properties of PGME, the hydrosphere is the preferential target of the substance in the environment (95.8% in water, 4.10% in air).
- Based on the SIMPLETREAT model, it is anticipated that, after a sewage treatment plant, EGBE will be degraded at a level of 87%, 12.6% of PGME will remain in water. The remaining fraction of PGME will be shared between adsorption to sludge and air emission.

3.1.2 Environmental concentrations

<u>Local concentrations</u>

Considering that the substance is readily biodegradable, has a low bioaccumulation potential and presents a low toxicity for organisms, a refined risk assessment has not be performed.

The PECs for the aquatic compartment are estimated using default scenarios suggested by the TGD.

At the production stage, releases to water have been calculated using generic scenario based on tables A and B of the TGD and an input regional tonnage of 77,270 tonnes corresponding to the largest PGME production at one site. **Table 3.1** gives the PECs for the aquatic compartment.

Table 3.1 Local PEC_{water}, PEC_{STP} for PGME according to EUSES (EC, 1996)

End uses	PEC_{water} mg/l (*)	PEC_{STP} mg/l (*)
Production Production site releasing PGME in seawater	0.249 $5.11.10^{-4}$	9.77
Chemical industry: chemicals used in synthesis**	0.020^{P}	0.632^{P}
Chemical industry: chemicals used in synthesis (captive use)**	0.015^{P}	0.436^{P}
Paints and coating: - Water based - Solvent based	 0.0598^{F} 0.228^{P} $4.57 \cdot 10^{-3\ PU}$ 0.281^{F} 0.228^{P} $4.57 \cdot 10^{-3\ PU}$	 0.553^{F} 2.24^{P} $1.34 \cdot 10^{-5\ PU}$ 2.76^{F} 2.24^{P} $1.79 \cdot 10^{-5\ PU}$
Printing inks	0.0808^{F} 0.0663^{P}	0.762^{F} 0.618^{P}
Detergents, cleaners	0.322^{F} 0.0863^{P}	3.17^{F} 0.817^{P}
Leather finishing agent	This use is already covered by the painting scenario	
Electronic industry	0.0847^{P}	0.801^{P}
Agriculture	$4.57 \cdot 10^{-3\ P}$	$-^{P}$
Cosmetics/Personal care	0.0464^{F} $6.54 \cdot 10^{-3\ PU}$	0.419^{F} 0.0197^{PU}

* F: Formulation; P: Processing; PU: Private Use
** Dilution factor = 40 and $EFFLUENT_{STP}$ = 10,000 m^3/day (see scenario for IC_3 chemicals used in synthesis)

Exposure assessment for the terrestrial compartment

According to the adsorption coefficient (log Koc = 0.76), the substance can be considered as very mobile in soils and will not be adsorbed on sludge in STP. Besides, the PGME is readily biodegradable in water. Finally, there is no direct release to soil. Therefore exposure of the terrestrial compartment is considered as negligible and PECs for this compartment will not be calculated.

Regional and continental concentrations

The **Table 3.2** shows the calculated regional and continental PECs for air, water, sediment, seawater and marine sediment using EUSES (EC, 2004).

Table 3.2 Regional PECs in air and water (calculations made by EUSES 2.0)

Compartment	PEC regional	PEC continental
Air	$2.64 \cdot 10^{-4}$ mg/m³	$4.16 \cdot 10^{-5}$ mg/m³
Water	$4.02 \cdot 10^{-3}$ mg/l	$7.30 \cdot 10^{-4}$ mg/l
Sediment	$3.22 \cdot 10^{-3}$ mg/kg (WWT)	$5.84 \cdot 10^{-4}$ mg/kg (WWT)
Seawater	$3.67 \cdot 10^{-4}$ mg/l	$2.07 \cdot 10^{-6}$ mg/l
Marine sediment	$2.98 \cdot 10^{-4}$ mg/kg (WWT)	$1.68 \cdot 10^{-6}$ mg/kg (WWT)

3.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) - RESPONSE (EFFECT ASSESSMENT)

Calculation of the PNEC for the freshwater compartment

Acute toxicity data for PGME for three trophic levels (fish, aquatic invertabrates, algae) are available. No chronic toxicity data is available. Therefore the PNEC should be derived, according to the TGD, from the lowest acute toxicity value with an assessment factor of 1,000. Yet, in the case of the PGME, there are a number of reasons to deviate from this rule and use an extrapolation factor of 100. PGME can be classified as a compound which acts by non-polar narcosis (OECD, 1995). This can be concluded from the observation that there is no significant difference between the $L(E)C_{50}$ values for the different species of fish, *Daphnia magna* and *Selenastrum capricornutum*. Furthermore, using the equations for non-polar narcotics given in Table 1 of Chapter 4 Part III of the TGD, ecotoxicity data can be estimated (see **Table 3.3**).

Table 3.3 QSAR ecotoxicity data for PGME

Species	Endpoint	Value (mg/L)
Pimephales promelas	96-hour LC_{50}	9,577
Daphnia magna	48-hour EC_{50}	12,596
Selenastrum capricornutum	72-96-hour EC_{50}	16,395

These data are reasonably consistent with the experimental data.

The test performed on algae shows 21% effect at a nominal concentration of 1,000 mg/l after 96 hours. This value is the lowest acute toxicity value. Even if it is not an EC_{50}, this value will be used to derive the $PNEC_{aqua}$. Applying an assessment factor of 100 to this value gives a $PNEC_{aqua}$ of 10 mg/L for the aquatic compartment.

Calculation of the PNEC for the freshwater compartment

No chronic toxicity data is available for PGME and only acute toxicity data for the three trophic levels on freshwater organisms are available. Therefore the PNEC should be derived according to the TGD from the lowest acute toxicity value with an assessment factor of 10,000. However, this compound acts by non-polar narcosis and to be consistent with freshwater compartment an assessment factor of 1,000 is applied on the value obtained for algae. This gives a $PNEC_{saltwater}$ of 1 mg/L.

Calculation of a PNEC for the sediment compartment

No test is available on sediment-dwelling organisms exposed via sediment. In absence of any ecotoxicological data for sediment-dwelling organisms, the PNEC may provisionally be calculated using the equilibrium partitioning method from the PNEC for aquatic compartment ($PNEC_{aqua}$) and the solid-water partition coefficient in suspended matter (Kp_{susp}).

Thus, the $PNEC_{sed}$ value is of 9.04 mg/kg wet weight of sediment.

Calculation of the PNEC for the marine sediment compartment

No test is available on sediment dwelling organisms exposed via sediment. The PNEC for organisms living in marine sediments may provisionally be calculated using the equilibrium partitioning method from the PNEC for the marine aquatic compartment ($PNEC_{saltwater}$).

Thus, the $PNEC_{marine\_sed}$ = 0.904 mg/kg wet weight of marine sediment.

PNEC for micro-organisms in STP

A NOEC ≥ 1,000 mg/l for sludge was determined from a respiration inhibition test. The $PNEC_{STP}$ may then be calculated using this value and an assessment factor of 10 which gives a $PNEC_{STP}$ value of 100 mg/L for organisms of STP.

Terrestrial compartment

No test on plants, earthworms or other soil-dwelling organisms is available. In the absence of any ecotoxicological data for soil-dwelling organisms, the $PNEC_{soil}$ may provisionally be calculated using the equilibrium partitioning method with the PNEC for aquatic compartment ($PNEC_{aqua}$) and the soil-water partition coefficient.

Thus, the $PNEC_{soil}$ value is of 2.18 mg/kg wet weight of soil.

Atmosphere

No data is available. The $PNEC_{air}$ can not be determined.

Secondary poisoning

As PGME is not classified T+, T or Xn and as the potential for bioaccumulation is very low, secondary poisoning can be considered to be negligible.

3.3 RISK CHARACTERISATION

3.3.1 Aquatic compartment

Considering that the substance is readily biodegradable, has a low bioaccumulation potential and presents a low toxicity for organisms, a refined risk assessment will not be performed.

The **Table 3.4** presents the calculated PEC/PNEC ratios for the aquatic compartment (water and STP).

Table 3.4 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004)

End uses	RCR water (*)	RCR STP (*)
Production Production: specific site located near the sea	0.0249 $5.11.10^{-4}$	0.0977
Chemical industry: chemicals used in synthesis	0.002 P	0.006 P
Chemical industry: chemicals used in synthesis (Captive use)	0.001 P	0.004 P
Paints and coating: - Water based - Solvent based	 $5.98 \cdot 10^{-3}$ F 0.0228 P $4.57 \cdot 10^{-4}$ PU 0.0281 F 0.0228 P $4.57 \cdot 10^{-4}$ PU	 $5.53 \cdot 10^{-3}$ F 0.0224 P $1.34 \cdot 10^{-7}$ PU 0.0276 F 0.0224 P $1.79 \cdot 10^{-7}$ PU
Printing inks	$8.08 \cdot 10^{-3}$ F $6.63 \cdot 10^{-3}$ P	$7.62 \cdot 10^{-3}$ F $6.18 \cdot 10^{-3}$ P
Detergents, cleaners	0.0322 F $8.63 \cdot 10^{-3}$ P	0.0317 F $8.17 \cdot 10^{-3}$ P
Leather finishing agent	This use is already covered by the painting scenario.	
Electronic industry	$8.47 \cdot 10^{-3}$ P	$8.01 \cdot 10^{-3}$ P
Agriculture	$4.57 \cdot 10^{-4}$ P	0 P
Cosmetics/Personal care	$4.64 \cdot 10^{-3}$ F $6.54 \cdot 10^{-4}$ PU	$4.19 \cdot 10^{-3}$ F $1.97 \cdot 10^{-4}$ PU

* F: Formulation; P: Processing; PU: Private Use

It can be noticed that no risk is expected for these compartments whatever end uses (even when both formulation and processing are considered on a same site).

Conclusions to the risk assessment for the surface water and STP

Conclusion (ii).

This conclusion does neither apply to the use of PGME in oilfield chemicals nor to its use in oil spill dispersants. These uses are not covered by this marine risk assessment.

As neither monitoring data on levels of PGME in sediment nor ecotoxicity data for benthic organisms are available, no risk characterisation is conducted for this compartment. In addition, the partition coefficient between sediment and water for PGME is low. So it can be assumed that the risk assessment for the sediment is covered by that for surface water.

Conclusions to the risk assessment for the sediment

Conclusion (ii).

3.3.2 Terrestrial compartment

According to the adsorption coefficient (log Koc = 0.76), the substance can be considered as very mobile in soils and will not be adsorbed to sludge in STP. Besides, the PGME is readily biodegradable in water. Finally, there is no direct release to soil. Therefore exposure of the terrestrial compartment is considered as negligible and PECs for this compartment will not be calculated.

It can be noticed that no risk is expected for this compartment whatever end uses.

<u>Conclusions to the risk assessment for the terrestrial compartment</u>

Conclusion (ii).

3.3.3 Atmosphere

No risk characterisation can be carried out for the air compartment, since there are no specific effect data.

3.3.4 Secondary poisoning

<u>Conclusions to the risk assessment for secondary poisoning</u>

Conclusion (ii).

4 HUMAN HEALTH

(to be added later).

5 RESULTS

5.1 ENVIRONMENT

The risk assessment does not cover the use of PGME in oilfield chemicals or its use in oil spill dispersants.

Conclusions to the risk assessment for the aquatic compartment

Conclusion (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.

Conclusion (ii) is applied to all levels of the life cycle of PGME: production, formulation, processing and private use.

Conclusions to the risk assessment for the terrestrial compartment

Conclusion (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.

Conclusion (ii) is applied to all levels of the life cycle of PGME: production, formulation, processing and private use.

Conclusions to the risk assessment for the atmospheric compartment

Conclusion (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.

Conclusion (ii) is applied to all levels of the life cycle of PGME: production, formulation, processing and private use.

Conclusions to the risk assessment for secondary poisoning

Conclusion (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.

Conclusion (ii) is applied to all levels of the life cycle of PGME: production, formulation, processing and private use.

5.2 HUMAN HEALTH

(to be added later).

European Commission
DG Joint Research Centre, Institute of Health and Consumer Protection
European Chemicals Bureau

EUR 22479 EN **European Union Risk Assessment Report**
1-methoxypropan-2-ol (PGME) – Part I – Environment

Editors: S.J. Munn, K. Aschberger, O. Cosgrove, S. Pakalin, A. Paya-Perez, B. Schwarz-Schulz, S. Vegro

Luxembourg: Office for Official Publications of the European Communities

2006 – III pp., 14 pp. – 17.0 x 24.0 cm

EUR – Scientific and Technical Research series; ISSN 1018-5593

The report provides the comprehensive summary of the risk assessment of the substance 1-methoxypropan-2-ol (PGME). It has been prepared by France in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to humans and the environment, laid down in Commission Regulation (EC) No. 1488/94.

Part I - Environment

The evaluation considers the emissions and the resulting exposure to the environment in all life cycle steps. Following the exposure assessment, the environmental risk characterisation for each protection goal in the aquatic, terrestrial and atmospheric compartment has been determined.

The environmental risk assessment for 1-methoxypropan-2-ol (PGME) concludes that there is at present no concern for the atmosphere, the aquatic ecosystem, the terrestrial ecosystem or for microorganisms in the sewage treatment plant. 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.

Part II – Human Health

This part of the evaluation considers the emissions and the resulting exposure to human populations in all life cycle steps. The scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks have been identified.

This part of the evaluation will be added later.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

European Commission – Joint Research Centre
Institute for Health and Consumer Protection
European Chemicals Bureau (ECB)

European Union Risk Assessment Report

1-methoxypropan-2-ol (PGME)
Part I - environment

CAS No: 107-98-2 EINECS No: 203-539-1

Series: 4th Priority List

Publications Office
Publications.eu.int