European Chemicals Bureau

Institute for Health and Consumer Protection

European Chemicals Bureau

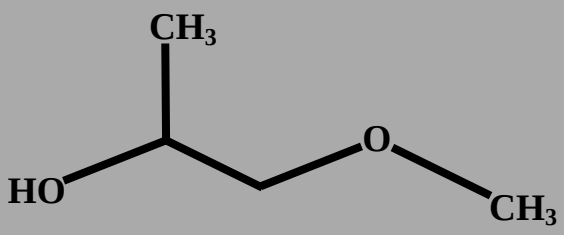
Existing Substances

European Union Risk Assessment Report

CAS No: 107-98-2

EINECS No: 203-539-1

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



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European Union Risk Assessment Report
1-methoxypropan-2-ol (PGME)

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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

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European Union Risk Assessment Report

1-METHOXYPROPAN-2-OL (PGME)

Part I - Environment

CAS No: 107-98-2

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RISK ASSESSMENT

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1-METHOXYPROPAN-2-OL (PGME)

Part I – Environment

CAS No: 107-98-2

EINECS No: 203-539-1

RISK ASSESSMENT

Final Report, 2006

France

The environmental risk assessment of 1-methoxypropan-2-ol (PGME) has been prepared by 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

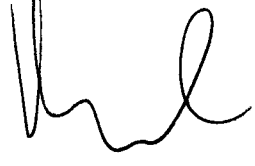
Date of Last Literature Search:	**2004**
Review of report by MS Technical Experts finalised:	**2005**
Final report:	**2006**

Foreword

We are pleased to present this Risk Assessment Report which is the result of in-depth work carried out by experts in one Member State, working in co-operation with their counterparts in the other Member States, the Commission Services, Industry and public interest groups.
The Risk Assessment was carried out in accordance with Council Regulation (EEC) 793/93[1] on the evaluation and control of the risks of "existing" substances. "Existing" substances are chemical substances in use within the European Community before September 1981 and listed in the European Inventory of Existing Commercial Chemical Substances. Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of these substances if they are produced or imported into the Community in volumes above 10 tonnes per year.
There are four overall stages in the Regulation for reducing the risks: data collection, priority setting, risk assessment and risk reduction. Data provided by Industry are used by Member States and the Commission services to determine the priority of the substances which need to be assessed. For each substance on a priority list, a Member State volunteers to act as "Rapporteur", undertaking the in-depth Risk Assessment and recommending a strategy to limit the risks of exposure to the substance, if necessary.
The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC) 1488/94[2], which is supported by a technical guidance document[3]. Normally, the "Rapporteur" and individual companies producing, importing and/or using the chemicals work closely together to develop a draft Risk Assessment Report, which is then presented at a meeting of Member State technical experts for endorsement. The Risk Assessment Report is then peer-reviewed by the Scientific Committee on Health and Environmental Risks (SCHER) which gives its opinion to the European Commission on the quality of the risk assessment.
If a Risk Assessment Report concludes that measures to reduce the risks of exposure to the substances are needed, beyond any measures which may already be in place, the next step in the process is for the "Rapporteur" to develop a proposal for a strategy to limit those risks.
The Risk Assessment Report is also presented to the Organisation for Economic Co-operation and Development as a contribution to the Chapter 19, Agenda 21 goals for evaluating chemicals, agreed at the United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992 and confirmed in the Johannesburg Declaration on Sustainable Development at the World Summit on Sustainable Development, held in Johannesburg, South Africa in 2002.
This Risk Assessment improves our knowledge about the risks to human health and the environment from exposure to chemicals. We hope you will agree that the results of this in-depth study and intensive co-operation will make a worthwhile contribution to the Community objective of reducing the overall risks from exposure to chemicals.

Roland Schenkel
Director General
DG Joint Research Centre

Mogens Peter Carl
Director General
DG Environment



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[1] O.J. No L 084, 05/04/199 p.0001 – 0075

[2] O.J. No L 161, 29/06/1994 p. 0003 – 0011

[3] Technical Guidance Document, Part I – V, ISBN 92-827-801 [1234]

0 OVERALL RESULTS OF THE RISK ASSESSMENT

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

Environment

The risk assessment does not cover the use of PGME in oilfield chemicals or its use in oil spill dispersants (see Section 3.1.2.1.3 and 3.1.2.1.4).

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.

Human Health

(to be added later).

CONTENTS

1 GENERAL SUBSTANCE INFORMATION 5

1.1 IDENTIFICATION OF THE SUBSTANCE 5

1.2 PURITY/IMPURITIES, ADDITIVES 5

1.3 PHYSICO-CHEMICAL PROPERTIES 5
1.3.1 Melting point 5
1.3.2 Boiling point 6
1.3.3 Relative density 6
1.3.4 Vapour pressure 6
1.3.5 Surface tension 6
1.3.6 Water solubility 7
1.3.7 Henry's law constant 7
1.3.8 Partition coefficient octanol water 8
1.3.9 Other physical-chemical properties 8
1.3.9.1 Flash point 8
1.3.9.2 Autoflammability 8
1.3.9.3 Oxidising properties 9
1.3.10 Summary 9

1.4 CLASSIFICATION 9
1.4.1 Current classification 9
1.4.2 Proposed classification 10

2 GENERAL INFORMATION ON EXPOSURE 11

2.1 PRODUCTION 11
2.1.1 Production processes 11
2.1.2 Production capacity 11

2.2 USES 12

3 ENVIRONMENT 14

3.1 ENVIRONMENTAL EXPOSURE 14
3.1.1 Environmental fate 14
3.1.1.1 Degradation in the environment 14
3.1.1.1.1 Atmospheric degradation 14
3.1.1.1.2 Aquatic degradation 15
3.1.1.1.3 Degradation in soil 16
3.1.1.1.4 Summary of environmental degradation 17
3.1.1.2 Distribution 18
3.1.1.2.1 Adsorption 18
3.1.1.2.2 Volatilisation 19
3.1.1.2.3 Distribution in wastewater treatment plants 19
3.1.1.3 Accumulation and metabolism 19
3.1.2 Aquatic compartment 19
3.1.2.1 Local exposure 20
3.1.2.1.1 Freshwater compartment 20
3.1.2.1.2 Marine environment 21
3.1.2.1.3 Local releases: PGME used in oilfield chemicals (processing) 22
3.1.2.1.4 Local releases: PGME used in oil spill dispersants (marine compartment) 23
3.1.2.2 Regional exposure 25
3.1.2.3 Continental exposure 25
3.1.3 Terrestrial compartment 25

3.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) - RESPONSE (EFFECT ASSESSMENT) 26
3.2.1 Aquatic compartment (incl. sediment) 26
3.2.1.1 Toxicity test results 26
3.2.1.1.1 Fish 26
3.2.1.1.2 Aquatic invertebrates 27
3.2.1.1.3 Algae 28
3.2.1.1.4 Microorganisms 29
3.2.1.1.5 Amphibians 29
3.2.1.2 Calculation of Predicted No Effect Concentration (PNEC) 29
3.2.1.2.1 Water 29
3.2.1.2.2 Sediment 30
3.2.1.2.3 Sewage Treatment Plant (STP) 31
3.2.2 Terrestrial compartment 31
3.2.3 Atmosphere 31
3.2.4 Secondary poisoning 31

3.3 RISK CHARACTERISATION 32
3.3.1 Aquatic compartment (incl. sediment) 32
3.3.1.1 Freshwater compartment and STP 32
3.3.1.2 Marine compartment 33
3.3.2 Terrestrial compartment 33
3.3.3 Atmosphere 34
3.3.4 Secondary poisoning 34

4 HUMAN HEALTH 35

5 RESULTS 36

5.1 ENVIRONMENT 36

5.2 HUMAN HEALTH 36

6 REFERENCES 37

Euses Calculations can be viewed as part of the report at the website of the European Chemicals Bureau: http://ecb.jrc.it

TABLES

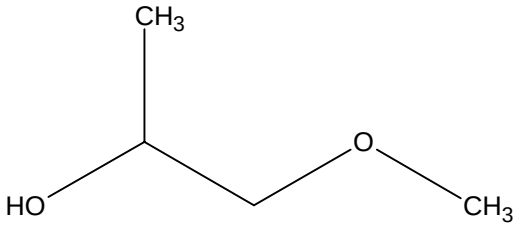
Table 1.1 Surface tension at 20°C 7
Table 1.2 Peroxide levels in PGME during storage under adverse (daylight) and recommended (dark) conditions. No antioxidants used. Results in mmol active oxygen/litre 9
Table 1.3 Summary of physico-chemical properties 9
Table 2.1 Overview of PGME production and sales in Europe for years 2001 to 2003 (data provided by CEFIC, 2004) 11
Table 2.2 Main producers of PGME 12
Table 2.3 Use of PGME in the EU 12
Table 3.1 Biodegradation test results for PGME 15
Table 3.2 Summary of the aerobic biodegradation of PGME in soil 17
Table 3.3 Mineralisation half lives of PGME in Londo Sandy Loam 17
Table 3.4 Estimation of biodegradation rate constants in the different compartments 17
Table 3.5 Partition coefficients between different compartments 19
Table 3.6 Parameters used for the calculation of exposure concentration for paint industry (worst case) 20
Table 3.7 Local PEC_{water}, PEC_{STP} for PGME according to EUSES (EC, 1996) 20
Table 3.8 Dispersants used today, application methods and dosages (Bonn Agreement, 2001) 24
Table 3.9 Regional PECs in air and water (calculations made by EUSES 2.0) 25

Table 3.10 Continental PECs in air and water (calculations made by EUSES 2.0) 25
Table 3.11 Short-term toxicity of PGME to fish 26
Table 3.12 Short term toxicity of PGME to aquatic invertebrates 27
Table 3.13 Short term toxicity of PGME to algae 28
Table 3.14 QSAR ecotoxicity data for PGME 29
Table 3.15 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004) 32

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 107-98-2
EINECS Number: 203-539-1
IUPAC Name: 1-methoxypropan-2-ol
Molecular formula: $C_4H_{10}O_2$
Structural formula:



Molecular weight: 90.1 g/mol
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

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

1.2 PURITY/IMPURITIES, ADDITIVES

The commercially supplied product is usually a mixture of two isomers 1-methoxypropan-2-ol (PGME, alpha isomer) and 2-methoxypropan-1-ol (beta isomer, CAS n°1589-47-5).

PGME is the main compound, totalising 99.5% of the product with 0.5% of 2-methoxypropan-1-ol, considered as an impurity.

No additive is contained in the marketed product.

1.3 PHYSICO-CHEMICAL PROPERTIES

At ambient temperature and pressure, PGME is a colourless liquid with an ether-like odour.

1.3.1 Melting point

The melting point of PGME ranges from –100°C to –95°C (BASF, 2001; BP, 2000; Dow, 2001; LYONDELL, 1999). A producer used an ASTM D-97 method reporting a result of -96°C (SHELL, 2000). The test reports are not available.

In Ullmann's encyclopaedia of industrial chemistry (1991), a value of -96°C for the melting point was reported.

A median value of –96°C has been calculated with the above data. This value will be used for the risk assessment.

1.3.2 Boiling point

The boiling point of PGME ranges from 117 to 122°C (BASF, 2001; BP, 2000; Dow, 2001; LYONDELL, 1999). A producer used an ASTM D-1078 method reporting values ranging from 117 to 125°C (SHELL, 2000). However, the test reports are not available.

In Ullmann's encyclopaedia of industrial chemistry (1991), a value of 120.1°C for the boiling point was reported at 1,013 hPa.

A median value of 120°C has been calculated using the above data. This value will be used for the risk assessment.

1.3.3 Relative density

The density of PGME ranges from 0.920 to 0.926 g/cm^3 at 20°C (BASF, 2001; BP, 2000; Dow, 2001). A producer used an ASTM D-4052 method reporting values ranging from 0.92 to 0.923 g/cm^3 (SHELL, 2000). At 25°C, a value of 0.92 g/cm^3 for the density of PGME was reported; (LYONDELL, 1999). However, the test reports are not available.

In Pullman's encyclopaedia of industrial chemistry (1991), a value of 0.923 for the density was reported at 20°C.

A median value of 0.921 g/cm^3 has been calculated using the above data. This value will be used for the risk assessment.

1.3.4 Vapour pressure

The vapour pressure of PGME ranges from 10 to 13.3 hPa at 20°C (BASF, 2001; BP, 2000; Dow, 2001; SHELL, 2000). At 25°C, a vapour pressure of 14.5 hPa is reported (LYONDELL, 1999). No test report is available.

A median value of 11.6 hPa at 20°C has been calculated using the above data. At 25°C, the value of 16.4 hPa has been calculated. This value will be used for the risk assessment.

1.3.5 Surface tension

A surface tension of 47.3 mN/m is reported by one producer. The concentration of the substance in water was 20%. The surface tension (**Table 1.1**) was also measured at higher concentrations (BP, 1998):

Table 1.1 Surface tension at 20°C

Concentration (% product in water)	Surface tension (mN/m) at 20°C
20	47.3
40	40.6
60	35.8
80	32.7
100	29.6

Surface active properties can be assumed for glycol ethers. The values reported in the literature for PGME tend to indicate that this substance is a surface active reagent. Indeed, OECD guideline n°115 suggests that surface tension measurements should be performed using a concentration of 1 g/L for soluble substances.

The fact that glycol ethers show surface active properties could thus lead to the disturbance of analytical method employed to measure some physico-chemical characteristics of glycol ethers.

However, there is a difference between the surface activity of traditional surfactants and substances that can reduce the surface activity of solutions like PGME. What is observed with the glycol ethers during the surface tension measurements is the typical non ideal behaviour of a mixture of a water miscible solvent such as methanol and ethanol. The reason for the observed relationship between surface tension and concentration is the disruption of the hydrogen bonding of the water causing non-linear behaviour of the surface tension against the concentration. In this case the substance is not migrating to the surface; it is not acting in the traditional surface active manner. Therefore it would not affect the measurements of the physical chemical properties. One should also notice that glycol ethers do not form micelles. They are fully miscible with water and form clear solutions.

Furthermore, considering the other properties of this substance (PGME is highly miscible in water, hydrosphere is the preferential target of PGME in the environment: > 90%, see Section 3.1.1.2), surface active properties of PGME will not be considered in this assessment.

1.3.6 Water solubility

PGME is fully miscible with water (BASF, 2001; BP, 2000; Dow, 2001; LYONDELL, 1999; SHELL, 2000).

The value of 100 g/l for the solubility of PGMA was reported. According to the chemical structure, PGME should be more soluble. Staples and Davies used a solubility of 500 g/l in their report. Therefore this value of 500 g/l will be retained for the risk assessment.

1.3.7 Henry's law constant

Values of 0.002-0.087 $Pa.m^3/mol$ were calculated at 25°C (BUA, 1995).

Staples and Davies (2002) calculated a Henry's law constant of 0.28 $Pa.m^3/mol$ from aqueous solubility and vapour pressure using a solubility of 500,000 mg/l and a vapour pressure of 1,573 Pa.

The Henry's law constant was also estimated using a structure activity relationship (HenryWin v3.10, US EPA and Syracuse Research Corporation, 2001). Calculated values ranged from 0.0018 $Pa.m^3/mol$ (group method) to 0.0056 $Pa.m^3/mol$ (bond method).

The Henry's law constant can be calculated using selected values of this report. The resulting value is 0.29 $Pa.m^3/mol$.

An average value of 0.12 $Pa.m^3/mol$ has been calculated using the above data. This value will be used for the risk assessment.

1.3.8 Partition coefficient octanol water

A log P_{OW} value was determined by reverse-phase HPLC by Pearson (1986). The HPLC system used was a reverse-phase C_{18}-coated silica gel column with a mobile phase of 3 volumes methanol and 1 volume water (final pH 6.8). Samples of an approximate 1 mg/ml solution in the above mobile phase were injected and the emergence of the material observed using refractive index detection. From the retention time of the peak the log P_{OW} value was determined. Fourteen reference substances with log P_{OW} ranging from 0.94 to 5.88 were used to generate a linear relationship between the retention time and log P_{OW} and to determine log P_{OW} of PGME.

Pearson (1986) also calculated a log P_{OW} value from chemical structure using the fragment addition method of Hansch and Leo (1979).

The log n-octanol/water partition coefficient value of PGME was determined by both reverse-phase HPLC and the Fragment-addition method to be < 1.

Gonsior (1990) also estimated a log P_{OW} value using the Pomona-Med Chem Structural fragment method. A value of –0.43 was reported.

Using a QSAR (US EPA and Syracuse Research Corporation, 2001: KOWWIN v1.66), a log P_{OW} value of –0.49 was estimated. This value will be used for the risk assessment.

1.3.9 Other physical-chemical properties

1.3.9.1 Flash point

The flash point of PGME ranges from 30°C to 35°C (BASF, 2001; BP, 2000; Dow, 2001; LYONDELL, 1999; SHELL, 2000). The test reports are not available.

In Ullmann's encyclopaedia of industrial chemistry (1991), a value of 38°C for the flash point was reported.

A median value of 32°C has been calculated using the above data. This value will be used for the risk assessment.

1.3.9.2 Autoflammability

Decomposition of PGME starts at temperature ranging from 270°C to 290°C (BASF, 2001; BP, 2000; Dow, 2001; LYONDELL, 1999; SHELL, 2000). The test reports are not available.

A median value of 278°C has been calculated using the above data. This value will be used for the risk assessment.

1.3.9.3 Oxidising properties

There are some references which suggest that glycol ethers can be prone to the formation of peroxides on storage. However data from one of the producers, shown below, indicates that peroxide levels for PGME remain virtually unchanged, even during prolonged storage under adverse conditions, as shown in **Table 1.2**.

Table 1.2 Peroxide levels in PGME during storage under adverse (daylight) and recommended (dark) conditions. No antioxidants used. Results in mmol active oxygen/litre

	In daylight	In the dark
Time 0	0.013	0.013
3 months	0.006	0.005
18 months	0.018	

The National Fire Protection Association's code for the reactivity of PGME is 0 indicating minimal hazard. In consequence, there is no requirement for classification R19.

1.3.10 Summary

Table 1.3 Summary of 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.m^3/mol

1.4 CLASSIFICATION

1.4.1 Current classification

PGME is currently not classified with respect to its effect on the environment.

1.4.2 Proposed 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

2.1 PRODUCTION

2.1.1 Production processes

In the production process methanol and propylene oxide are reacted at a pressure of 26 bar and a temperature ranging from 95 to 180°C. The reaction is catalysed homogeneously in closed system. The reaction product is separated in a number of distillation steps. Excess methanol is recovered in the first distillation column and recycled back to the reactor. The desired PGME product, 1-methoxy-2-propanol, is recovered in the second distillation column. The by-product 2-methoxy-1-propanol is recovered in the third column and stored for subsequent conversion. The bottom stream is recycled and reused as catalyst (Personal communication Shell, 20/01/03).

Main producers have continuous production plants (24 hours per day, 7 days a week) with continuous feed and outlet (Personal communication Dow, 19/02/02).

2.1.2 Production capacity

The production and sales data for years 2001 to 2003 are given by the **Table 2.1**.

Table 2.1 Overview of PGME production and sales in Europe for years 2001 to 2003 (data provided by CEFIC, 2004)

In tonnes	2001	2002	2003	Figures retained
Production	171,000	185,400	188,000	188,000
Imports	0	0	0	0
Exports	29,500	42,500	50,000	46,000
Net into stock	2,000	-1,500	-500	-
Captive use (PGMA production)	53,500	61,000	56,500	58,500
Sales in EU	86,000	83,400	82,000	83,500
Total use in EU	139,500	144,400	138,500	142,000

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 five producers in the EU (see **Table 2.2**).

Table 2.2 Main producers of PGME

Company	Localisation
BASF	Ludwigshafen (Germany)
Lyondell*	Rotterdam (Netherlands)
BP	Lavera (France)
Dow	Stade (Germany)
Shell	Hoogvliet (Netherlands)

* LYONDELL acquired ARCO in 1998

According to recent information (Personal communication BP, 20/05/03), BP stopped its production of PGME.

From the **Table 2.2**, it appears that some production sites are located in the same area. Consequently the locations of both German sites and the Dutch one have been checked so as to establish whether they could pertain to the same region (TGD definition EC, 2003). Distances between these different sites are > 200 km. So, in the regional assessment, none of these sites will be considered in a same region

2.2 USES

The industrial and use categories of PGME are summarised in **Table 2.3**. PGME is mainly used as solvents. The dimmed lines correspond to negligible uses.

A breakdown of the uses of PGME in Europe has been established based on the data collected for years 2001 to 2003 by CEFIC (2004) (see **Table 2.3**). The total used tonnage recorded is 142,000 tonnes taking into account the captive use. The analysis of this set of data has led to a choice which is meant to represent a reasonable worst case. The final data choice is based mainly on averages but some expert judgement has also been applied to adjust for market knowledge and the fact that supply via distributors adds some uncertainty to the numbers. Typically, 25-40% of volume goes via distributors. To reflect these uncertainties, the figures are quoted as rounded numbers. 2002 and 2003 data should be given more weight as some errors have possibly been made during assessment of the 2001 data in allocating users to the appropriate end use categories.

Table 2.3 Use of PGME in the EU

End use	Stage of the life cycle	Industry category	Use category	2001	2002	2003	Retained proposal	
							Quantity used (tonnes)	Percentage of total use
Chemical industry: chemicals used in synthesis	Processing	3: chemicals used in synthesis	33: Intermediate	21,140	3,000	3,900	3,500	2.5%
				53,500 (captive use)	61,000	56,500	58,500 (Captive use)	41.7% (Captive use)
Paints and coating*	Formulation Processing Private use	14: Paints, lacquers and varnishes	48: Solvent	32,585	54,500	53,500	54,000	38.5%

Table 2.3 continued overleaf

Table 2.3 continued Use of PGME in the EU

End use	Stage of the life cycle	Industry category	Use category	2001	2002	2003	Retained proposal	
							Quantity used (tonnes)	Percentage of total use
Printing inks*	Formulation Processing	12: pulp, paper and board industry	48: Solvent	11,793	12,000	12,000	12,000	8.5%
Others*	Formulation Processing	16: other	55: other	11,586	0	0	0	0
Detergents, cleaners	Formulation Private/public use	5: Personal/ domestic 6: Public domain	48: Solvent	4,345	7,000	7,700	7,500	5.3%
Leather finishing agent	Processing	7: Leather processing industry	48: Solvent	517	2,900	400	1,900	1.3%
Electronic industry	Processing	4: Electrical/ electronic industry	48: Solvent	2,069	1,300	1,500	1,500	1%
Agriculture	Processing	1: agricultural industry	48: Solvent	0	1,100	1,200	1,150	0.8%
Cosmetics/ Personal care	Formulation Private use	5: Personal/ domestic	48: Solvent	1,655	700	700	1,000	0.7%
Adhesive		5: Personal/ domestic	48: Solvent	207	400	500	400	0.2%
Metal cleaning		6: Public domain	48: Solvent	0	400	400	400	0.2%
Oil spill dispersant/ Oilfield chemicals		6: Public domain	48: Solvent	103	100	200	150	0.1%
Total				139,500	144,400	138,500	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

3.1.1.1 Degradation in the environment

3.1.1.1.1 Atmospheric degradation

Photodegradation

Dilling et al. (1976) tested the photodegradation of PGME in air under simulated atmospheric conditions. Test was performed with an ultraviolet light source that consisted of 2 general electric 275-W reflector sunlamps each of which had a short wavelength cut-off of 290 nm. The ultraviolet intensity was estimated to be 2.6 times that of the natural sun at noon on a summer day. A concentration of 5 ppm of NO was added to the reactor simulating smog conditions. The temperature of the reactor was maintained at 27 ± 1°C. The disappearance rates of organic compounds in the reactor were determined by flame ionisation GC. Under these conditions, the half-life of PGME in the air was calculated to be 3.1 hours. Nevertheless the result of this test is not taken into account in the risk assessment since test conditions are not representative of natural surroundings.

Tuazon et al. (1998) investigated the products of the gas phase reactions of the OH radicals and PGME. The products observed from PGME were methyl formate (CAS n° 107-31-3), methoxyacetone (CAS n° 5878-19-3) and acetaldehyde (CAS n° 75-07-0).

A QSAR method can be applied. A degradation rate constant of $1.6 \cdot 10^{-11}$ $cm^3.molecule^{-1}.s^{-1}$ was calculated. A half life of 7.8 hours was estimated (US EPA and Syracuse Research Corporation, 2001: AOPWIN v1.90).

Using a relative method, Aschmann and Atkinson (1998) have measured rate constants for the gas-phase reactions of the OH radicals with PGME of $(20.9 \pm 3.1) \cdot 10^{-12}$ $cm^3.molecule^{-1}.s^{-1}$. Aschmann and Atkinson (1998) have also measured rate constants for the reactions of PGME with NO_3 radicals and O_3 of $(1.7 \pm 0.7) \cdot 10^{-15}$ $cm^3.molecule^{-1}.s^{-1}$ and $< 1.1 \cdot 10^{-19}$ $cm^3.molecule^{-1}.s^{-1}$ respectively.

According to EC (2003), rate constant for degradation in air ($k_{deg\text{-}air}$) can be calculated from the degradation with OH-radicals rate constant determined experimentally by Aschmann and Atkinson (1998). The average OH-radicals concentration over 24 hours in western Europe is assumed to be $5 \cdot 10^5$ molecules.cm^{-3}. Therefore, $k_{deg\text{-}air} = 0.9$ d^{-1}. This value will be used in the risk assessment.

3.1.1.1.2 Aquatic degradation

Hydrolyse

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.

Aerobic biodegradation

Several aerobic biodegradation studies of PGME are available and reported in **Table 3.1**.

Table 3.1 Biodegradation test results for PGME

Inoculum	PGME concentration	Test	Results	Microbial inhibition	10-Day window	Reliability	Reference
Sewage sludge	20 mg/l	Modified Sturm test (directive 84/449/EEC, C.5)	65-69% after 28 days	Not tested	Respected	2	Miller and Watkinson, 1985
Sewage sludge	3 mg/l	OECD Guide-line 301 D	2 – 4% after 28 days	Tested: no toxic	Not respected	2	Miller and Watkinson, 1985
Industrial sewage	37.8 mg/l	OECD Guide-line 301 E	89% after 29 days	Tested: no toxic	Respected	2	Pagga, 1985
Activated sludge	86 mg/l	OECD Guide-line 301 E	96% after 28 days	Not tested	Respected	1	Handley and Horton, 1994.
Activated sludge	100 mg/l	OECD Guide-line 302 C	88 – 92% after 28 days	Not tested	No data	1	CITI, 1992
Activated sludge, adapted	3.75– 7.5 mgC/l	Other	72.5-82.4% after 28 days	No tested	No data	2	Wu et al., 1986

All the studies were conducted according to the standard OECD Guide Lines except the test performed by Wu et al. (1986).

PGME seems to be readily biodegradable according to all test reports except in the "Closed Bottle Test" (OECD Guide Line 301D) reported by Miller and Watkinson (1985) where a biodegradation of only 2 to 4% occurred after 28 days (the biodegradation is expressed as theoretical oxygen demand). However, a modified Sturm test (Directive 84/449/EEC, C.5) was performed by the same authors along with a microbial inhibition test on a pure strain of *Ps. Fluorescens*. A degradation of 65 to 69% after 28 days was observed. PGME up to a concentration of 1,000 mg/l did not inhibit the activity of *Ps. Fluorescens.*

The absence of degradation of PGME in the "Closed Bottle Test" could result from incapability of the particular strain of microorganism to adapt to the substance. This assumption is confirmed by the presence of lag periods in all of the tests:

- A-20 day lag period in the Sturm Test (Miller and Watkinson, 1985)
- A-17 day lag period in a modified screening test (Pagga, 1985)
- A 14 to 16-day lag period in another modified screening test (Handley and Horton, 1994)
- No information is given on an eventual lag period for the modified MITI test (CITI, 1992)

- No information is given on an eventual lag period but the test was performed with adapted sludge (Wu et al., 1986)

All the different strains of microorganisms used in the tests go through a period of adaptation before the beginning of biodegradation.

The particular strain used in the Closed Bottle Test (not provided by the same sewage works as the Modified Sturm Test) may not be capable of using PGME as a source of carbon.

In conclusion, PGME can be considered as readily biodegradable in aerobic conditions

Anaerobic biodegradation

Only one test report is available. Goodwin (1998) measured the biodegradation of PGME (50 mg/l related to DOC) during 81 days at 34.8°C in the darkness with an inoculum of municipal digester sludge collected from a wastewater treatment plant which treats predominantly domestic sewage.

Test mixtures were prepared containing pre-reduced mineral, 10% anaerobic digester sludge inoculum and PGME. Biodegradation of an acetate/propionate solution was run in parallel to monitor the viability of the inoculum. Toxicity controls were also prepared.

Gas production from the reaction mixtures was measured by the syringe method on days 10, 17, 28, 42, 56, 70 and 81. A lag period of approximately 30 days occurred before any degradation was observed.

A biodegradation of 38% after 81 days was reported and the presence of the test substance did not appear to inhibit gas production indicating no apparent toxicity to the anaerobic sludge inoculum.

3.1.1.1.3 Degradation in soil

Aerobic biodegradation

Studies were carried out on the degradation of PGME by soil microorganisms under aerobic condition at 25°C (Gonsior and West, 1991, 1995).

Three different soil samples were used. A sandy soil and a sandy loam (classified as a Tappan series) were collected in Bay country (Michigan). A second sandy loam (classified as a Londo series) was collected in Midland (Michigan). The samples were collected to a depth of 15 cm and were screened through a 2 mm mesh sieve (the Tappan sample was not sieved due to its high water content). Organic and inorganic content as well as soil texture were determined. The samples were then stored at 4°C.

Bacterial counts ranged from $9.3 \cdot 10^5$ bacteria per gram of soil for the sand to $9.9 \cdot 10^6$ bacteria per gram of soil for the Londo sandy loam. Calculations were based on the dry weight of the soil.

Carbon-14 labelled PGME (labelled on the methoxy substituent) was obtained with a radiochemical purity of 94%.

Biodegradation was examined in batch soil microcosms. Reaction mixtures were prepared adding 20 g of soil (dry weight) and 20 g of water to 60 ml serum bottles. Carbon-14 labelled PGME at nominal concentrations ranging from 1 to 100 ppm was added. Following this addition

the microcosms were sealed and incubated in the dark at 25 ± 2°C with continuous mixing on a rotor.

The disappearance of PGME and formation of products in the soil microcosms were monitored by HPLC.

The results are summarised in **Table 3.2**.

Table 3.2 Summary of the aerobic biodegradation of PGME in soil

Soil	Initial concentration (ppm) Nominal/Measured	Time for 50% removal (days)	Maximum $^{14}CO_2$ (%)
Londo Sandy Loam	1/0.2	< 1	62
	10/9.9	< 2	64
	100/100	< 5	57
Tappan Sandy Loam	1/0.4	< 1	57
	100/100	< 7	59
Sand	1/0.4	< 4	76
	100/100	> 56a	28b

a) 40% degradation after 56 days;
b) $^{14}CO_2$ measured after 56 days

Mineralisation was determined by measuring $^{14}CO_2$ only in Londo Sandy Loam (see **Table 3.3**). $^{14}CO_2$ was the only major product detected in the experiment with PGME.

Table 3.3 Mineralisation half lives of PGME in Londo Sandy Loam

Initial concentration (nominal)	Mineralisation half lives (days)
1 ppm	1
10 ppm	4
100 ppm	7

Degradation of PGME depends on the nature of soil and the amount of microorganisms in soils. In sandy soils degradation is slower reflecting the lower concentration of microorganisms.

Degradation will also depend on the concentration of PGME in the microcosm. The time required to degrade 50% of PGME increased in each soil as the initial concentration of PGME increased.

3.1.1.1.4 Summary of environmental degradation

As no biodegradation rates are available for surface freshwater, surface saltwater, soil and sediment, the following rate can be estimated according to the procedure outlined in the TGD (EC, 2003):

Table 3.4 Estimation of biodegradation rate constants in the different compartments

Compartment	Biodegradation rate (d^{-1})
Surface freshwater	$K_{freshwater} = 4.7 \cdot 10^{-2}$
Surface saltwater	$K_{saltwater} = 1.4 \cdot 10^{-2}$
Sediment	$K_{sed} = 2.3 \cdot 10^{-3}$
Soil	$K_{soil} = 2.3 \cdot 10^{-2}$

3.1.1.2 Distribution

In an Air-biota-sediment-soil-water compartment model (EQC model v1.0 based on the level I fugacity model developed by Mackay), the following physical and chemical parameters were used as the basis for the calculation of the distribution of PGME in the different environmental compartments:

- Molecular weight: 90.1 g/mol
- Temperature: 20°C
- Vapour pressure: 1160 Pa
- Log Pow: -0.49
- Melting point: -96°C

The predicted distribution of PGME is:

– 4.104% to air
– 0.085% to soil
– 95.8% to water
– 0.002% to sediment
– 0% to suspended sediment
– 0% to biota (fish)

Based on the above results, water is the preferential target compartment at equilibrium.

3.1.1.2.1 Adsorption

No experimentally derived value of Koc is available. Using the Q(S)AR relationship recommended in the TGD (EC, 2003) for non-hydrophobic chemicals, a Koc value of 5.7 l/kg (log Koc = 0.76) is calculated.

The solid-water partition coefficient in each compartment (soil, sediment, suspended matter) can be calculated from the Koc value and the fraction of organic carbon in the compartment proposed in the TGD. The results are presented in **Table 3.5**.

Table 3.5 Partition coefficients between different compartments

Compartments	Weight fraction of organic carbon in compartment	Partition coefficient solid-water in compartment
Soil	0.02 kg/kg	Kp_{soil} = 0.114 l/kg
Sediment	0.05 kg/kg	Kp_{sed} = 0.285 l/kg
Suspended matter	0.1 kg/kg	Kp_{susp} = 0.57 l/kg

3.1.1.2.2 Volatilisation

Based on the Henry's law constant of 0.12 $Pa.m^3.mol^{-1}$, the air-water partitioning coefficient ($K_{air\text{-}water}$) can be calculated. A $K_{air\text{-}water}$ of $5.06 \cdot 10^{-5}$ indicates that volatilisation of PGME from surface water and moist soil is expected to be very low.

3.1.1.2.3 Distribution in wastewater treatment plants

The behaviour of the substance in a waste water treatment plant can be estimated on the basis of the SIMPLETREAT model included in the EUSES program with the following parameters:

- Biodegradation rate: 1 h^{-1} (ready biodegradable)
- Log Kow = -0.49
- Log H = log 0.12 = -0.9

The results of the model lead to 87.3% of the substance degraded in the STEP and 12.6% released to surface water. There is no adsorption on sludge (0.04%) and no release to air (0.05%).

3.1.1.3 Accumulation and metabolism

No experimental data is available on bioaccumulation.

Using a QSAR (BCFWIN v2.14), a BCF of 3.16 was estimated. This value will be used for the risk assessment (US EPA and Syracuse Research Corporation, 2001).

In conclusion, PGME has a low potential for accumulation in biota

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

3.1.2.1 Local exposure

3.1.2.1.1 Freshwater compartment

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. Indeed, as there are only five PGME production sites in Europe, the regional production will not be set at 10% of total PGME production (TGD default) but at the maximum volume produced at one site.

All uses listed in **Table 2.3** (except the two last lines which are considered as minor uses) are taken into account in this risk assessment. For the category "paints and coating", two sub-categories are defined: water-borne paints solvent-borne paints. According to a survey performed by CEPE (2002), among the paints which contain PGME, 10% are water-borne paints and 90% are solvent-borne paint. Moreover, the same survey shows that the fraction of PGME in water-borne and solvent-borne paints goes up to respectively 10% and 60%.

As far as the above data may not be representative of paint industry and in order to see whether a risk can be identified using maximising figures (worst case), the figures presented in **Table 3.6** will be used.

Table 3.6 Parameters used for the calculation of exposure concentration for paint industry (worst case)

End uses: paints and coating	Percentage of PGME in formulation	Percentage of total paint use containing PGME
Water-borne paints	20%	20%
Solvent-borne paints	80%	100%

Leather finishing

PGME is quoted as being used in leather finishing operations, which is effectively a "coating" operation where a preparation is applied by air atomised spraying in a spray booth. Actual usage rates are quoted as up to 0.4 g/kg of dry finished leather, which, following the above assumptions, would lead to total glycol ethers consumption of up to 250 tpa. There will in addition be wastage from over spray and emissions to water from the over spray control systems. However, since this is a coating operation, it is already covered by the existing painting scenario. Consequently, there will not be a separate risk characterisation for this use.

For the other categories, default values suggested by the TGD (Table A, Table B) will be chosen in the risk assessment.

Table 3.7 gives the PECs for the aquatic compartment.

Table 3.7 Local PEC_{water}, PEC_{STP} for PGME according to EUSES (EC, 1996)

End uses	PEC_{water} mg/l (*)	PEC_{STP} mg/l (*)
Production	0.249	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)

Table 3.7 continued overleaf

Table 3.7 continued Local PECwater, PECSTP for PGME according to EUSES (EC, 1996)

End uses	PEC_{water} mg/l (*)	PEC_{STP} mg/l (*)
Paints and coating:		
- Water based	0.0598 (F)	0.553 (F)
	0.228 (P)	2.24 (P)
	$4.57 \cdot 10^{-3}$ (PU)	$1.34 \cdot 10^{-5}$ (PU)
- Solvent based	0.281 (F)	2.76 (F)
	0.228 (P)	2.24 (P)
	$4.57 \cdot 10^{-3}$ (PU)	$1.79 \cdot 10^{-5}$ (PU)
Printing inks	0.0808 (F)	0.762 (F)
	0.0663 (P)	0.618 (P)
Detergents, cleaners	0.322 (F)	3.17 (F)
	0.0863 (P)	0.817 (P)
Leather finishing agent	This use is already covered by the painting scenario (see Section 3.1.2.1.1)	
Electronic industry	0.0847 (P)	0.801 (P)
Agriculture	$4.57 \cdot 10^{-3}$ (P)	- (P)
Cosmetics/Personal care	0.0464 (F)	0.419 (F)
	$6.54 \cdot 10^{-3}$ (PU)	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)

3.1.2.1.2 Marine environment

At one production site, releases are directly emitted into the marine environment. PEC for the marine compartment is estimated using the Technical Guidance Document and data provided by the industry.

$$PEC_{seawater} = 0.511 \text{ µg/l}$$

No specific element is available to define specific exposure scenarios for PGME releases during its use. Consequently, the use of the generic methodology proposed by the TGD for the marine exposure assessment will contribute to increase one more time the level of conservatism of this assessment. Consequently, for end-uses, no exposure assessment is needed for the marine environment. The high level of conservatism taken for the exposure assessment for freshwater is considered sufficient to take into account the marine compartment.

Two uses should be considered specifically for the marine risk assessment: the use of PGME as oil spill dispersant and oilfield chemical. The assessments of these uses are specifically discussed in the sections hereafter.

3.1.2.1.3 Local releases: PGME used in oilfield chemicals (processing)

Regulations on oilfield chemicals

In June 2000, OSPAR introduced Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals. At the heart of OSPAR Decision 2000/2 are two Recommendations: Recommendation 2000/4 on a Harmonised Pre-Screening Scheme for Offshore Chemicals, which facilitates the substitution of chemicals with certain characteristics by less hazardous alternatives and Recommendation 2000/5.

Decision 2000/2 and its supporting Recommendations entered into force on 16 January 2001. The Decision requires offshore chemicals to be ranked according to their calculated Hazard Quotients (HQ - ratio of Predicted Environmental Concentration (PEC) to Predicted No Effect Concentration (PNEC). It also obliges authorities to use the CHARM "hazard assessment" module as the primary tool for ranking.

Details on the national regulations put in place in order to comply with OSPAR recommendations have been found for two countries (United Kingdom and Norway). However other countries which have offshore oil and gas installations[4] may have similar regulations in place following harmonisation of such schemes in 1996.

– Norway

The Norwegian State Pollution Control Authority (SFT) regulates the use of drilling fluids/muds through discharge permits. Water based muds are tested under OSPAR formats for bio-accumulation potential and bio-degradability and given a discharge permit if judged to be environmentally friendly. Synthetic muds are similarly evaluated and can be given a discharge permit according to their properties. All oil-based muds are injected or taken to shore for treatment. The discharge of solids containing more than 1% oil, by weight, is forbidden - whether the drilling fluid is water-, oil- or synthetic-based. The regulations also deal explicitly with well testing, workover and cementing.

Norwegian regulations:

- Norwegian State Pollution Control Authority (SFT) 1998. Requirements for Ecotoxicological Testing and Environmental Assessment of Offshore Chemicals and Drilling Fluids. SFT, Oslo

- Norwegian State Pollution Control Authority (SFT) 1999a. Environmental Monitoring of Petroleum Activities on the Norwegian Shelf; Guidelines 99:01. SFT, Oslo

- Norwegian State Pollution Control Authority (SFT) 1999b. Pollution Control Act, 1981. SFT, Oslo)

Norway uses the standard OSPAR "A" and "B" lists for offshore chemicals and requires that discharge of these "shall be reduced as much as possible, e.g., through recycling". Operators are required to ensure the purity of the substances they use, with minimum contamination by other chemicals. Discharge of unused chemicals into the sea is expressly forbidden, even if they are on list A or B and their toxicity is therefore well known. All discharges must have a permit and chemicals not on the lists must be separately tested and notified.

[4] In some countries there are no offshore oil and gas installations in the OSPAR maritime area under the jurisdiction of the Contracting Parties (i. e. Belgium, Finland, France, Portugal, Sweden).

– United Kingdom

The Offshore Chemical Notification Scheme (OCNS) was originally introduced in 1979. In 1993, the UK Government introduced a revised scheme, which classified chemicals using test protocols approved by the Oslo and Paris Commissions (OSPAR). This was modified in detail, in early 1996, to meet the requirements of the OSPAR Harmonised Offshore Chemical Notification Format (HOCNF) which co-ordinates the testing requirements for oilfield chemicals throughout the NE Atlantic sector.

In June 2000, OSPAR introduced Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals. In the UK this is to be administered under the Offshore Chemical Regulations 2002 (OCR 2002) which came into force on 15th May2002.

The UK operates the Offshore Chemical Notification Scheme (OCNS[5]). This is operated by the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) on behalf of the Department for Trade and Industry (DTI). CEFAS is an Executive Agency of the UK Government's Department for Environment, Food and Rural Affairs (DEFRA). The OCNS requires the registration of all chemicals used in the actual exploration, exploitation and associated offshore processing of petroleum on the UK Continental Shelf. Dossiers on individual products rather than substances have to be notified. The required dossiers must include acute toxicity data on marine species from the three tropic levels as well as other data. Because individual products are notified, detailed information on usage rates and composition are available allowing more precise risk characterisations to be performed using the CHARM model (Thatcher et al., 2004) and the products ranked according to the hazard they present. However, for reasons of commercial confidentiality, the toxicity data, usage and composition information is not published.

Because they use detailed information supplied under confidentiality terms, specific assessments performed under such regulations should be regarded as more precise than those that could be carried out in this assessment. For instance, detailed information is provided by the manufactures on actual usage and emission rates. Therefore, no risk assessment for the use of PGME in oilfield chemicals will be performed in this document.

3.1.2.1.4 Local releases: PGME used in oil spill dispersants (marine compartment)

The development of oil spill dispersants has started in the beginning of the 70’s with the increase in oil transportation and as a consequence the increase in number of accidents. A summary of dispersants used today is provided in **Table 3.8** and a list of agreed dispersants according to the Bonn Agreement is also available[6].

[5] http://www.cefas.co.uk/ocns/index.htm

[6] This list of agreed dispersants will be updated in 2005.

Table 3.8 Dispersants used today, application methods and dosages (Bonn Agreement, 2001)

Standard name	Generation	Type	Application method	Solvent	Dosage (dispersant / oil)
Conventional dispersants	Second	1	Not diluted on ships	No aromatic hydrocarbons	30 –100%
Concentrated dispersants	Third	2	Diluted on ships	Water-based (e.g., glycol ether)	5 – 15% (concentrated products)
		3	Not diluted on ships or airplanes	Hydrocarbon-based	

It is difficult to know how often dispersants are used against oil spills. A survey of international uses of dispersants was performed by Lindgren et al. (2001). From this survey it seems clear that most of the time mechanical actions are recommended for combating oil spills and that the use of chemicals such as dispersants should be avoided as long as possible. This is particularly the case in the Baltic area, which falls under the HELCOM's recommendations (Helsinki Commission; Denmark, Finland, Germany, Latvia, Lithuania, Poland, Sweden and the Russian Federation).

In specific situations dispersants can nevertheless be used if the national authority approves it. This is also the case in the USA and Canada where mechanical methods are used unless weather prevents the use of these methods.

In Belgium, France, United Kingdom and Germany, dispersants are used, particularly in England where the total number of approved dispersants is high in comparison with other countries. However dispersants in these different countries are applied under specific rules and recommendations and usually after approval by the government or the competent authority in this field. Apart from these theoretical considerations, it seems that dispersants are nevertheless used in a lot of situations because it is often the easiest way to manage an oil spill (personal com. Cedre). Therefore small oil spills resulting from usual practice are most of the time treated with dispersants when of course this is possible.

Lessard and Demarco, 2000 report that the rate of usage of dispersants has gone up over the past 30 years and that dispersants have been successfully applied in half as many major spills during the 1990s as during the prior 25 years. Application rates of dispersants depend on the amount of oil to be treated. Usual application rates seem to be around 5 to 15% from information compiled on product fact-sheets (Cedre, 2004).

Oil spill dispersants are only used on occasions when an oil spill occurs in the environment and so may be used locally in relatively large amounts on very infrequent occasions. This should be consequently treated as an intermittent release.

Figures on the number of oil spills detected are available for the Baltic Sea. Von Viebahn, (2002) reports that 250 to 650 oil spills are detected each year. It is also stated in the same report that the number of oil spills in the North Sea is higher; however exact figures are not available. More information on annual oil spills would be useful in order to propose a regional scenario. However due to a lack of time this is not possible at present.

In the same way, specific data (amount of oil released, dispersant used, etc.) are available on different oil spills, major as well as minor spills, in different locations. It is possible from the data available to construct worst case scenarios and assess local PEC, however this implies the development of specific and detailed emission scenario for major and minor spills. This could become difficult considering that a "typical oil spill" cannot be defined. Each presents unique circumstances, depending on location, quantity and type of oil, prevailing weather conditions etc.

It has also to be taken into consideration that the decision whether to use a dispersant is made with the regulatory authorities' case-by-case and on a risk benefit basis. It is generally accepted that dispersants create adverse effects but their use is intended to mitigate the even worse potential effects of environmentally hazardous oil products. For this reason, even if detailed composition information was available, it would still not be possible to carry out such a risk benefit analysis within the framework of the Existing Substances risk evaluation process.

3.1.2.2 Regional exposure

Regional computations are done by means of multimedia fate models based on the fugacity concept. The standardised regional environment of the TGD (EC, 2003) is used. The **Table 3.9** shows the calculated regional PECs for air, water, sediment, seawater and marine sediment using EUSES (EC, 2004).

Table 3.9 Regional PECs in air and water (calculations made by EUSES 2.0)

Compartment	PEC regional
Air	$2.64 \cdot 10^{-4}$ mg/m^3
Water	$4.02 \cdot 10^{-3}$ mg/l
Sediment	$3.22 \cdot 10^{-3}$ mg/kg (wwt)
Seawater	$3.67 \cdot 10^{-4}$ mg/l
Marine sediment	$2.98 \cdot 10^{-4}$ mg/kg (wwt)

3.1.2.3 Continental exposure

Table 3.10 presents the continental PECs for air and water using EUSES (EC, 2004).

Table 3.10 Continental PECs in air and water (calculations made by EUSES 2.0)

Compartment	PEC continental
Air	$4.16 \cdot 10^{-5}$ mg/m^3
Water	$7.30 \cdot 10^{-4}$ mg/l
Sediment	$5.84 \cdot 10^{-4}$ mg/kg (wwt)
Seawater	$2.07 \cdot 10^{-6}$ mg/l
Marine sediment	$1.68 \cdot 10^{-6}$ mg/kg (wwt)

3.1.3 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.

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

Studies are classified as valid if they fully describe the test material used, the test organism, the test method and conditions and if the endpoint concentration is based upon measured levels. Where only some of these criteria are described the tests may be used with care or considered not valid. Moreover for some studies or results, some data are lacking, i.e. the original paper is not available but only a citation.

3.2.1 Aquatic compartment (incl. sediment)

3.2.1.1 Toxicity test results

3.2.1.1.1 Fish

Acute toxicity

Studies on acute toxicity of PGME to fish are summarised in **Table 3.11**.

Table 3.11 Short-term toxicity of PGME to fish

Species	Method	S/SS[a]	N/M[b]	Duration	Toxicity endpoint	Validity	References
Leuciscus idus	Guideline DIN 38412	S	N	96 hours	4,640 < LC_{50} < 10,000 mg/l LC_{50} = 6,812 mg/l (geometric mean) NOEC= 4,640 mg/l	2	Kirsch and Munk, 1989
Pimephales promelas	Other: ASTM	S	N	96 hours	LC_{50} = 20,800 mg/l	2	Bartlett et al., 1981
Onchorhynchus mykiss	Other	SS	N	96 hours	LC_{50} > 1,000 mg/l	2	Pearson, 1986

a) The test was performed with a static (S) or semi-static (SS) system.
b) The concentrations are nominal (N) or measured (M)

Kirsch and Munk (1989) studied the acute toxicity of PGME to the *Leuciscus idus*. The test was carried out under static conditions at 20-22°C. The water used for the test was reconstituted freshwater prepared from fully demineralised water with a pH of about 8 and a total hardness of about 105 mg/l $CaCO_3$. Dissolved oxygen was monitored throughout the test ranging from 7.8 and 9 mg/l. The exposure concentrations ranged from 1,000 to 10,000 mg/l. Based on nominal concentrations of PGME, the 96-hour LC_0 was determined to be 4,640 mg/l. The 96-hour LC_{100} was determined to be 10,000 mg/l. An approximation of the 96-hour LC_{50} can be made by calculating the geometric mean between 96-hour LC_0 and 96-hour LC_{100}. A value of 6,812 mg/l was calculated. The No Observed Effect Concentration (NOEC) was determined to be 4,640 mg/l.

Bartlett et al. (1981) studied the acute toxicity of PGME to *Pimephales promelas*. The test was carried out under static conditions at 12°C. The test water was taken from Lake Huron (Michigan) with a total hardness of about 105 mg/l $CaCO_3$. The amounts of dissolved oxygen

that were monitored throughout the test were not indicated. The pH values were 8 ± 0.5. The exposure concentrations ranged from 8,175 to 30,000 mg/l. Based on nominal concentrations of PGME, the 96-hour LC_{50} was determined to be 20,800 mg/l. According to the Directive 92/CEE, method C1 "acute toxicity of fish", a water temperature between 20 and 24°C is recommended for *Pimephales promelas*. Therefore, the test can be considered as valid but with restrictions.

Pearson (1986) studied the acute toxicity of PGME to *Oncorhynchus mykiss*. The test was carried out under semi-static conditions (daily renewal of the test water) at 18.5 ± 0.9°C. The test water was reconstituted freshwater prepared from fully demineralised water with a total hardness between 222 and 262 mg/l $CaCO_3$. Dissolved oxygen and pH were monitored throughout the test ranging from 7.8 to 9 mg/l and from 7.4 to 8.4, respectively. The exposure concentration was 1,000 mg/l. Based on this nominal concentration, the 96-hour LC_{50} was determined to be superior to 1,000 mg/l since no mortality was observed throughout the test.

The 96-hour LC_{50} (6,812 mg/l) reported for *Leuciscus idus* by Kirsch and Munk (1989) will be taken into account.

Long-term toxicity

No result from long-term test with fish is available.

3.2.1.1.2 Aquatic invertebrates

Acute toxicity

Acute toxicity studies of PGME to *Daphnia magna* are summarised in **Table 3.12**.

Table 3.12 Short term toxicity of PGME to aquatic invertebrates

Species	Method	Duration	Toxicity endpoint	Test validity	References
Daphnia magna	Directive 84/449/EEC C.2	48 hours	LC_{50} > 500 mg/l	2	Foerster, 1988
Daphnia magna	Other	48 hours	LC_{50} > 1,000 mg/l	2	Pearson, 1986
Daphnia magna	Other: ASTM	48 hours	LC_{50} = 23,300 mg/l	2	Bartlett et al., 1981

All the tests were performed under static conditions. And all the concentrations are based on nominal concentrations.

During the test performed by Foerster (1988), the water had a temperature between 18 and 20°C, a total hardness of 270 ± 50 mg/l $CaCO_3$, a pH between 7.7 and 8.3 and a dissolved oxygen concentration between 8.33 and 8.84 mg/l. *Daphnia*, less than 24 hours of age, were exposed to concentrations ranging from 62.5 to 500 mg/l. Based on these nominal concentrations, the 48-hour LC_{50} was determined to be superior to 500 mg/l since no immobility was found during the test.

During the test performed by Bartlett et al. (1981), the test water was taken from Lake Huron, Michigan with a total hardness of about 105 mg/l $CaCO_3$. The amounts of dissolved oxygen that were monitored throughout the test were not indicated. The pH values were 8 ± 0.5. *Daphnia* were exposed to the concentrations ranging from 1,412 to 50,000 mg/l. Based on these nominal concentrations, the 48-hour LC_{50} was determined to be 23,300 mg/l.

During the test performed by Pearson (1986), the test water was reconstituted freshwater prepared by dissolving a co-solvant in glass-distilled deionised water. During the test, the water had a temperature between 18 and 22°C, a total water hardness of 178 mg/l $CaCO_3$, a pH of 8.1 and a dissolved oxygen concentration ranging from 9 to 9.2 mg/l. *Daphnia*, less than 24 hours of age, were exposed to a concentration of 1,000 mg/l of PGME. Based on this nominal concentration, the 48-hour LC_{50} was determined to be superior to 1,000 mg/l since no immobility was observed throughout the test.

The 48-hour LC_{50} of 23,300 mg/l will be taken into account.

Long-term toxicity

No result from long-term test with invertebrates is available.

3.2.1.1.3 Algae

Acute toxicity

Acute toxicity studies of PGME to *Selenastrum capricornutum* are summarised in **Table 3.13**.

Table 3.13 Short term toxicity of PGME to algae

Species	Method	Duration	Toxicity endpoint	Test validity	References
Selenastrum capricornutum	Test method ET-11-1987-1	7 days	EC_{50} > 1,000 mg/l (biomass)	2	Dill and Milazzo, 1988
Selenastrum capricornutum	Other	96 hours	EC_{50} > 1,000 mg/l	2	Pearson, 1986

A 7-day acute toxicity test was performed on *Selenastrum capricornutum* by Dill and Milazzo (1988). The initial algal cell concentration was about 1,000 cells/ml. Temperature was maintained at 24 ± 2°C throughout the test. The pH values ranged from 7.4 to 7.6 and a continuous illumination of 4,304 ± 430 lux was provided. Inhibition was measured on (cells/ml) and on biomass (total cell volume/ml). Exposure concentrations ranged from 63 to 1,000 mg/l (nominal concentrations). A slight inhibition on cell count (7.1%) was observed after 7 days for all of the concentrations except for 500 mg/l. No significant inhibition was observed for biomass. Based on the nominal concentrations, the EC_{50} (biomass) was determined to be superior to 1,000 mg/l.

A 96-hour toxicity test was performed on *Selenastrum capricornutum* by Pearson (1986). The initial algal cell concentration was about 500 cells/ml. Temperature ranged from 22 to 26°C. The pH value ranged from 7.4 to 7.6 and a continuous illumination of about 3,000 lux was provided. PGME was added to the test flasks along with a co-solvant to give concentrations ranging from 1 to 1,000 mg/l. None of the concentrations tested caused more than 21% reduction in cell number compared to the mean cell number in the controls. Based on the nominal concentrations, the EC_{50} was determined to be superior to 1,000 mg/l.

The concentration values are nominal concentration that will be used in the determination of the PNEC for the aquatic compartment.

Long-term toxicity

No result from long-term test with algae is available.

3.2.1.1.4 Microorganisms

A respiration inhibition test (OECD Guide Line 209) was performed, applying GLP, by Klecka et al. (1985) on activated sludge obtained from a local municipal waste water treatment plant. 3,5-dichlorophenol was used as a reference compound. Test reaction mixtures (activated sludge and PGME) were incubated for 3 hours at ambient temperature (21°C) and at pH ranging from 7.4 to 8. Following the 3 hours period, the rate of oxygen consumption and the dissolved organic carbon were analysed. The inhibitory effect is expressed as a percentage of the mean of two control respiration rates.

Based on the nominal concentration, IC_{50} was determined in this study to be superior to 1,000 mg/L. The NOEC value is 1,000 mg/l.

3.2.1.1.5 Amphibians

No result from toxicity test with amphibians is available.

3.2.1.2 Calculation of Predicted No Effect Concentration (PNEC)

3.2.1.2.1 Water

Freshwater

Acute toxicity data for PGME for three trophic levels (fish, aquatic invertebrates, 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 TGD (EC, 2003), ecotoxicity data can be estimated (see **Table 3.14**).

Table 3.14 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 by Pearson (1986) 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.

Saltwater

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 by Pearson (1986). This gives a $PNEC_{saltwater}$ of 1 mg/l.

3.2.1.2.2 Sediment

Freshwater sediment

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}).

$PNEC_{sed} = (K_{susp\text{-}water}/RHO_{susp}) \cdot PNEC_{aqua} \cdot 1{,}000$

Where: $K_{susp\text{-}water}$ (partition coefficient suspended matter-water)

$= Fwater_{susp} + Fsolid_{susp} \cdot Kp_{susp} \cdot RHOsolid / 1{,}000 = 1.04\ m^3.m^{-3}$

$Fwater_{susp}$ (fraction water in suspended matter) $= 0.9\ m^3.m^{-3}$

$Fsolid_{susp}$ (fraction solids in suspended matter) $= 0.1\ m^3.m^{-3}$

Kp_{susp} (solid-water partition coefficient in suspended matter) $= 0.57\ l.kg^{-1}$

RHOsolid (density of the solid phase) $= 2{,}500\ kg.m^{-3}$

RHOsusp (bulk density of wet suspended matter) $= 1{,}150\ kg.m^{-3}$

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

Marine sediment

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.

3.2.1.2.3 Sewage Treatment Plant (STP)

A NOEC ≥ 1,000 mg/l for sludge was determined from the respiration inhibition test (Klecka et al., 1985). 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.

3.2.2 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.

$PNEC_{soil} = (K_{soil\text{-}water}/RHO_{soil}) \cdot PNEC_{aqua} \cdot 1{,}000$

Where: $K_{soil\text{-}water}$ (partition coefficient soil-water)

$= Fair_{soil} \cdot K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} \cdot Kp_{soil} \cdot RHOsolid / 1{,}000$

$= 0.371\ m^3.m^{-3}$

$K_{air\text{-}water}$ (partition coefficient air-water) $= 4.22 \cdot 10^{-5}$

$Fair_{soil}$ (fraction air in soil) $= 0.2\ m^3.m^{-3}$

$Fwater_{soil}$ (fraction water in soil) $= 0.2\ m^3.m^{-3}$

$Fsolid_{soil}$ (fraction solids in soil) $= 0.6\ m^3.m^{-3}$

Kp_{soil} (solid-water partition coefficient in soil) $= 0.114\ l.kg^{-1}$

RHOsolid (density of the solid phase) $= 2{,}500\ kg.m^{-3}$

RHOsoil (bulk density of wet soil) $= 1{,}700\ kg.m^{-3}$

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

3.2.3 Atmosphere

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

3.2.4 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

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.

3.3.1 Aquatic compartment (incl. sediment)

3.3.1.1 Freshwater compartment and STP

Table 3.15 presents the calculated PEC/PNEC ratios for the aquatic compartment (water and STP).

Table 3.15 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004)

End uses	RCR water (*)	RCR STP (*)
Production	0.0249	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	$5.98 \cdot 10^{-3}$ (F)	$5.53 \cdot 10^{-3}$ (F)
	0.0228 (P)	0.0224 (P)
	$4.57 \cdot 10^{-4}$ (PU)	$1.34 \cdot 10^{-7}$ (PU)
- Solvent based	0.0281 (F)	0.0276 (F)
	0.0228 (P)	0.0224 (P)
	$4.57 \cdot 10^{-4}$ (PU)	$1.79 \cdot 10^{-7}$ (PU)
Printing inks	$8.08 \cdot 10^{-3}$ (F)	$7.62 \cdot 10^{-3}$ (F)
	$6.63 \cdot 10^{-3}$ (P)	$6.18 \cdot 10^{-3}$ (P)
Detergents, cleaners	0.0322 (F)	0.0317 (F)
	$8.63 \cdot 10^{-3}$ (P)	$8.17 \cdot 10^{-3}$ (P)
Leather finishing agent	This use is already covered by the painting scenario (see Section 3.1.2.1.1)	
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)	$4.19 \cdot 10^{-3}$ (F)
	$6.54 \cdot 10^{-4}$ (PU)	$1.97 \cdot 10^{-4}$ (PU)

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

It can be noticed that no risk is expected for these compartments whatever end uses.

For some end uses, formulation and processing steps can be achieved at a same site (see **Table** 2.3). So, in order to characterise the total risk at such sites it is necessary to add the calculated

risks for each step. According to **Table 3.15** no risk is identified for all end uses where both formulation and processing are considered.

Conclusions to the risk assessment for the surface freshwater and STP

Conclusion (ii).

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).

3.3.1.2 Marine compartment

The Risk characterisation (RCR) for marine environment at the production stage is $5.11 \cdot 10^{-4}$. No risk is identified at this level.

For end-uses, no risk characterisation for the marine compartment is deemed necessary. Indeed, no specific exposure information is available for this environment and the level of conservatism used in the exposure assessment for freshwater is considered as sufficient for the protection of the marine compartment (see Section 3.1.2.1.2). Furthermore PGME is readily biodegradable and has a low potential for accumulation in biota. Consequently, this substance will not remain in the environment and secondary poisoning is not expected.

Based on the risk assessment performed for freshwater and on the lack of specific hazard identified for the marine environment, no risk is expected in the marine compartment.

Conclusions to the risk assessment for the seawater

Conclusion (ii).

This conclusion does neither apply to the use of PGME in oilfield chemicals nor to its use in oil-spill dispersants (see Section 3.1.2.1.3 and 3.1.2.1.4, respectively).

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.

Conclusions to the risk assessment for the terrestrial compartment

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

Conclusions to the risk assessment for secondary poisoning:

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 (see Section 3.1.2.1.3 and 3.1.2.1.4).

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).

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ABBREVIATIONS

ADI	Acceptable Daily Intake
AF	Assessment Factor
ASTM	American Society for Testing and Materials
ATP	Adaptation to Technical Progress
AUC	Area Under The Curve
B	Bioaccumulation
BBA	Biologische Bundesanstalt für Land- und Forstwirtschaft
BCF	Bioconcentration Factor
BMC	Benchmark Concentration
BMD	Benchmark Dose
BMF	Biomagnification Factor
BOD	Biochemical Oxygen Demand
bw	body weight / *Bw*, *bw*
C	Corrosive (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
CA	Chromosome Aberration
CA	Competent Authority
CAS	Chemical Abstract Services
CEC	Commission of the European Communities
CEN	European Standards Organisation / European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CMR	Carcinogenic, Mutagenic and toxic to Reproduction
CNS	Central Nervous System
COD	Chemical Oxygen Demand
CSTEE	Scientific Committee for Toxicity, Ecotoxicity and the Environment (DG SANCO)
CT_{50}	Clearance Time, elimination or depuration expressed as half-life
d.wt	dry weight / dw
dfi	daily food intake
DG	Directorate General
DIN	Deutsche Industrie Norm (German norm)
DNA	DeoxyriboNucleic Acid
DOC	Dissolved Organic Carbon
DT50	Degradation half-life or period required for 50 percent dissipation / degradation
DT90	Period required for 90 percent dissipation / degradation
E	Explosive (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
EASE	Estimation and Assessment of Substance Exposure Physico-chemical properties [Model]

EbC50	Effect Concentration measured as 50% reduction in biomass growth in algae tests
EC	European Communities
EC10	Effect Concentration measured as 10% effect
EC50	median Effect Concentration
ECB	European Chemicals Bureau
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECVAM	European Centre for the Validation of Alternative Methods
EDC	Endocrine Disrupting Chemical
EEC	European Economic Communities
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EN	European Norm
EPA	Environmental Protection Agency (USA)
ErC50	Effect Concentration measured as 50% reduction in growth rate in algae tests
ESD	Emission Scenario Document
EU	European Union
EUSES	European Union System for the Evaluation of Substances [software tool in support of the Technical Guidance Document on risk assessment]
F(+)	(Highly) flammable (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
FAO	Food and Agriculture Organisation of the United Nations
FELS	Fish Early Life Stage
foc	Organic carbon factor (compartment depending)
GLP	Good Laboratory Practice
HEDSET	EC/OECD Harmonised Electronic Data Set (for data collection of existing substances)
HELCOM	Helsinki Commission -Baltic Marine Environment Protection Commission
HPLC	High Pressure Liquid Chromatography
HPVC	High Production Volume Chemical (> 1000 tonnes/annum)
IARC	International Agency for Research on Cancer
IC	Industrial Category
IC50	median Immobilisation Concentration or median Inhibitory Concentration
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database (existing substances)
IUPAC	International Union for Pure and Applied Chemistry
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues

Koc	organic carbon normalised distribution coefficient
Kow	octanol/water partition coefficient
Kp	solids-water partition coefficient
L(E)C50	median Lethal (Effect) Concentration
LAEL	Lowest Adverse Effect Level
LC50	median Lethal Concentration
LD50	median Lethal Dose
LEV	Local Exhaust Ventilation
LLNA	Local Lymph Node Assay
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
LOED	Lowest Observed Effect Dose
LOEL	Lowest Observed Effect Level
MAC	Maximum Allowable Concentration
MATC	Maximum Acceptable Toxic Concentration
MC	Main Category
MITI	Ministry of International Trade and Industry, Japan
MOE	Margin of Exposure
MOS	Margin of Safety
MW	Molecular Weight
N	Dangerous for the environment (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC
NAEL	No Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NOEC	No Observed Effect Concentration
NTP	National Toxicology Program (USA)
O	Oxidising (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
OC	Organic Carbon content
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJ	Official Journal
OSPAR	Oslo and Paris Convention for the protection of the marine environment of the Northeast Atlantic
P	Persistent
PBT	Persistent, Bioaccumulative and Toxic
PBPK	Physiologically Based PharmacoKinetic modelling

PBTK	Physiologically Based ToxicoKinetic modelling
PEC	Predicted Environmental Concentration
pH	logarithm (to the base 10) (of the hydrogen ion concentration $\{H^+\}$
pKa	logarithm (to the base 10) of the acid dissociation constant
pKb	logarithm (to the base 10) of the base dissociation constant
PNEC	Predicted No Effect Concentration
POP	Persistent Organic Pollutant
PPE	Personal Protective Equipment
QSAR	(Quantitative) Structure-Activity Relationship
R phrases	Risk phrases according to Annex III of Directive 67/548/EEC
RAR	Risk Assessment Report
RC	Risk Characterisation
RfC	Reference Concentration
RfD	Reference Dose
RNA	RiboNucleic Acid
RPE	Respiratory Protective Equipment
RWC	Reasonable Worst-Case
S phrases	Safety phrases according to Annex IV of Directive 67/548/EEC
SAR	Structure-Activity Relationships
SBR	Standardised birth ratio
SCE	Sister Chromatic Exchange
SCHER	Scientific Committee on Health and Envionment Risks (DG SANCO)
SDS	Safety Data Sheet
SETAC	Society of Environmental Toxicology And Chemistry
SNIF	Summary Notification Interchange Format (new substances)
SSD	Species Sensitivity Distribution
STP	Sewage Treatment Plant
T(+)	(Very) Toxic (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
TDI	Tolerable Daily Intake
TG	Test Guideline
TGD	Technical Guidance Document
TNsG	Technical Notes for Guidance (for Biocides)
TNO	The Netherlands Organisation for Applied Scientific Research
ThOD	Theoritical Oxygen Demand
UC	Use Category
UDS	Unscheduled DNA Synthesis
UN	United Nations

UNEP	United Nations Environment Programme
US EPA	Environmental Protection Agency, USA
UV	Ultraviolet Region of Spectrum
UVCB	Unknown or Variable composition, Complex reaction products of Biological material
vB	very Bioaccumulative
VOC	Volatile Organic Compound
vP	very Persistent
vPvB	very Persistent and very Bioaccumulative
v/v	volume per volume ratio
w/w	weight per weight ratio
WHO	World Health Organisation
WWTP	Waste Water Treatment Plant
Xn	Harmful (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)
Xi	Irritant (Symbols and indications of danger for dangerous substances and preparations according to Annex II of Directive 67/548/EEC)

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

EUR 22474 EN **European Union Risk Assessment Report**
1-methoxypropan-2-ol (PGME) – Part I – Environment, Volume 66

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

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The report provides the comprehensive 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.

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