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2-METHOXY-1-METHYLETHYL ACETATE (PGMA)
Part I – Environment

CAS No: 108-65-6

EINECS No: 203-603-9

Summary Risk Assessment Report

2006 **EUR 22485 EN**

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

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EUR 22485 EN

ISSN 1018-5593

Luxembourg: Office for Official Publications of the European Communities, 2006

Printed in Italy

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2006

France

Rapporteur for the risk assessment of 2-methoxy-1-methylethyl acetate (PGMA) is the Ministry of the Environment (MEDD)

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

PREFACE

This report provides a summary, with conclusions, of the environmental part of the risk assessment report of the substance 2-methoxy-1-methylethyl acetate (PGMA) hat has been prepared by France in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

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

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

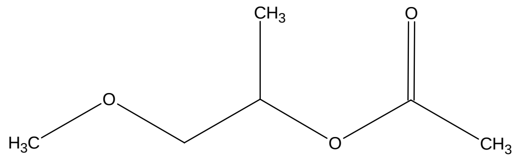
CONTENTS

TABLES

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 108-65-6
EINECS Number: 203-603-9
IUPAC Name: 2-methoxy-1-methylethyl acetate
Molecular weight: 132.16 g.mol^{-1}
Molecular formula: $C_6H_{12}O_3$
Structural formula:



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 PHYSICO-CHEMICAL PROPERTIES

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
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

1.3 CLASSIFICATION

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

2 GENERAL INFORMATION ON EXPOSURE

The total use of PGMA varied between years 2001 and 2003 between 61,500 and 68,700 tonnes. in EU15. A figure of 63,200 tonnes is retained for this assessment. PGMA is currently manufactured with volumes exceeding 1,000 tonnes/year by three producers in the EU.

The industrial and use categories of PGMA are summarised in **Table 2.1**. 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 2.1**). 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 2.1 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 2.1 continued overleaf

Table 2.1 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.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 Environmental fate

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

- Hydrolysis is not expected to be an important removal process in the environment (PGMA is stable at pH 4 and 7 and has a half-life of 8.1 days at pH 9.
- An estimated atmospheric half-life value of ~10.8 hours has been derived for PGMA.
- According to standard tests on ready biodegradation and further experimental data which confirmed these biodegradation rates, PGMA can be regarded as readily biodegradable (half-lives in surface water, soil and sediment can be estimated for PGMA, respectively 15, 30 and 300 days).
- $K_{air-water}$ of $1.73.10^{-4}$ indicates that volatilisation of PGMA from surface water and moist soil is expected to be very low.
- In view of the estimated BCF (3.16) calculated based on the log Kow, PGMA is expected to have a low bioaccumulation potential.
- Based on the results from a multimedia fugacity model and the physico-chemical properties of PGMA, the hydrosphere is the preferential target of the substance in the environment (89.5% in water, 10.4% in air).
- Based on the SIMPLETREAT model, it is anticipated that, after a sewage treatment plant, PGMA will be degraded at a level of 87.1%, 12.6% of PGMA will remain in water. The remaining fraction of PGMA will be shared between adsorption to sludge and air emission.

3.1.2 Environmental concentrations

Local concentrations

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.

At the production stage, releases to water have been calculated using data provided by the industry.

Table 3.1 Local PEC_{water} and PEC_{STP} for PGMA according to EUSES (EC, 2004)

End uses	PEC_{water} mg/l (*)	PEC_{STP} mg/l (*)
Production Production site releasing PGMA in seawater	0.071 $3.23 \cdot 10^{-4}$	2.800 0.178
Paints and coating: - Water based - Solvent based	 0.186^{F} 0.113^{P} $1.41 \cdot 10^{-3\ PU}$ 0.278^{F} 0.229^{P} $1.41 \cdot 10^{-3\ PU}$	 1.85^{F} 1.12^{P} $6.72 \cdot 10^{-6\ PU}$ 2.77^{F} 2.28^{P} $1.82 \cdot 10^{-5\ PU}$
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} 0.0168^{P}	0.637^{F} 0.154^{P}
Metal cleaning	0.0438^{F} 0.0125^{P}	0.424^{F} 0.111^{P}
Detergents, cleaners	0.0173^{F} $5.58 \cdot 10^{-3\ P}$	0.159^{F} 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)

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

Exposure assessment for the 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.

Regional and continental concentrations

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

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

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

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

Calculation of the PNEC for the freshwater compartment

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-day ≥ 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.

Calculation of the PNEC for the saltwater compartment

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 $L(E)C_{50}$ value is lower than the lowest NOEC, a factor of 1,000 is chosen. This gives a $PNEC_{saltwater}$ of 0.0635 mg/l.

Calculation of a PNEC for the sediment compartment

No test is available on sediment-dwelling organisms exposed via sediment.

In absence of any ecotoxicological data for sediment-dwelling organisms, the PNEC may provisionally be calculated using the equilibrium partitioning method from the PNEC for aquatic compartment ($PNEC_{aqua}$) and the solid-water partition coefficient in suspended matter (Kp_{susp}). Thus, the $PNEC_{sed}$ value is of 0.715 mg/kg wet weight of sediment.

Calculation of the PNEC for the marine sediment compartment

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

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

PNEC for micro-organisms in 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.

Terrestrial compartment

No test on plants, earthworms or other soil-dwelling organisms is available. In the absence of any ecotoxicological data for soil-dwelling organisms, the $PNEC_{soil}$ may provisionally be calculated using the equilibrium partitioning method with the PNEC for aquatic compartment ($PNEC_{aqua}$) and the soil-water partition coefficient. Thus, the $PNEC_{soil}$ value is of 0.252 mg/kg wet weight of soil.

Atmosphere

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

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)

Table 3.3 presents the calculated PEC/PNEC ratios for the aquatic compartment (freshwater, STP) for each end uses.

Table 3.3 Risk characterisation (RCR) for aquatic compartment according to EUSES (EC, 2004)

End uses	RCR water (*)	RCR STP (*)
Production Production site releasing PGMA in seawater	0.113 $5.08 \cdot 10^{-3}$	0.37 0.02
Paints and coating: - Water based - Solvent based	 0.293 ^{F} 0.178 ^{P} $2.22 \cdot 10^{-3\ PU}$ 0.438 ^{F} 0.361 ^{P} $2.22 \cdot 10^{-3\ PU}$	 0.242 ^{F} 0.146 ^{P} $8.79 \cdot 10^{-7\ PU}$ 0.362 ^{F} 0.298 ^{P} $2.39 \cdot 10^{-6\ PU}$
Electronic industry	0.126 ^{P}	0.103 ^{P}
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

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

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. 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

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.

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

Conclusion (ii).

3.3.3 Atmosphere

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

3.3.4 Secondary poisoning

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

Conclusion (ii).

4 HUMAN HEALTH

(to be added later).

5 RESULTS

5.1 ENVIRONMENT

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).

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

EUR 22485 EN **European Union Risk Assessment Report**
2-methoxy-1-methylethyl acetate (PGMA)– Part I – Environment

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

Luxembourg: Office for Official Publications of the European Communities

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

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

The report provides the comprehensive summary of the risk assessment of the substance 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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European Union Risk Assessment Report

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CAS No: 108-65-6 EINECS No: 203-603-9

Series: 4th Priority List

Publications Office
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