European Chemicals Bureau

Institute for Health and Consumer Protection

European Chemicals Bureau

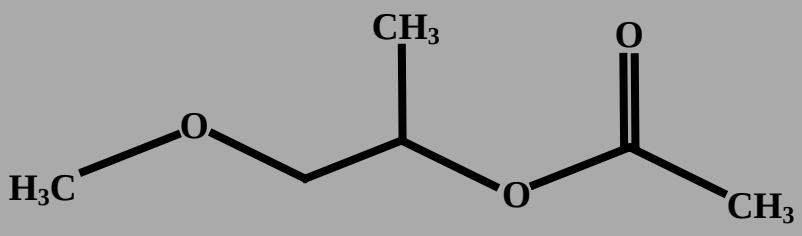
Existing Substances

European Union Risk Assessment Report

CAS No: 108-65-6

EINECS No: 203-603-9

2-methoxy-1-methylethyl acetate (PGMA)
Part I - environment



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European Union Risk Assessment Report
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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.

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Part I - Environment

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RISK ASSESSMENT

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2-METHOXY-1-METHYLETHYL ACETATE (PGMA)

Part I – Environment

CAS No: 108-65-6

EINECS No: 203-603-9

RISK ASSESSMENT

Final Report, 2006

France

The environmental risk assessment of 2-methoxy-1-methylethyl acetate (PGMA) 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:

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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]

OVERALL RESULTS OF THE RISK ASSESSMENT

CAS Number: 108-65-6
EINECS Number: 203-603-9
IUPAC Name: 2-methoxy-1-methylethyl acetate

Synonyms: 1-methoxy 2-acetoxy propane; 1-methoxy 2-propyl acetate; 1-methoxy-2-propanol acetate; 1-methoxy-2-propyl acetate; 2-acetoxy-1-methoxypropane; 2-propanol, 1-methoxy-, acetate; acetate de l'ether methylique de propylene glycol; acetate de 2-methoxy-1-methylethyle; Dowanol PMA glycol ether acetate; methoxy propyl acetate; propylene glycol methyl ether acetate; propylene glycol monomethyl ether acetate; PGMEA; PGMA

Environment

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 PGMA: 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 PGMA: 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 PGMA: 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 PGMA: production, formulation, processing and private use.

Human Health

(to be added later).

CONTENTS

1 GENERAL SUBSTANCE INFORMATION 3

1.1 IDENTIFICATION OF THE SUBSTANCE 3

1.2 PURITY/IMPURITIES, ADDITIVES 3

1.3 PHYSICO-CHEMICAL PROPERTIES 3
1.3.1 Melting point 3
1.3.2 Boiling point 4
1.3.3 Relative density 4
1.3.4 Vapour pressure 4
1.3.5 Surface tension 4
1.3.6 Water solubility 5
1.3.7 Henry's law constant 5
1.3.8 Partition coefficient octanol water 5
1.3.9 Other physical-chemical properties 6
1.3.9.1 Flash point 6
1.3.9.2 Autoflammability 6
1.3.10 Summary 6

1.4 CLASSIFICATION 7
1.4.1 Current classification 7
1.4.2 Proposed classification 7

2 GENERAL INFORMATION ON EXPOSURE 8

2.1 PRODUCTION 8
2.1.1 Production processes 8
2.1.2 Production capacity 8

2.2 USES 9
2.2.1 Introduction 9

3 ENVIRONMENT 11

3.1 ENVIRONMENTAL EXPOSURE 11
3.1.1 Environmental fate 11
3.1.1.1 Degradation in the environment 11
3.1.1.1.1 Atmospheric degradation 11
3.1.1.1.2 Aquatic degradation 11
3.1.1.1.3 Degradation in soil 12
3.1.1.1.4 Summary of environmental degradation 14
3.1.1.2 Distribution 14
3.1.1.2.1 Adsorption 14
3.1.1.2.2 Volatilisation 15
3.1.1.2.3 Distribution in wastewater treatment plants 15
3.1.1.3 Accumulation and metabolism 15
3.1.2 Aquatic compartment 15
3.1.2.1 Local exposure 16
3.1.2.1.1 Freshwater compartment 16
3.1.2.1.2 Marine compartment 17
3.1.2.2 Regional exposure 18
3.1.2.3 Continental exposure 18
3.1.3 Terrestrial compartment 18

3.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) - RESPONSE (EFFECT ASSESSMENT) 19

3.2.1 Aquatic compartment (incl. sediment) ... 19
3.2.1.1 Toxicity test results ... 19
3.2.1.1.1 Fish ... 19
3.2.1.1.2 Aquatic invertebrates ... 20
3.2.1.1.3 Algae ... 22
3.2.1.1.4 Microorganisms ... 22
3.2.1.1.5 Amphibians ... 22
3.2.1.2 Calculation of Predicted No Effect Concentration (PNEC) ... 23
3.2.1.2.1 Water ... 23
3.2.1.2.2 Sediment ... 23
3.2.1.2.3 Sewage Treatment Plant (STP) ... 24
3.2.2 Terrestrial compartment ... 24
3.2.3 Atmosphere ... 24
3.2.4 Secondary poisoning ... 25

3.3 RISK CHARACTERISATION ... 26
3.3.1 Aquatic compartment (incl. sediment) ... 26
3.3.2 Terrestrial compartment ... 27
3.3.3 Atmosphere ... 28
3.3.4 Secondary poisoning ... 28

4 HUMAN HEALTH ... 29

5 RESULTS ... 30

5.1 ENVIRONMENT ... 30

5.2 HUMAN HEALTH ... 30

6 REFERENCES ... 31

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

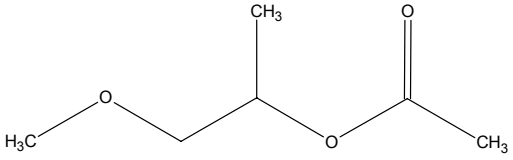
TABLES

Table 1.1 Summary of physico-chemical properties ... 6
Table 2.1 Overview of PGMA production and sales in Europe for years 2001 to 2003 (data provided by CEFIC, 2004) ... 8
Table 2.2 Main producers of PGMA ... 8
Table 2.3 Use of PGMA in the EU ... 9
Table 3.1 Biodegradation test results for PGMA ... 12
Table 3.2 Summary of the aerobic biodegradation of PGMA in soil ... 13
Table 3.3 Estimation of biodegradation rate constants in the different compartments ... 14
Table 3.4 Partition coefficients between different compartments ... 15
Table 3.5 Aquatic emission data from production sites of PGMA ... 16
Table 3.6 Local PEC_{water} and PEC_{STP} at the production stage ... 16
Table 3.7 Parameters used for the calculation of exposure concentration for paint industry ... 17
Table 3.8 Local PEC_{water} and PEC_{STP} for PGMA according to EUSES (EC, 2004) ... 17
Table 3.9 Regional PECs in air and water (calculations made by EUSES 2.0) ... 18
Table 3.10 Continental PECs in air and water (calculations made by EUSES 2.0) ... 18
Table 3.11 Short-term toxicity of PGMA to fish ... 19
Table 3.12 Short-term toxicity of PGMA to aquatic invertebrates ... 21
Table 3.13 Long-term toxicity of PGMA to aquatic invertebrates ... 21
Table 3.14 Short-term toxicity of PGMA to algae ... 22
Table 3.15 Risk characterisation for aquatic compartment for each production site ... 26
Table 3.16 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004) ... 26

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 108-65-6
EINECS Number: 203-603-9
IUPAC Name: 2-methoxy-1-methylethyl acetate
Molecular formula: $C_6H_{12}O_3$
Structural formula:



Molecular weight: 132.16 $g.mol^{-1}$
Synonyms: 1-methoxy 2-acetoxy propane; 1-methoxy 2-propyl acetate; 1-methoxy-2-propanol acetate; 1-methoxy-2-propyl acetate; 2-acetoxy-1-methoxypropane; 2-propanol, 1-methoxy-, acetate; acetate de l'ether methylique de propylene glycol; acetate de 2-methoxy-1-methylethyle; Dowanol PMA glycol ether acetate; methoxy propyl acetate; propylene glycol methyl ether acetate; propylene glycol monomethyl ether acetate; PGMEA; PGMA

In the risk assessment, the name PGMA will be used for the substance, as this is the most common name.

1.2 PURITY/IMPURITIES, ADDITIVES

The commercially supplied product is usually a mixture of substances: 2-methoxy-1-methylethyl acetate (PGMA, CAS n°108-65-6) and 2-methoxypropyl acetate (CAS n°70657-70-4).

PGMA is the main compound, totalising more than 99.5% of the product with less than 0.5% of 2-methoxypropyl acetate, considered as an impurity.

No additive is contained in the marketed product.

1.3 PHYSICO-CHEMICAL PROPERTIES

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

1.3.1 Melting point

The melting point of PGMA ranges from –88°C to < -67°C (BP, 2000; DOW, 2001). A producer used as ASTM D-97 method reporting a result of –65°C (SHELL, 2000). The test reports are not available.

A median value of -76°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 PGMA ranges from 140 to 146°C (BP, 2000; DOW, 2001; LYONDELL, 1999). A producer used an ASTM D-1078 method reporting values ranging from 143 to 149°C (SHELL, 2000). And another producer used a DIN 53 171 method reporting values ranging from 145 to 147°C (BASF, 2001). However, the test reports are not available.

A median value of 146°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 PGMA ranges from 0.964 to 0.97 g/cm^3 at 20°C (DOW, 2001; SHELL, 2000). At 25°C, the density of PGMA is 0.96 g/cm^3 (LYONDELL, 1999). A producer used a DIN-51 757 method reporting values ranging from 0.965 to 0.97 g/cm^3 at 20°C (BASF, 2001). However, the test reports are not available.

A median value of 0.967 g/cm^3 has been calculated at 20°C using the above data. This value will be used for the risk assessment.

1.3.4 Vapour pressure

The vapour pressure of PGMA ranges from 3.37 to 4.9 hPa at 20°C (BASF, 2001; BP, 2000; DOW, 2001; SHELL, 2000). At 25°C, the value of 5.07 hPa is reported (LYONDELL, 1999). No test report is available.

A median value of 4.2 hPa at 20°C has been calculated using the above data. At 25°C, the value of 5.93 hPa has been calculated. This last value will be used for the risk assessment.

1.3.5 Surface tension

A surface tension of 30.4 mN/m is reported at 20°C by one producer. The concentration of the substance in water was unknown (BP, 1998).

Surface active properties can be assumed for glycol ethers. The values reported in the literature for PGMA tend to indicate that this substance is a surface-active reagent even if no indication has been found about the concentration of the substance during the test quoted above. 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 PGMA. 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 (PGMA is highly miscible in water, hydrosphere is the preferential target of PGMA in the environment: 90%, see Section 3.1.1.2), surface active properties of PGMA will not be considered in this assessment.

1.3.6 Water solubility

PGMA is very soluble in water.

Chemicals Evaluation and Research Institute (1998) measured the solubility in water using flask method (OECD GL 105). The test report is not available, but it was validated by the Japanese authorities within the OECD SIDS activities. A value above 100 g/l was measured at 25°C. This value will be used in the risk assessment.

1.3.7 Henry's law constant

Staples and Davies (2002) calculated Henry's law constant from aqueous solubility and vapour pressure using a solubility of 160 g/l and a vapour pressure of 517 Pa. Value was 0.43 $Pa.m^3/mol$.

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 0.059 $Pa.m^3/mol$ (group method) to 0.367 $Pa.m^3/mol$ (bond method).

The Henry's law constant can be calculated using selected values of this report. The resulting value is 0.78 $Pa.m^3/mol$.

According to these values, PGMA is stable in water.

An average value of 0.41 $Pa.m^3/mol$ 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 PGMA.

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

The log Pow values of PGMA determined by HPLC and the fragment-addition method were respectively 1.2 and < 1.

Gonsior (1990) also estimated a log P_{OW} value using the Pomona-Med Chem Structural fragment method. A value of 0.56 was calculated.

Using a QSAR (US EPA and Syracuse Research Corporation, 2001: KOWWIN v1.66), a log P_{OW} of 0.52 was estimated.

BASF (2001) reported a partition coefficient octanol water for PGMA of 0.43. No test report is available.

Chemicals Evaluation and Research Institute (1998) measured the partition coefficient between octanol and water using the flask-shaking method (OECD GL 107). The test report is not available, but it was validated by the Japanese authorities within the OECD SIDS activities. A value of 0.36 at 25°C was measured.

The partition coefficient octanol water of 0.36 will be chosen for the risk assessment as it was obtained by an experimental method.

1.3.9 Other physical-chemical properties

1.3.9.1 Flash point

The flash point of PGMA ranges from 42°C to 50°C (BASF, 2001; BP, 2000; DOW, 2001; LYONDELL, 1999; SHELL, 2000). The test reports are not available.

An average value of 45.8°C has been calculated using the above data. This value will be used for the risk assessment.

1.3.9.2 Autoflammability

Decomposition of PGMA starts at temperature ranging from 272°C to 354°C (BASF, 2001; BP, 2000; DOW, 2001; LYONDELL, 1999; SHELL, 2000). The test reports are not available.

An average value of 317.8°C was calculated using the above data. This value will be used for the risk assessment.

1.3.10 Summary

Table 1.1 Summary of physico-chemical properties

Property	Value
Physical state	Liquid
Melting point	-76°C
Boiling point	146°C
Relative density	0.967 at 20°C
Vapour pressure	5.93 hPa at 25°C

Table 1.1 continued overleaf

Table 1.1 continued Summary of physico-chemical properties

Property	Value
Water solubility	100 g/l at 25°C
Partition coefficient n-octanol/water (log value)	0.36
Flash point	45.8°C
Autoflammability	317.8°C
Henry's constant	0.41 Pa.m^3/mol

1.4 CLASSIFICATION

1.4.1 Current classification

PGMA 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, PGMA is not classified as dangerous for the environment.

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION

2.1.1 Production processes

It all takes place in fixed bed ion-exchange reactors connected with a dedicated distillation column with a continuous recycle stream of the raw materials. The synthesis of PGMA occurs by reaction of 1-methoxypropan-2-ol with acetic acid in a closed system.

Main producers have continuous production plants (24 hours per day, 7 days a week) with continuous feed and outlet.

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 PGMA production and sales in Europe for years 2001 to 2003 (data provided by CEFIC, 2004)

In tonnes	2001	2002	2003	Figures retained
Production	71,200	84,300	78,000	78,000
Imports	0	0	0	0
Exports	2,500	19,500	19,500	14,800
Net into stock	0	800	-2,400	-
Sales in EU	68,700	64,000	61,500	63,200
Total use in EU	**68,700**	**64,000**	**61,500**	**63,200**

PGMA is currently manufactured with volumes exceeding 1,000 tonnes/year by three producers in the EU (see **Table 2.2**).

Table 2.2 Main producers of PGMA

Company	Localisation
BASF	Ludwigshafen (Germany)
BP	Lavera (France)
Haltermann	Kallo (Belgium)

From the **Table 2.2**, it appears that some production sites are located in the same area. Consequently the locations of both German site and the Belgian one have been checked so as to establish whether they could pertain to the same region (TGD definition EC, 2003). Distances between Kallo and Ludwigshafen are > 200 km. So, in the regional assessment, these sites will not be considered in a same region.

2.2 USES

2.2.1 Introduction

The industrial and use categories of PGMA are summarised in **Table 2.3**. PGMA 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 63,200 tonnes. 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.

Moreover, some uses have been reported in the past that seem to no longer exist or errors could have occurred when allocating volumes to end-uses. For some of these uses, the percentage of total use has been set at 0 since no information has confirmed that PGMA was still used in this sector. For some other uses figures reported does not seem to indicate a real annual use of the substance since stockpiles could be made during several years without using the product.

Table 2.3 Use of PGMA 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
Paints and coating*	Formulation Processing (90%) Private use (10%)	14: Paints, lacquers and varnishes	48: Solvent	47,135	56,000	54,000	55,000	87%
Electronic industry	Processing	4: Electrical/electronic industry	48: Solvent	9,851	3,000	2,300	2,600	4.1%
Chemical industry: chemicals used in synthesis	Processing	3: chemicals used in synthesis	33: Intermediate	5,994	2,500	2,200	2,500	3.9%
Printing inks*	Formulation Processing	12: pulp, paper and board industry	48: Solvent	4,994	1,300	1,600	1,500	2.4%

Table 2.3 continued overleaf

Table 2.3 continued Use of PGMA 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
Metal cleaning*	Formulation Processing	6: Public domain	48: Solvent	0	1,000	900	1,000	1.6%
Detergents, cleaners	Formulation Private/public use	5: Personal/domestic 6: Public domain	48: Solvent	616	0	300	400	0.6%
Adhesive	Private use	5: Personal/domestic	48: Solvent	68	200	200	200	0.3%
Agriculture	Processing	1: agricultural industry	48: Solvent	68	0	0	0	0%
Total				**68,726**	**64,000**	**61,500**	**63,200**	**~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 coatings 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

A degradation rate constant of $1.2 \cdot 10^{-11}$ $cm^3.molecule^{-1}.s^{-1}$ was calculated using a QSAR. A half life of 10.8 hours was estimated (US EPA and Syracuse Research Corporation, 2001: AOPWIN v1.90).

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 calculated by QSAR method. The average OH-radicals concentration over 24 hours in Western Europe is assumed to be $5 \cdot 10^5$ molecules.cm^{-3}. Therefore, $k_{deg\text{-}air}$ = 0.5 d^{-1}. This value will be used in the risk assessment.

3.1.1.1.2 Aquatic degradation

Hydrolyse

Hydrolyse of PGMA as a function of pH (4, 7 and 9) was performed according to the OECD GuideLine 111 by Chemicals Evaluation and Research Institute (1998). The test report is not available, but it was validated by the Japanese authorities within the OECD SIDS activities. No hydrolyse occurred in 5 days at 50°C at pH 4 and 7. At pH 9, hydrolyse rates were determined at 60, 70 and 80°C, and it was extrapoled to 25°C using the Arrhenius relationship. The calculated rate constant was $3.57 \cdot 10^{-3}$. A half life of 8.1 days can be calculated at 25°C and at pH 9. The breakdown products were not studied. At pH 4 and 7, PGMA is stable.

Aerobic biodegradation

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

Table 3.1 Biodegradation test results for PGMA

Inoculum	PGMA concentration	Test	Results	10 Day inhibition	Microbial inhibition	Reliability	Reference
Activated sludge	76.4 mg/l	OECD GL 301F	90% after 28 days	Respected	Not tested	1	Goodwin and West, 1998
Activated sludge	73 mg/l	OECD GL 301E	70% after 28 days	Not respected	Not tested	2	Handley and Mead, 1994
Activated sludge, adapted	3.75-15 mg C/l	Other	70.5-93.4% after 43 days	No data	No tested	2	Wu et al., 1996
Industrial sewage	785 mg/l	OECD GL 302B	90% after 8 days		Tested	2	Pagga and Haid, 1985

The manometric respirometry test (OECD GL 301F) was performed by Goodwin and West (1998). The time required to achieve 10% degradation of PGMA was 1.3 days, while the average extent of biodegradation at the end of the 10 day-window was 83%. An abiotic control was prepared by adding PGMA in chemically-sterilised mineral medium (formaldehyde). This abiotic control was used to verify the lack of O_2 consumption and/or CO_2 evolution in absence of biological activity. The result showed no net O_2 consumption or CO_2 production over the entire duration of the test. Finally, biodegradation of benzoate was 107% after 28 days. Therefore, PGMA can be considered as readily biodegradable.

In the OECD GL 301E (Closed Bottle Test) test performed by Handley and Mead (1994), an abiotic control was included. The results of the abiotic control showed a 31% loss of DOC after 28 days. According to the authors, this loss is considered to be due to adsorption of PGMA to the glassware and/or the cellular material present from the poisoned inoculum. Therefore the loss of DOC in the other test vessels cannot be attributed to microbial degradation alone. The degradation of 70% reported was obtained after correction taking into account the loss observed in the abiotic control. The 10-day window criteria is not met.

The Zahn and Wellens test (OECD GL 302B) performed by Pagga and Haid (1985) showed that PGMA is inherently biodegradable. It was considered valid with restrictions because industrial sewage was used as inoculum. In industrial sewages, adapted microbial populations are more likely to be present than in domestic sewages.

Wu et al. (1996) performed a biodegradation test. This test was not conducted according to the standard OECD Guide Line. After 45 days, the biodegradation ranges from 70.5% to 93.4% according to the substance concentration. Otherwise, sludge used as inoculum is an acclimated sludge. Therefore, this test is considered to be valid with restriction.

Based on the result of Goodwin and West (1998), PGMA is considered to be readily biodegradable. The other results support this conclusion.

3.1.1.1.3 Degradation in soil

Aerobic biodegradation

Studies were carried out on the degradation of PGMA 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 approximately 15 cm below the surface following removal of vegetation 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 PGMA (labelled on the methoxy substituent) was obtained with a radiochemical purity superior to 98%.

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 PGMA at nominal concentration ranging from 2 to 20 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 PGMA 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 PGMA in soil

Soil	Initial concentration (ppm) Nominal/Measured	Time for 50% removal (days)	Maximum $^{14}CO_2$ (%)
Londo Sandy Loam	2/2.5	< 1	57
	20/20	< 1	46
Tappan Sandy Loam	20/20	< 1	-[a]
Sand	20/20	< 1	-

a) No data

Complete degradation of PGMA occurred in less than 1 day. The substantial degradation of the parent compound had occurred during the several hours required to prepare and analyse the day 0 samples. The intermediate product, identified as ^{14}C-PGME, rapidly degraded to $^{14}CO_2$. The maximum amount of $^{14}CO_2$ produced was 57% of the initially applied radioactivity.

Degradation of PGMA will depend on the nature and the amount of the microorganisms. Similar results were obtained at concentrations of 2 and 20 ppm demonstrating that PGMA concentration is not a factor influencing biodegradation rates.

Anaerobic biodegradation

Studies were carried out on the degradation of PGMA by soil microorganisms under anaerobic condition (Gonsior and West, 1991, 1995).

PGMA rapidly degraded to PGME in anaerobic microcosms. Thereafter, no degradation of PGME was apparent after two months. $^{14}CO_2$ detected in the microcosms was less than 3% of the initially applied radioactivity.

3.1.1.1.4 Summary of environmental degradation

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

Table 3.3 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 PGMA in the different environmental compartments:

- Molecular weight: 132.16 g/mol
- Temperature: 20°C
- Vapour pressure: 430 Pa
- Log Pow: 0.36
- Melting point: -76.5°C

The predicted distribution of PGMA is:

- 10.4% to air
- 0.079% to soil
- 89.5% 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 QSAR relationship recommended in the TGD (EC, 2003) for non-hydrophobic chemicals, a Koc value of 15.8 l/kg (log Koc = 1.2) is calculated.

The solid-water partition coefficient in each compartment (soil, sediment, suspended matter) can be calculated from the Koc value using the default content of organic carbon in each compartment proposed in the TGD. The results are presented in **Table 3.4**.

Table 3.4 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} = 0.316 l/kg
Sediment	0.05 kg/kg	Kp_{sed} = 0.79 l/kg
Suspended matter	0.1 kg/kg	Kp_{susp} = 1.58 l/kg

3.1.1.2.2 Volatilisation

Based on the Henry's law constant of 0.41 $Pa.m^3.mol^{-1}$, the air-water partitioning coefficient ($K_{air\text{-}water}$) can be calculated. A $K_{air\text{-}water}$ of $1.73 \cdot 10^{-4}$ indicates that volatilisation of PGMA 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 = 0.36
- Log H = log 0.41 = -0.39

The results of the model leads to 87.1% of the substance degraded in the STEP and 12.6% released to surface water. There is no adsorption to sludge (0.15%) and no release to air (0.15%).

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, PGMA has a low potential of 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 compartments 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 data provided by the industry. The data for each site are given in **Table 3.5**.

Table 3.5 Aquatic emission data from production sites of PGMA

Site	Emission in water
1	Reference year: 2000 Release to water: 217.5* kg/day in wastewater (365* days/year). Flow of STP = 5* m^3/s ; 10th percentile of receiving water flow = 734* m^3/s ; dilution in receiving water = 147*
2	Reference years: 2002 Release to wastewater treatment plant: 9.89* kg/day (91 days of production). Before discharge to receiving waters, the effluent undergoes a dilution by a factor of 100 (mixing with seawater). Receiving water is the sea. The real dilution for marine environment is unknown. The releases of PGMA occur in a region where the tidal influences are really low. For those particular seas it is proposed in the TGD to use only a dilution factor of 10 instead of 100. Flow of STP = 7,000* m^3/day.
3	Reference year: 2000 Release to water: 10* kg/day in STP influent (365* days/year). Flow of STP = 449* m^3/j; dilution in receiving water = 40 (default).

* Original data provided by industry or calculated with original data. Other one is calculating using default TGD values

As there are only three PGMA production sites in Europe, the regional production will not be set at 10% of total PGMA production (TGD default) but at the maximum volume produced at one site. The PECs for each production site have been calculated using TGD method (EC, 2003) and the results are shown in **Table 3.6**.

Table 3.6 Local PEC_{water} and PEC_{STP} at the production stage

Site	PEC_{STP}	PEC_{water}
1	63.4 µg/l	1.84µg/l
2	178 µg/l	-*
3	2.8 mg/l	71.5 µg/l

* See Section 3.1.2.1.2

All uses listed in **Table 2.3** are taken into account in this risk assessment. For the category "paints and coating", two sub-categories are defined: water-borne paints and solvent-borne paints. According to a survey performed by CEPE (2002), among the paints which contain PGMA, 5% are water-borne paints and 95% are solvent-borne paints. Moreover, the same survey shows that the fraction of PGMA in water-borne paints goes up to 5% and solvent-borne paints may contain up to 53% PGMA.

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 3.7** will be used.

Table 3.7 Parameters used for the calculation of exposure concentration for paint industry

End uses: Paints and coating	Percentage of PGMA in formulation	Percentage of total paint use
Water-borne paints	10%	10%
Solvent-borne paints	70%	100%

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

The **Table 3.8** gives the PECs for the aquatic compartment.

Table 3.8 Local PEC_{water} and PEC_{STP} for PGMA according to EUSES (EC, 2004)

End uses	PEC_{water} mg/l (*)	PEC_{STP} mg/l (*)
Paints and coating:		
- Water based	0.186 (F)	1.85 (F)
	0.113 (P)	1.12 (P)
	$1.41 \cdot 10^{-3}$ (PU)	$6.72 \cdot 10^{-6}$ (PU)
- Solvent based	0.278 (F)	2.77 (F)
	0.229 (P)	2.28 (P)
	$1.41 \cdot 10^{-3}$ (PU)	$1.82 \cdot 10^{-5}$ (PU)
Electronic industry	0.0798 (P)	0.784 (P)
Chemical industry: chemicals used in synthesis**	0.0172 (P)	0.633 (P)
Printing inks	0.065 (F)	0.637 (F)
	0.0168 (P)	0.154 (P)
Metal cleaning	0.0438 (F)	0.424 (F)
	0.0125 (P)	0.111 (P)
Detergents, cleaners	0.0173 (F)	0.159 (F)
	$5.58 \cdot 10^{-3}$ (P)	0.0417 (P)
Adhesive	$1.8 \cdot 10^{-3}$ (PU)	$3.92 \cdot 10^{-3}$ (PU)

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

** For this use, the effluent flow rate for the STP has been set at 10,000 m^3/day and the dilution factor at 40 (according to the specific emission scenario of the TGD for IC 3)

3.1.2.1.2 Marine compartment

The releases of one site of production (Site 2) are directly emitted into the marine environment. PECs for the marine compartment are estimated using default scenario suggested by the TGD as proposed for the other environmental compartment. Thus, $PEClocal_{seawater} = 0.323$ µg/l.

No specific element is available to define specific exposure scenarios for PGMA 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.

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	$2.49 \cdot 10^{-4}$ mg/m³
Water	$1.41 \cdot 10^{-3}$ mg/l
Sediment	$1.44 \cdot 10^{-3}$ mg/kg (WWT)
Seawater	$1.45 \cdot 10^{-4}$ mg/l
Marine sediment	$1.5 \cdot 10^{-4}$ 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	$5.38 \cdot 10^{-5}$ mg/m³
Water	$3.36 \cdot 10^{-4}$ mg/l
Sediment	$3.43 \cdot 10^{-6}$ mg/kg (WWT)
Seawater	$1.99 \cdot 10^{-6}$ mg/l
Marine sediment	$2.05 \cdot 10^{-6}$ mg/kg (WWT)

3.1.3 Terrestrial compartment

According to the adsorption coefficient (log Koc = 1.2), the substance can be considered as mobile in soils and will not be adsorbed to sludge in STP. Besides, the PGMA 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)

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 PGMA to fish are summarised in **Table 3.11**.

Table 3.11 Short-term toxicity of PGMA to fish

Species	Method	S/SS/F[a]	M/N[b]	Duration	Toxicity endpoint	Validity	References
Oryzias latipes	OECD GL 203	SS	M	96 hours	LC_{50} > 100 mg/l	1	Environment Agency of Japan, 1998
Oryzias latipes	OECD GL 204	F	M	14 days	NOEC = 47.5 mg/l LC_{50} = 63.5 mg/l	1	Environment Agency of Japan, 1998
Pimephales promelas	Other	S	N	96 hours	LC_{50} = 161 mg/l	2	Batchelder and Milazzo, 1980
Oncorhynchus mykiss	OECD GL 203	S	N	96 hours	100 < LC_{50} < 180 mg/l LC_{50} = 134 mg/l[c] NOEC = 100 mg/l	2	Gelbke and Munk, 1987
Oncorhynchus mykiss	Other: similar to the OECD GL 203	S	N	96 hours	LC_{50} = 130 mg/l	2	Pearson, 1986

a) The test was performed with a static (S), semi-static (SS) or flow though (F) system.
b) The concentrations are nominal (N) or measured (M)
c) Geometric mean

The Environment Agency of Japan (1998) studied the acute toxicity of PGMA to *Oryzias latipes* under semi-static conditions (daily renewal of the test water) at 24 ± 2°C during 96 hours. The test water was dechlorinated tap water with a total hardness of 25 mg/l $CaCO_3$. The amounts of dissolved oxygen that were monitored throughout the test ranged from 5.6 to 9.1. The pH values ranged from 7.6 to 7. The exposure concentrations ranged from 10 to 100 mg/l and were measured by gas chromatography. The loss of the substance was less than 20%. Based on the nominal concentrations, the 96-hour LC_{50} was determined to be superior to 100 mg/l.

The Environment Agency of Japan (1998) studied also the acute toxicity of PGMA to *Oryzias latipes* using flow-though conditions during 14 days. The experimental conditions were almost the same as the semi-static test. The exposure concentrations ranged from 40 to 100 mg/l and were measured by gas chromatography. Based on the geometric mean of the measured concentrations, the 14-day LC_{50} was determined to be 63.5 mg/l. The no observed effect

concentration (NOEC) was determined to be 47.5 mg/l. The NOEC cannot be considered as a long term result and will only be used as supporting information.

The test reports from the Environment Agency of Japan (1998) are not available. Yet, all the data were validated by the Japanese authorities within the OECD SIDS program and will be taken into account for the determination of the PNEC for the aquatic compartment.

Batchelder and Milazzo (1980) studied the acute toxicity of PGMA to *Pimephales promelas.* The test was carried out under static conditions at 12 ± 1°C. The test water was taken from Lake Huron (Michigan). A rough range-finding test set between 1 and 10,000 mg/l indicated the proper range was between 100 and 1,000 mg/l. The definitive test was set with nine concentrations from 97 to 973 mg/l. Exposure lasted for 96 hours, with observations made every 24 hours. A 16-hour light/8-hour dark photoperiod was maintained. There is no information on the evolution of the concentration in the medium (no measured concentrations) during the test. Based on the nominal concentrations, the 96-hour LC_{50} was 161 mg/l. Based on the OECD Guide Line 203 on "acute toxicity of fish", a water temperature between 21 to 25°C is recommended for *Pimephales promelas*. Therefore, this test will not be taken into account in the risk assessment.

Gelbke and Munk (1987) studied the acute toxicity of PGMA to *Oncorhynchus mykiss.* The test was carried out under static conditions at 12 ± 1°C. The water used for the test was reconstituted freshwater prepared from fully demineralised water with a total hardness of about 250 mg/l $CaCO_3$. The amounts of dissolved oxygen that were monitored throughout the test ranged from 10 to 11.6 mg/l. The pH values ranged from 7.6 to 7.9. The exposure concentrations ranged from 100 to 1,000 mg/l. Based on the nominal concentrations of PGMA, the 96 h-LC_0 was determined to be 100 mg/l. The 96-hour LC_{100} was determined to be 180 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 134 mg/l was calculated. The no observed effect concentration (NOEC) was determined to be 100 mg/l.

Pearson (1986) studied the acute toxicity of PGMA to *Oncorhynchus mykiss*. The test was carried out under static conditions at a temperature ranging from 17.5°C to 18.4°C. The interval of water temperature used during the test is not really adapted to the species. The temperature recommended by OECD Guide Line 203 is of 13 to 17°C. However, the difference is small and due to the low toxicity of PGMA to fish the results of this test will be taken into account. The test water was reconstituted freshwater prepared from fully demineralised water with a total hardness between 220 and 256 mg/l $CaCO_3$. Dissolved oxygen and pH were monitored throughout the test ranging from 9.4 to 10.2 mg/l and from 8.2 to 8.5 respectively. The exposure concentrations ranged from 100 to 1,000 mg/l. Based on these nominal concentrations, the 96-hour LC_{50} was determined to be 130 mg/l.

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 PGMA to *Daphnia magna* are summarised in **Table 3.12**.

Table 3.12 Short-term toxicity of PGMA to aquatic invertebrates

Species	Method	S/SS	Duration	Toxicity endpoint	Validity	References
Daphnia magna	Other	S	48 hours	EC_{50} = 380 mg/l	2	Pearson, 1986
Daphnia magna	Other: guideline for testing chemicals (EPA, 1975)	SS	48 hours	EC_{50} > 500 mg/l	2	BASF, 1987
Daphnia magna	Other	S	48 hours	EC_{50} = 408 mg/l	2	Batchelder and Milazzo, 1980

Pearson (1986) studied the acute toxicity of PGMA to the *Daphnia magna*. This test was carried out under static conditions. 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 to 22°C, a total water hardness of 164 mg/L $CaCO_3$, a pH ranging from 8.2 to 8.4 and a dissolved oxygen concentration ranging from 9 to 9.2 mg/. *Daphnia*, less then 24 hours in age, were exposed to concentrations ranging from 5 to 1,000 mg/l of PGMA. Based on these nominal concentrations, the 48-hour LC_{50} was determined to be 380 mg/l.

BASF (1987) carried out a 48 hour acute test under semi-static conditions. The test water was dechlorinated tap water with a total hardness of 242 mg/L $CaCO_3$. During the test, the water had a temperature between 18 and 20°C, a pH ranging from 7.7 to 8.3 and a dissolved oxygen concentration ranging from 7.9 to 8.6 mg/l. *Daphnia*, less then 24 hours in age, were exposed to a concentration of 500 mg/l of PGMA. Based on this nominal concentration, the 48-hour LC_{50} was determined to be superior to 500 mg/l as no immobility was observed.

Batchelder and Milazzo (1980) studied the acute toxicity of PGMA to *Daphnia magna*. The test was carried out under static conditions at 20 ± 1°C. The test water was taken from Lake Huron (Michigan). A rough range-finding test was made, and the 48-hour LC_{50} was indicated to be between 100 and 1,000 mg/l. The definitive test consisted of exposing *Daphnia* to concentrations of PGMA ranging from 70 to 2,500 mg/l. There is no information on the evolution of the concentration in the medium (no measured concentrations) during the test. Based on these nominal concentrations, the 48-hour LC_{50} was determined to be 408 mg/l.

Long-term toxicity

Chronic toxicity value of PGMA to *Daphnia magna* is summarised in **Table 3.13**.

Table 3.13 Long-term toxicity of PGMA to aquatic invertebrates

Species	Method	Duration	Toxicity endpoint	Validity	References
Daphnia magna	OECD GL 202, part 2	21 days	NOEC ≥ 100 mg/l EC_{50} > 100 mg/l	1	Environment Agency of Japan, 1998

The Environment Agency of Japan (1998) carried out a chronic toxicity test under semi-static conditions (renewal: 3 times a week) during 21 days. The test water was dechlorinated tap water with a total hardness ranging from 236 to 251 mg/L $CaCO_3$. The amounts of dissolved oxygen that were monitored throughout the test ranged from 7.4 to 8.6 mg/l. The pH values ranged from 7.2 to 7.8. Temperature ranged from 19.4 to 20.8°C. The exposure concentration was 100 mg/l and was measured by gas chromatography. The measured concentrations were 88.6 to 99.9% of the nominal concentration. Based on the nominal concentrations, the 21-day LC_{50} was determined to be superior to 100 mg/l. The no observed effect concentration (NOEC) was determined to be ≥ 100 mg/l.

3.2.1.1.3 Algae

Toxicity studies of PGMA to *Selenastrum capricornutum* are summarised in **Table 3.14**.

Table 3.14 Short-term toxicity of PGMA to algae

Species	Method	Duration	Toxicity endpoint	Validity	References
Selenastrum capricornutum	OECD GL 201	72 hours	EC_{50} > 1,000 mg/l NOEC ≥ 1,000 mg/l	1	Environment Agency of Japan, 1998
Selenastrum capricornutum	other	96 hours	EC_{50} > 1,000 mg/l	2	Pearson, 1986

A 72 hour acute toxicity test was performed on *Selenastrum capricornutum* by the Environment Agency of Japan (1998). The initial algal cell concentration was about $1 \cdot 10^4$ cells/ml. Temperature was 23 ± 2°C. The pH values ranged from 7.4 to 7.6 and a continuous illumination ranging from 4,000 to 5,000 lux was provided. The exposure concentrations ranged from 95 to 1,000 mg/l and were measured during the test (the loss of the substance is less than 20%). Based on the nominal concentrations, the LC_{50} was determined to be superior to 1,000 mg/l since no inhibition of growth was observed. The no observed effect concentration (NOEC) was determined to be ≥ 1,000 mg/l.

The test report from the Environment Agency of Japan (1998) is not available. Yet, all the data were validated by the Japanese authorities within the OECD SIDS program and will be taken into account for the determination of the PNEC for the aquatic compartment.

A 96-hour acute 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 values ranged from 7.4 to 7.6 and a continuous illumination of about 3,000 lux was provided. PGMA 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 a 10% reduction in cell number compared to the mean cell number in the controls. Based on the nominal concentrations, the 96-hour EC_{50} was determined to be superior to 1,000 mg/l since no inhibition of growth was observed.

3.2.1.1.4 Microorganisms

No result from toxicity with microorganisms is available.

3.2.1.1.5 Amphibians

No result from toxicity with amphibians is available.

3.2.1.2 Calculation of Predicted No Effect Concentration (PNEC)

3.2.1.2.1 Water

Freshwater

There are acute toxicity data for PGMA on the three trophic levels (fish, aquatic invertebrate and algae). These data show that the most sensitive species seems to be the fish (14-day LC_{50} = 63.5 mg/l).

Chronic data are only available for aquatic invertebrates and algae. As the acute data on fish is lower than the chronic data on algae and invertebrates (the lowest chronic data being NOEC *Daphnia* 21 days ≥ 100 mg/l), an assessment factor of 100 will be used to the acute result on fish to derive the PNEC (instead of a factor of 50 on the lowest NOEC value). Indeed, according to the TGD (2003), in cases where the acutely most sensitive species has an $L(E)C_{50}$ value (here 63.5 mg/L) lower than the lowest NOEC value (here, 100 mg/L), the PNEC may be derived by using an assessment factor of 100 to the lowest $L(E)C_{50}$ of the short-term tests.

So the $PNEC_{aqua}$ value is 0.635 mg/l

Saltwater:

Only toxicity data on freshwater organisms are available. The PNEC derived using the acute toxicity test on fish and an assessment factor of 1,000. Usually, an assessment factor of 500 should apply. However, as the lowest L(E)C50 value is lower than the lowest NOEC, a factor of 1,000 is chosen. This gives a $PNEC_{saltwater}$ of 0.0635 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)

$= Fwater_{susp} + Fsolid_{susp} \cdot Kp_{susp} \cdot RHOsolid / 1{,}000 = 1.295\ m^3.m^{-3}$

$Fwater_{susp}$ (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) = $1.58\ l.kg^{-1}$

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 0.715 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 $PNEC_{marine\_sed}$ = 0.0715 mg/kg wet weight of marine sediment.

3.2.1.2.3 Sewage Treatment Plant (STP)

No test is available on the toxicity of PGMA for microorganisms such as the respiration inhibition test and the nitrification test. According to the TGD, it is appropriate to consider the test concentration from a positive ready biodegradability test to be an acceptable alternative to a NOEC. During the test performed by Goodwin and West (1998) according to OECD 301F method, a concentration of 76.4 mg/l of PGMA was used. This value will be considered as a NOEC. The $PNEC_{STP}$ may then be calculated using this value and an assessment factor of 10 which gives a $PNEC_{STP}$ value of 7.64 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)

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

$= 0.674\ m^3.m^{-3}$

$K_{air\text{-}water}$ (partition coefficient air-water) $= 1.5 \cdot 10^{-4}$

$Fair_{soil}$ (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) $= 0.316\ l.kg^{-1}$

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 0.252 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 PGMA is not classified T+, T or Xn and as the potential for bioaccumulation is 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)

The **Table 3.15** presents the calculated PEC/PNEC ratios for the aquatic compartment at the production stage (for each site).

Table 3.15 Risk characterisation for aquatic compartment for each production site

Site	RCR_{STP}	RCR_{water}
1	$8.3 \cdot 10^{-3}$	$2.9 \cdot 10^{-3}$
2	0.02	$5.08 \cdot 10^{-3}$ a)
3	0.37	0.113

a) The releases of production site 2 are directly emitted into the marine environment. The risk characterisation is therefore calculated for the saltwater compartment.

For all production sites, **Conclusion (ii)** is applied.

Conclusions to the risk assessment for the aquatic compartment, including seawater (for all production sites)

Conclusion (ii).

Table 3.16 presents the calculated PEC / PNEC ratios for the aquatic compartment (freshwater, STP) for each end uses.

Table 3.16 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004)

End uses	RCR water (*)	RCR STP (*)
Paints and coating:		
- Water based	0.293 (F)	0.242 (F)
	0.178 (P)	0.146 (P)
	$2.22 \cdot 10^{-3}$ (PU)	$8.79 \cdot 10^{-7}$ (PU)
- Solvent based	0.438 (F)	0.362 (F)
	0.361 (P)	0.298 (P)
	$2.22 \cdot 10^{-3}$ (PU)	$2.39 \cdot 10^{-6}$ (PU)
Electronic industry	0.126 (P)	0.103 (P)

Table 3.16 continued overleaf

Table 3.16 continued Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004)

End uses	RCR water (*)	RCR STP (*)
Chemical industry: chemicals used in synthesis	0.027 (P)	0.083 (P)
Printing inks	0.102 (F) 0.0265 (P)	0.0833 (F) 0.0202 (P)
Metal cleaning	0.069 (F) 0.0197 (P)	0.0555 (F) 0.0145 (P)
Detergents, cleaners	0.0273 (F) $8.78 \cdot 10^{-3}$ (P)	0.0208 (F) $5.45 \cdot 10^{-3}$ (P)
Adhesive	$2.84 \cdot 10^{-3}$ (PU)	$5.14 \cdot 10^{-4}$ (PU)

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

For some end uses, formulation and processing steps can be achieved at a same site. 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 3.16** no risk is identified for all end uses where both formulation and processing are considered for freshwater compartment.

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 PGMA 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.

As neither monitoring data on levels of PGMA 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 PGMA is low. So it can be assumed that the risk assessment for the sediment is covered by that for surface water.

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

Conclusions to the risk assessment for the aquatic compartment, including seawater (for uses)

Conclusion (ii).

3.3.2 Terrestrial compartment

According to the adsorption coefficient (log Koc = 1.2), the substance can be considered as mobile in soils and will not be adsorbed to sludge in STP. Besides, the PGMA 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

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 PGMA: 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 PGMA: 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 PGMA: 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 PGMA: 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
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 (> 1,000 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 Environmental 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 22484 EN **European Union Risk Assessment Report
2-methoxy-1-methylethyl acetate (PGMA)– Part I – Environment,
Volume 67**

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The report provides the comprehensive risk assessment of the substance 2-methoxy-1-methylethyl acetate (PGMA). 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 2-methoxy-1-methylethyl acetate (PGMA) 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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