THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

# ANNEX XV TRANSITIONNAL REPORT

SUBMITTED BY: FRANCE

DATE: 19.11.2008

**SUBSTANCE NAME**: **PGMA (**propylene glycol monomethyl ether acetate)

CAS NUMBER: 108-65-6
EC NUMBER: 203-603-9

# A. SUMMARY

PGMA has a very low acute and chronic toxicity by all routes of exposure. However, risks have been identified for repeated dermal exposure and for local effects (chronic irritation of the respiratory tract) in specific occupational scenarios together with eye and respiratory tract irritation and repeated dose toxicity (local effects) for specific consumer scenarios.
Based on the type of effects observed and the uncertainty related to the exposure assessment (restrictive), it seems neither appropriate nor proportional to propose a restriction as the probability that the health effects highlighted in the RAR occurs seems to be low.
Anyhow, in order to reduce consumer exposure to solvents based products, we highly recommend Industry to substitute as much as possible dangerous solvents in their products and industry and MS to provide a high degree of information to consumers about the use of these products and to establish a reactive vigilance on solvents based consumer's products.

# B. INFORMATION ON HAZARD AND RISK

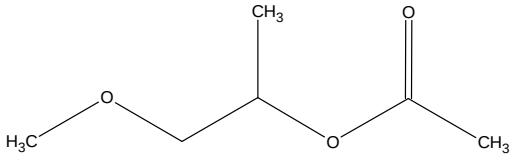
Unless specified in the text as another reference, and instead the paragraph B.9, this part has been agreed by TCNES based on the RARs [1;2]. Only summaries are reported here, more details are available in the documents attached in the technical dossier and cited in reference.

## B.1 Identity of the substance(s) and physical and chemical properties

This part has been agreed by TCNES based on the RAR finalised the 28th October 2008 [3]

### *B.1.1 Name and other identifiers of the substance(s)*

CAS Number: 108-65-6
EINECS Number: 203-539-1
IUPAC Name: 2-methoxy-1-methylethyl acetate
Molecular formula: $C_6H_{12}O_3$
Structural formula: $CH_3O\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-}COCH_3$




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.

### *B.1.2 Composition of the substance(s)*

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, totalizing 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.

### *B.1.3 Physico-chemical properties*

**Table 1.1: Summary of physico-chemical properties of PGME**

| 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 |

### *B.1.4 Justification for grouping*

Not relevant for this dossier.

## B.2 Manufacture and uses

### *B.2.1 Manufacture and import of a substance*

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.

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

| 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 1.2**).

**Table 1.2** Main producers of PGMA

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

From the **Table 1.2**, 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.

### *B.2.2 Uses*

The industrial and use categories of PGMA are summarised in **Table 2.1**. PGMA is mainly used as solvents in paints or surface coatings (solvent-based or water-based). Other uses reported are solvent in the electronic industry, in the chemical industry, in inks, cleaners, and adhesives. Over the past decades ethylene glycol methyl ether and ethylene glycol ethyl ether acetates, have progressively been replaced by propylene glycol derivatives.

A breakdown of the uses of PGMA 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<br>Processing (90%)<br>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<br>Processing | 12: pulp, paper and board industry | 48: Solvent | 4,994 | 1,300 | 1,600 | 1,500 | 2.4% |
| Metal | Formulation | 6: Public domain | 48: Solvent | 0 | 1,000 | 900 | 1,000 | 1.6% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| cleaning* | Processing | | | | | | | |
| Detergents, cleaners | Formulation<br>Private/public use | 5: Personal/domestic<br>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.

In the Swedish product register (KEMI 2002), 1097 products containing PGMA (of which 126 were private household products) have been identified : 66 % are paints (or hardeners for paints), varnishes or adhesives , 8 % diluents, 1 % solvents and 1 % cleaning agents.

In the Danish product register (Arbeidstilsynet 2001), 1758 products containing PGMA have been identified, of which 83 were private household products. The most common uses were paints and varnishes (48 %), solvents (11 %), process regulators (11 %), adhesives/binding agents (6 %) and cleaning/washing agents (3 %).

Other data extracted from the French product register SEPIA (INRS 2002) showed that 265 products registered between 1997 and 2002 contained PGMA. The main use category was: paints, varnishes and inks (79 %).

The distribution of concentration intervals in the main type of products is presented in the tables 2.3 and 2.2.

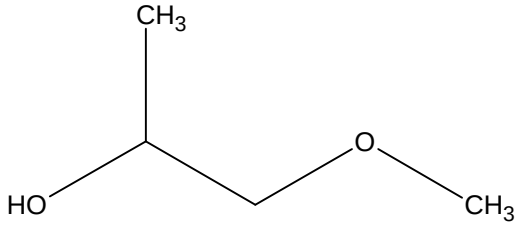
**Table 2.2: Concentration of PGMA in the main use categories in the Danish product register (2001)**

| Content % | Cleaning agents | Solvents | Paints | Process regulators | Adhesives |
|---|---|---|---|---|---|
| [0-1] | 5 | 7 | 341 | 25 | 36 |
| ]1-5] | 4 | 6 | 189 | 28 | 21 |
| ]5-10] | 12 | 14 | 133 | 37 | 12 |
| ]10-20] | 8 | 29 | 116 | 76 | 15 |
| ]20-50] | 14 | 91 | 45 | 23 | 14 |
| ]50-80] | 3 | 24 | 12 | 5 | 3 |
| ]80-100] | 4 | 27 | - | | |

**Table 2.3: Concentration of PGMA in the main use categories in the French product register SEPIA (INRS, 2002)**

| Concentration (%) | Paints, varnishes and inks | Metallurgical and mechanical sectors products | Cleaning products |
|---|---|---|---|
| [0-1] | 29 | 1 | - |
| ]1-5] | 63 | 5 | - |
| ]5-10] | 38 | 1 | - |

| | | | |
|---|---|---|---|
| ]10-20] | 40 | 4 | 2 |
| ]20-50] | 5 | 1 | 2 |
| ]50-100] | 1 | - | 1 |




### *B.2.3 Uses advised against by the registrants*

No data available.

### *B.2.4 Description of targeting*

The major occupational routes of exposure to PGMA are inhalation and skin contact. Assuming proper hygiene measures are applied, oral exposure would normally not occur in the workplace.

Workers may be significantly exposed during the production of PGMA, its use as a processing solvent in the chemical industry or during the formulation and use of PGMA containing products.

Occupational exposure assessment will be carried out through three main categories of scenarios:

(a) the manufacture of PGMA and its use as a processing solvent,

(b) the formulation of products containing PGMA,

(c) the use of products containing PGMA.

The third category will focus on particular sub-scenarios for exposure in the most frequent type of use, or particular pattern of use, when relevant.

## B.3 Classification and labelling

### *B.3.1 Classification in Annex I of Directive 67/548/EEC*

PGMA is listed in annex I according to the 19$^{th}$ ATP to Directive 67/548/EEC under index number: 607-195-00-7 as R10, Xi; R36; S2-25

### *B.3.2 Classification in classification and labelling inventory/Industry's self classification(s) and labelling*

No data available.

## B.4 Environmental fate properties

This part has been agreed by TCNES. Details can be found in the RAR [2].

### *B.4.1 Degradation*

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

**Table 4.1** Estimation of biodegradation rate constants in the different compartments

| **Compartment** | **Biodegradation rate ($d^{-1}$)** |
|---|---|
| Air | $K_{deg\text{-}air} = 0.5$ |
| Surface freshwater | $Kfreshwater = 4.7 . 10^{-2}$ |
| Surface saltwater | $Ksaltwater = 1.4 . 10^{-2}$ |
| Sediment | $Ksed = 2.3 . 10^{-3}$ |
| Soil | $Ksoil = 2.3 . 10^{-2}$ |

### *B.4.2 Environmental distribution*

Based on an Air-biota-sediment-soil-water compartment model (EQC model v1.0 based on the level I fugacity model developed by Mackay), water is the preferential target compartment at equilibrium.

### *B.4.3 Bioaccumulation*

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 for accumulation in biota.

### *B.4.4 Secondary poisoning*

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

## B.5 Human health hazard assessment

This part has been agreed by TCNES based on the RAR finalised the 28th October 2008 [4]. For more details, please refer to this document.

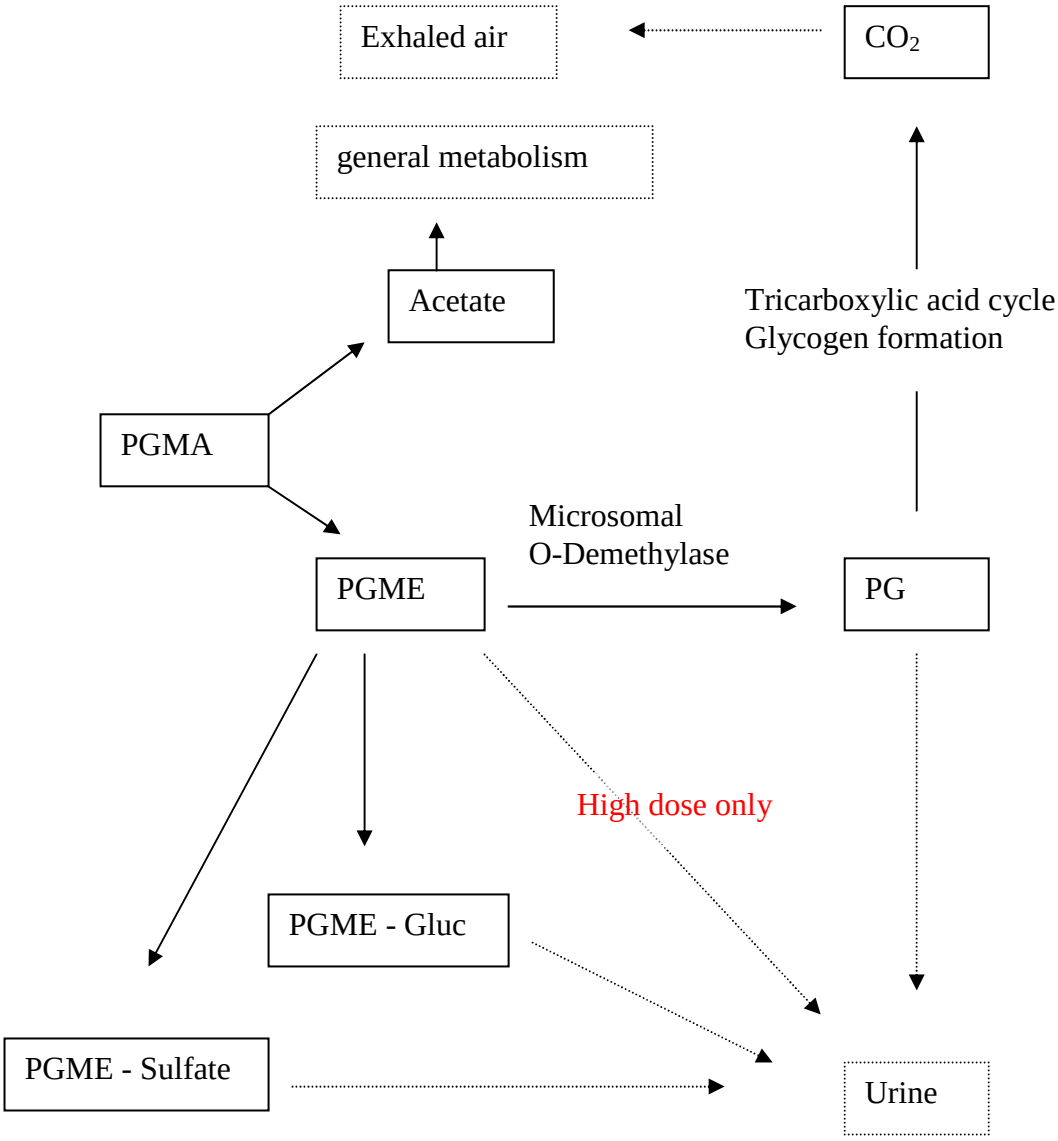
### *B.5.1 Toxicokinetics*

PGMA is readily absorbed via oral and inhalation route. An absortion percentage of 100 % can be taken into account for these routes of exposure. Dermal absorption of PGMA is lesser than PGME (between 3 and 4 fold less). For dermal absorption it was found that dermal absorption for PGMA was approximately 30% of that of PGME in rats: an absorption factor of 10 % will hence be taken into account for RC.

PGMA is rapidly hydrolysed *in vivo* in PGME and acetate (blood half life of PGMA is about 2 min for a low dose of PGMA). Hydrolysis can also occur locally (i.e. in the respiratory tract). A detailed assessment of the PGME metabolism is available in the PGME RAR (see r406_0508_hh).

PGMA has the same metabolic pathway as PGME:

**Figure 5.1: Metabolic pathway of PGMA**




The maximum concentrations of PGMA are found in liver and blood. There is no signs of accumulation after exposure.

Elimination occurs by urine as metabolites and by pulmonary elimination of $CO_2$ formed by the metabolism of PG (about 50 % of PGMA doses by this way of elimination).

### *B.5.2 Acute toxicity*

Acute toxicity of this chemical is low in rodents because LD50 values are greater than 5,000 mg/kg bw by oral or dermal routes and greater than 10,800 mg/$m^3$ by inhalation, moreover a nominal concentration of 23,463 mg/m3 did not cause adverse effects.

No classification is needed whichever the route of exposure.

**Table 5.1: summary of acute toxicity studies**

| Experimental condition | LD/LC 50 | Effects | Validity | Reference |
|---|---|---|---|---|
| Inhalation route | | | | |
| Inhalation Rat | | Concentrated vapour (8h) $LC_0$ | 2 | UCC (1961) |
| Inhalation Rat (6h) | | $LC_0$ 23,463mg/$m_3$ | 2 | Dow Chem. Co., 1980 |
| Inhalation Rat (3h) | | $LC_0$ 10,800mg/$m_3$ (male) | 2 | Dow Chem. Co., 1985 |
| Inhalation Mouse (3h) | | $LC_0$ 10,800mg/$m_3$ (male) | 2 | Dow Chem. Co., 1985 |
| Dermal route | | | | |
| Dermal Rat | > 5,000 mg/kg | | 2 | Dow Chem. Co., 1980 |
| Dermal Rat | > 2000 mg/kg | Inflammation on the site of administration, no systemic effects | 2 | Shell, 1985b |
| Dermal Rabbit | | $LC_0$ 19,400mg/kg | 2 | UCC (1961) |
| Oral route | | | | |
| Oral Rat | 13,700mg/kg bw (male) | | 2 | UCC (1961) |
| Oral Rat | 6190 mg/kg bw (male)<br>5155 mg/kg bw (female) | Gait abnormalities, coma/ | 2 | Shell, 1985b |
| Oral Rat | >10,000mg/kg bw (male) | | 2 | Dow Chem. Co., 1992 |

| | | | | |
|---|---|---|---|---|
| | 8,532mg/kg bw (female) | | | |

### *B.5.3 Irritation*

In animal studies (rabbits), PGMA was found to be non-irritating to the skin and mildly irritating to the eye. PGMA is not expected to be severely irritating for the respiratory tract at usual PGMA levels of exposure. No classification is needed for irritation.

**For risk characterisation, a cross-reading can be done with PGME and the NOAEC of 100 ppm will be taken into account for local effects on the respiratory tract.**

### *B.5.4 Corrosivity*

PGMA is not a corrosive substance.

### *B.5.5 Sensitisation*

PGMA was found to be non-sensitizing for the skin in guinea pigs. PGMA is not expected to be a respiratory sensitiser. No classification is needed for these end-points.

### *B.5.6 Repeated dose toxicity*

The NOAEL for repeat dose oral toxicity (by gavage) in rats was 1,000 mg/kg bw/day for both sexes. An inhalation study reveals that the critical effects are toxicity in kidney and nasal cavities in rats, whereas only degeneration of olfactory epithelium occurs in mice. A NOAEC for repeat inhalation systemic toxicity in rats was established at 300 ppm (1.62 mg/L) for males and at 1,000 ppm (5.39 mg/L) for females. However, a NOAEC for inhalation toxicity in mice (local effects) was not established because the lowest dose at 300 ppm (1.62 mg/L) induced a minimum effect on nasal cavity. For local effects (degeneration of olfactory epithelium) a LOAEC of 300 ppm can be taken into account.

Regarding general systemic toxicity, only short term studies are available (2 weeks), and in these studies only renal effects specific to male rat were observed. As PGMA is rapidly hydrolysed *in vivo* to PGME, the results obtained for PGME can apply for chronic toxicity. In this case, a NOAEL of 300 ppm could be taken into account for systemic effects based on the 2-year rat study performed with PGME and leading to liver effects at doses of 1000 ppm.

In absence of dermal data for PGMA, dermal data on PGME will be used for dermal risk characterisation: no systemic effects were reported at 1000 mg/kg (the only tested dose in a 21-day study by dermal route).

### *B.5.7 Mutagenicity*

This chemical is not genotoxic with and without an exogenous metabolic activation system in bacterial test and chromosomal aberration test *in vitro*. PGMA did not induce UDS in rat hepatocytes.

### *B.5.8 Carcinogenicity*

No data available.

PGMA id rapidly hydrolysed to PGME. There is a 2-year study available on PGME which has showed that no carcinogenicity is expected. This can also apply for PGMA (for thr PGME moiety).

The main concern could be du to the formation of acetate and the effects on the nasal epithelium. The degenerative effects seen in the 3-week study may lead to carcinogenic effect due to local irritation and subsequent enhanced cell proliferation. This would be due to the acetate moiety only. This hypothetical effect will not be taken into account in the risk characterisation for carcinogenicity because:

- in general no ester acetate is classified for carcinogenicity by inhalation route,
- this irritant effect will be taken into account in the repeated dose toxicity section

### *B.5.9 Toxicity for reproduction*

PGMA did not produce any fertility effects in rats A NOAEL of 1000 mg/kg were seen in a screening study via oral route. In this study, effects on oestus cycle were not recorded. Due to the metabolism of PGMA, effects seen with PGME can be expected (see 2 generation study by inhalation route with PGME). These effects led to a NOAEC of 1000 ppm (5400 $mg/m^3$ for PGMA). This NOAEC can be taken into account for PGMA.

For developmental effects, there was no evidence of teratogenicity of PGMA in an inhalation study performed on rats. In this study a NOAEL of 500 ppm (2,700 mg/m3) was observed for dams for systemic toxicity and 4,000 ppm (22,464 mg/m3) for foetuses for developmental effects (no effects at the highest tested dose).

### *B.5.10 Other effects*

### *B.5.11 Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response*

## B.6 Human health hazard assessment of physico-chemical properties

This part has been agreed by TCNES based on the RAR finalised the 28th October 2008 [5]

### *B.6.1 Explosivity*

PGMA has no explosive properties.

### *B.6.2 Flammability*

PGMA is flammable (flash point is 42°C). Vapours can form flammable and explosive mixtures with air within the range of 1.5 to 12 % volume. Information on flammability and safety measures should be given on the label and the safety data sheet. There is at present no need for further information or risk reduction measures beyond those which are being applied already.

It is also noted that oxidation by air may involve peroxidation of the substance, which may increase explosive properties. A general warning to this effect is recommended. Use of antioxidants reduces the potential to peroxidation.

### *B.6.3 Oxidising properties*

PGMA has no oxidising properties.

## B.7 Environmental hazard assessment

Agreed by TCNES based on the RAR [2] . For more details, please refer to this document.

### *B.7.1 Aquatic compartment (including sediment)*

**Table 7.1: Summary of aquatic PNEC**

| **Compartment** | **PNEC** |
|---|---|
| Aquatic compartment | 0.635 mg/l |
| Saltwater | 0.0635 mg mg/l |
| Wet weight of sediment | 0.715 mg/kg |
| Wet weight of marine sediment | 0.0715 mg/kg |

### *B.7.2 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.
Thus, the $PNEC_{soil}$ value is of 0.252 mg/kg wet weight of soil.

### *B.7.3 Atmospheric compartment*

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

### *B.7.4 Microbiological activity in sewage treatment systems*

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.

### *B.7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)*

PGMA is not classified T+, T or Xn and its potential for bioaccumulation is very low , secondary poisoning can be considered to be negligible.

## B.8 PBT and vPvB assessment

PGMA is not classified T+, T or Xn and its potential for bioaccumulation is very low. [2]

### *B.8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII*

### *B.8.2 Emission characterisation*

## B.9 Exposure assessment

### *B.9.1 General discussion on releases and exposure*

Humans may be exposed to PGMA at workplace, via consumer products and indirectly via the environment (i.e. ingestion of surface water). The highest potential exposure is likely to occur during occupational exposure.

Workers and consumers are primarily exposed via inhalation and dermal routes. PGMA is readily absorbed through the skin including absorption from direct contact with liquid or aerosol form or contact with vapours. This compound has a relatively low vapour pressure (0.49 kPa at 20°C). Therefore, dermal exposure from direct contact with the liquid may be predominant or contribute significantly to overall exposure.

Exposure may occur during manufacture and during formulation and use of products. PGMA is a solvent used in many industrial activities or consumer applications. Over the past decades ethylene glycol methyl ether and ethylene glycol ethyl ether acetates, have progressively been replaced by propylene glycol derivatives. The main use of PGMA is in paints or surface coatings (solvent-based or water-based). Other uses reported are solvent in the electronic industry, in the chemical industry, in inks, cleaners, and adhesives.

In the Swedish product register (KEMI 2002), 1097 products containing PGMA (of which 126 were private household products) have been identified : 66 % are paints (or hardeners for paints), varnishes or adhesives , 8 % diluents, 1 % solvents and 1 % cleaning agents.

In the Danish product register (Arbeidstilsynet 2001), 1758 products containing PGMA have been identified, of which 83 were private household products. The most common uses were paints and varnishes (48 %), solvents (11 %), process regulators (11 %), adhesives/binding agents (6 %) and cleaning/washing agents (3 %).

Other data extracted from the French product register SEPIA (INRS 2002) showed that 265 products registered between 1997 and 2002 contained PGMA. The main use category was: paints, varnishes and inks (79 %).

### *B.9.2 Occupationnal exposure*

#### B.9.2.1 Manufacture and use as intermediate

See 4.1.1.2.1 (Manufacture and use as intermediate) of the human health part of the EU-RAR (attached to annex XV dossier).

### B.9.2.2 Formulation of products containing PGMA

See 4.1.1.2.2 (Formulation of products containing PGMA) of the human health part of the EU-RAR (attached to annex XV dossier).

### B.9.2.3 Use of products containing PGMA

See 4.1.1.2.3 (Use of products containing PGMA) of the human health part of the EU-RAR (attached to annex XV dossier).

### B.9.2.4 Summary of occupational exposure

For more details, see 4.1.1.2.4 of the human health part of the EU-RAR (attached to annex XV dossier).

**Table 9.2: Summary of proposed reasonable worst case exposures**

| Scenario | 8-hour TWA inhalation ($mg/m^3$) | External dermal exposure (mg/day) |
|---|---|---|
| 1 - Manufacture | 3.5 | 42 |
| 2 - Formulation | 43 | 1,500 (loading)<br>500 (filling) |
| 3 - Use of products<br>3.1 Coating/Painting*<br>- Industrial<br>Spraying<br>Other works<br>- decorative<br><br>3.2 Printing<br>- silk screening<br>- general printing | <br><br><br><br>71<br>71<br>71<br><br><br>40<br>44 | <br><br><br><br>3,000<br>360<br>120<br><br><br>23<br>168 |

* The conclusions refer to solvent-based paints. Exposure from use of water-based paints (lower PGMA content) would be much lower.

As pointed out in the report, dermal exposure may make a significant contribution to overall exposure and needs to be considered carefully. The estimates based on measured data from RISKOFDERM should be preferred to the EASE estimates as they represent real exposure situation and EASE is known to be a weak model for this purpose.

RISKOFDERM measured data are however overestimated, especially when measurements have been done with gloves and when they are based on the much less volatile DEGBE. The level of overestimation cannot be estimated but the uncertainty caused by the

measurement method should be taken into account for risk characterisation in the evaluation of the MOS. This is particularly relevant for scenario 1 (formulation) and scenario 2 (painting).

| Scenario | 8-hour TWA inhalation ($mg/m^3$) | External dermal exposure (mg/day) |
|---|---|---|
| 1 - Manufacture | 3.5 | 42 |
| 2 - Formulation | 43 | 1,500 (loading)<br>500 (filling) |
| 3 - Use of products<br>3.1 Coating/Painting*<br>- Industrial<br>Spraying<br>Other works<br>- decorative<br><br>3.2 Printing<br>- silk screening<br>- general printing | <br><br><br>71<br>71<br>71<br><br><br>40<br>44 | <br><br><br>3,000<br>360<br>120<br><br><br>23<br>168 |

* The conclusions refer to solvent-based paints. Exposure from use of water-based paints (lower PGMA content) would be much lower.

### *B.9.3 Consumers exposure*

See 4.1.1.3.1 (Exposure from uses) of the human health part of the EU-RAR (attached to annex XV dossier) [6].

**Table 9.3: Summary of proposed reasonable worst case exposures in the main scenarios**

| SCENARIO | INHALATION ($MG/M^3$) | INHALATION (MG/KG/D) | SKIN (MG/KG/D) | SUM OF EXPOSURES (MG/KG/D) |
|---|---|---|---|---|
| 1. AQUEOUS PAINTS AND FLOOR VARNISHES | 71 | 23.7 | 2.8 | 26.5 |
| 2. HOUSE CLEANERS | 330 | 1.5 | 9.8 | 11.3 |

### *B.9.4 Human exposed via the environment*

See 4.1.1.4 of the human health part of the EU-RAR (attached in the annex XV dossier).

### *B.9.5 [Summary of] environmental exposure assessment*

The concentrations calculated in intake media (drinking water, fish, plant roots and leaves, milk, meat, air) relating to the estimation of the indirect exposure of humans via the

environment and the subsequent estimation of human intakes via different routes were evaluated in the RAR [7] with the corresponding total daily intakes. Both local and regional levels were taken into consideration and the estimation of local environmental exposures has been performed for all scenarios evaluated. Concerning the production step, only the worst case has been reported. All calculations have been performed using EUSES 2 and default parameters of this software have been used, excepted for the body weight for which a value of 60 kg as been used. Absorption by dermal, oral and inhalation routes is taken as it has been defined for the consumers, i.e. 10%, 100% and 100% respectively. The highest indirect exposure is estimated for the processing of solvent-borne paints and coating: 0.174 $mg.kg^{-1}.day^{-1}$. It can also be noted that the highest exposures are to be expected through intake of air and leaves of plants. Moreover, based on the regional concentrations, the total daily intake for humans is $1.67 \times 10^{-4}$ $mg.kg^{-1}.day^{-1}$. These two figures will be taken forward into the risk characterisation.

### *B.9.6 Combined human exposure assessment*

Combined exposure was assessed only for workers and no risk was identified for occupational combined exposure.

## B.10 Risk characterisation

See 4.1.3 of the human health part of the EU-RAR (agreed by TCNES) attached to the annex XV dossier.

### *B.10.1 Human health*

#### B.10.1.1 General aspects

**Table 10.1: Summary of effects**

| Substance name | Inhalation (N(L)OAEC) | Dermal (N(L)OAEL) | Oral (N(L)OAEL) |
|---|---|---|---|
| Acute toxicity | > 10,800mg/m³<br>750 ppm* or 2800 mg/m³ – CNS depression in human PGME data (4116 mg/m³)* | > 5000 mg/kg | > 5000 mg/kg |
| Irritation / corrositivity | < 300 ppm (100 ppm from PGME data) | NA | NA |
| Sensitization | NA | NA | NA |
| Repeated dose toxicity (local) | < 300 ppm | ND | NA |
| Repeated dose toxicity (systemic) | 300 ppm *(1620 mg/m³) | > 1470 mg/kg * | NA |
| Mutagenicity | NA | NA | NA |
| Carcinogenicity | ND | ND | ND |
| Fertility impairment | 1000 ppm ** | NA | NA |
| Developmental toxicity | NA | NA | NA |

NA: not applicable
ND: no data

- * based on PGME data (conversion factor of 1.47 (conversion of PGME dermal dose to PGMA dermal dose))
- ** based on PGME data and is consistent with the results of the screening study.

| Substance name | Inhalation (N(L)OAEC) | Dermal (N(L)OAEL) | Oral (N(L)OAEL) |
|---|---|---|---|
| Acute toxicity | > 10,800mg/m$^3$<br>750 ppm* or 2800 mg/m$^3$ – CNS depression in human PGME data (4116 mg/m$^3$)* | > 5000 mg/kg | > 5000 mg/kg |
| Irritation / corrositivity | < 300 ppm (100 ppm from PGME data) | NA | NA |
| Sensitization | NA | NA | NA |
| Repeated dose toxicity (local) | < 300 ppm | ND | NA |
| Repeated dose toxicity (systemic) | 300 ppm *(1620 mg/m$^3$) | > 1470 mg/kg * | NA |
| Mutagenicity | NA | NA | NA |
| Carcinogenicity | ND | ND | ND |
| Fertility impairment | 1000 ppm ** | NA | NA |
| Developmental toxicity | NA | NA | NA |

NA: not applicable
ND: no data

- * based on PGME data (conversion factor of 1.47 (conversion of PGME dermal dose to PGMA dermal dose))
- ** based on PGME data and is consistent with the results of the screening study.

### B.10.1.2 Workers

Conclusion iii applies to applies for systemic toxicity due to repeated dermal exposure for formulation or industrial spraying scenarios; and for local effects (chronic irritation of the respiratory tract) due to repeated exposure for coating and painting scenario: industrial (spraying and other works) or decorative.

**Table 10.2: Occupational risk assessment of PGMA for repeated dose toxicity.**

| Scenario | | Risk assessment for inhalation exposure | | | Risk assessment for dermal exposure to liquid PGMA | | |
|---|---|---|---|---|---|---|---|
| | | 8-hour TWA inhalation ($mg/m^3$) | MOS<br>Minimal MOS = 12.5 | Conclusion | Estimated Skin exposure mg/day worst case<br>(mg/kg bw/d | MOS<br>Minimal MOS = 60 | Conclusion |
| Formulation | | 43 | 37 | ii | 3000<br>(42.9) | 34 | iii |
| Use of products | 3.1 Coating/Painting<br>Industrial - spraying | 71 | 23 | ii | 3000<br>(42.9) | 34 | iii |

**Table 10.2 bis : Risk characterisation for inhalation exposure – local effects**

| Scenario | | Risk assessment for inhalation exposure – local effects | | |
|---|---|---|---|---|
| | | 8-hour TWA inhalation ($mg/m^3$) | MOS<br>Minimal MOS = 37.5 | Conclusion |
| Use of products | Coating/Painting | | | |
| | Industrial (spraying and other works) | 71 | 23 | iii |
| | Decorative | 71 | 23 | iii |

* Y (inhalation internal dose) = X (value of the 8-hour TWA inhalation (mg/m3)) x 10 m3 (inhaled air during a workday) x 1 (100 % absorption by inhalation) / 70 (mean bw of a worker)
* Z = 0.10/0.90 x Y = 0.11 Y (dermal absorption of vapour PGME could count for 10 % of the internal dose of PGME)
* For dermal exposure internal dose is calculated for a 70 kg bw worker with a percentage of absorption of 30 % (liquid PGME, worst case)

These MOS are calculated using worst case scenarios for dermal exposure and without use of PPE. It might be considered that using PPE conclusion ii could be reached instead for all scenarios.

For all other scenarios and end-points there is no concern (**Conclusion ii).**

### B.10.1.2 Consumers

**Conclusion iii** applies for eye and respiratory tract irritation for house cleaners scenarios and for repeated dose toxicity (local effects) for aqueous paints and floor varnishes and for house cleaners scenarios.

**Table 10.3: MOS and conclusion for eye and respiratory tract irritation**

| Scenario | Inhalation (mg/m3) | MOS minimal MOS = 3 | Conclusion |
|---|---|---|---|
| 2. HOUSE CLEANERS | 330 | 1.7 | iii |

**Table 10.3bis: MOS and conclusion for repeated dose toxicity (local effects)**

| Scenario | Inhalation | |
|---|---|---|
| | MOS minimal MOS = 75 | Conclusion |
| 1. AQUEOUS PAINTS AND FLOOR VARNISHES | 23 | iii |
| 2. HOUSE CLEANERS | 5 | iii |

Conclusion ii is reached for all other consumers' scenarios concerning all other toxicological end-points.

### B.10.1.3 Indirect exposure to humans via environment

The key health effects is repeated dose toxicity and reproductive toxicity (fertility effects). The other endpoints such as mutagenicity or carcinogenicity are not characterised since there are no concern for these effects. Comparison of the total internal dose of 96 $mg.kg^{-1}$ (corresponding to the NOAEC of 1620 ppm for repeated dose toxicity via inhalation and calculated assuming respiratory volume of 20 $m^3$ a day and a mean human bw of 60 kg) with the highest estimated exposure at regional ($1.67\times10^{-4}$ $mg.kg^{-1}.day^{-1}$) and local (0.174 $mg.kg^{-1}.day^{-1}$) levels leads to margins of safety of, respectively, $5.75\times10^5$ and 552 which do not lead to concern (the reference MOS for repeated dose toxicity is 25). For fertility end-point, effects seen with PGME can be expected (see 2 generation study by inhalation route with PGME; 6h/day and 5 days a week). These effects led to a NOAEC of 1000 ppm (5400 $mg/m^3$ for PGMA) leading to a total internal dose of 321 mg/kg/d which leads to margin of safety of $1.92\times10^6$ and 1845 for regional and local levels. No concern is anticipated with a reference MOS for reproductive toxicity by inhalation of 25.

**Summary of risk characterisation for exposure via the environment**

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

This conclusion applies for all endpoints in relation to local and regional exposure.

### *B.10.2 Environment*

The environmental risk assessment of PGMA leads to the following conclusions: (see EU-RAR [2]) :

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.

## B.11 Summary on hazard and risk

Acute toxicity of PGMA is low in rodents. This chemical is mildly irritating to eye, but not to skin. PGMA is not skin-sensitising in guinea pigs. For repeated dose toxicity, inhalation studies demonstrated that PGMA caused local irritation effect probably because of the hydrolysis *in situ* in PGME and acetate. Although no classification regarding irritation has been warranted, the value of 100 ppm was taken into account in the risk characterisation for local effects on the respiratory tract.
The only risk identified for workers are for systemic toxicity due to repeated dermal exposure for formulation or industrial spraying scenarios; and for local effects (chronic

irritation of the respiratory tract) due to repeated exposure for coating and painting scenario: industrial (spraying and other works) or decorative.
For consumers**,** eye and respiratory tract irritation for house cleaners scenarios and for repeated dose toxicity (local effects) for aqueous paints and floor varnishes and for house cleaners scenarios have been identified as scenarios for which a need for limiting the risks is identified.

Two bacterial mutation tests, unscheduled DNA synthesis in rat hepatocytes and chromosomal aberration test *in vitro* show negative results. An UDS study was also negative. No data is available for carcinogenicity. Cross-reading with PGME data is possible because of the rapid hydrolysis of PGMA to PGME and acetate. No carcinogenic properties are expected for PGME moiety and risk of seeing carcinogenic development due to the local irritation caused by the acetate moiety is taken into account by the RDT risk characterisation. PGMA did not produce any fertility effects in rats and there was no evidence of teratogenicity of PGMA.

Environmental risk assessment and indirect exposure to humans via environment lead to conclusion that further information and/or testing are not needed and that risk reduction measures already applied are sufficient.

## B.12 Summary of existing legal requirements

### *B.12.1 For workers*

PGMA is listed in annex I according to the 19$^{th}$ ATP to Directive 67/548/EEC under index number: 607-195-00-7 as R10, Xi; R36; S2-25. Based on the effects assessment provided in the RAR, it has been proposed and agreed by the TCNES to simplify the classification to R10.

As a result of its classification as hazardous substance, PGMA is subject to general regulations concerning its supply and handling.

Safety Data Sheets:

In accordance with article 31 (title IV) of Regulation (EC) No 1907/2006, the supplier of a substance or a preparation that meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II.

The information system for hazardous substances and preparations in the form of labelling and the safety data sheets is considered sufficient in principle to provide the user with sufficient information for the selection of suitable occupational safety measures. The SDS should contain all relevant information from the risk assessment report.

Occupational safety and health regulations:

At the European level, the following directives are primarily applicable as general regulations for occupational safety and health of workers in the production and use of PGMA:

- 98/24/EC on the protection of workers from the risk related to exposure to chemical agent at work.
- 89/656/EEC on the use of personal protective equipment

Only limited knowledge is available about the extent to which the EU member states have in each case transposed these basic requirements into national law.

Occupational exposure Limits:

OELs apply to workplace air concentrations of chemicals. They are normally intended to protect workers against short-term adverse effects (irritation) or long-term effects (respiratory tract irritation) after months or years of exposure. When applicable, a "short-term exposure limit" (STEL) may be proposed or imposed to protect against the former effects, and/or a "time-weighted average" (TWA) for the latter. The short term value ordinarily refers to a 15 minutes or so duration, the second to a shift (generally considered as an 8-hour shift).

In accordance to Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, table 12.1 presents the OELs recommended for PGMA in various countries. They are provided for information and are not an indication of the level of control of exposure achieved in practice in workplaces.

**Table 12.1: Occupational Exposure Limit values for PGME**

| Country | 8-hr TWA | | STEL, 15 min | |
|---|---|---|---|---|
| | $mg/m^3$ | ppm | $mg/m^3$ | ppm |
| Austria | 110 | 20 | 220 | 40 |
| Denmark | 110 | 20 | - | - |
| Germany | 110 | 20 | 240 | 80 |
| Norway[a] | 110 | 20 | - | - |
| Switzerland[a] | 110 | 20 | 220 | 40 |
| Austria | 275 | 50[1] | 550 | 100 |
| Belgium | 275 | 50[1] | 550 | 100 |
| Denmark | 275 | 50[1] | 550 | 100 |
| European Union | **275** | **50[1]** | **550** | **100** |
| France | **275** | **50[1]** | **550** | **100** |

| | | | | |
|---|---|---|---|---|
| Germany | 270 | 50[1] | 270 | 50 |
| Hungary | 275 | 50[1] | 550 | - |
| Italy | 275 | 50[1] | 550 | 100 |
| Spain | 275 | 50[1] | 550 | 100 |
| Sweden | 120 | 50[1] | 400 | 75 |
| Switzerland | 275 | 50[1] | 275 | 50 |
| The Netherlands | 550 | - | | |
| United Kingdom | 274 | 50[1] | 548 | 100 |

NOTA A: WITH SKIN NOTATION
a: Directive 2000/39/CE of 8 June 2000
b: with skin notation
1: http://bgia-online.hvbg.be/LIMITVALUE

In France, a recent survey on glycol ethers exposure assessment indicates that all occupational exposures to PGMA are much below the exposure limits: for the years 2000 to 2006, the COLCHIC database collected 615 personal atmospheric sampling results of PGME. The arithmetic mean value of 60 to 480 minutes samplings was 11.58 mg/m$^3$ (median 2.34 mg/m$^3$, 95$^{th}$ percentile 39.5 mg/m$^3$; see also database extract reported in the RAR in 4.1.1.2.3 to see the decreasing tendency). There is few data which could help to extrapolate these results to other EU countries where PGMA is also produced or used.

Personal protective equipment:

According to community Legislation, workers have to be provided with suitable Personal Protection Equipment (PPE) if their health is at risk due to exposure against chemicals. PPE that protects against the risks of PGMA is available and has to be indicated in the SDS.
On account of probable irritation effects of PGMA (still classified as R36 in annex I of directive 67/548/EC), the use of suitable protective equipment is in general widely accepted, if dermal exposure cannot be excluded by other technical or organisational measures. French investigations within the framework of the assessment of occupational exposure to glycol ethers also noted that individual protections are often made available instead of collective measures to protect the workers both from dirt associated with the activities and contact with toxic products. Finally, the skin notation provided with the EU-OELs should improve the acceptance of gloves.

Considering the uncertainties highlighted along the risk assessment the legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

No data regarding the number of workers exposed are available but due to the wide range of products containing PGMA, it is assumed that a large number of workers in many professional sectors in several member states of EU may be exposed daily or occasionally. Few data are available to extrapolate most of information on workers protection collected in

France to other countries of the community. ECHA should ask the forum to work on that matter.

According to the results or in order to adopt a more protective strategy, the Commission should request the SCOEL to reconsider the OELs values adopted few years ago in the light of the risk assessment report.

### *B.12.2 For consumers*

In the RAR, it is reported that PGMA can be found in a wide variety of commercial products all over Europe, including solvents, cleaning agents, paints, varnishes, inks and adhesives. However, a recent French investigation reported in a survey on glycol ethers exposure in France, reported that the glycol ethers mainly marketed in 2006, for consumers, are in order descending: the PGME, the PGPE the DPGME the PGBE the DEGBE the DPGnBE and DEGEE[[8]]. This is in step with the information provided in the annex XV transitional dossier for PGME where two French studies did not revealed the presence of PGMA in several window cleaners or "multi-uses" house cleaners contrary to PGME. In addition, following a survey conducted in 2004 among its members, FIPEC indicated to AFSSET in 2006 that over 75% of coatings designed to paint a room or varnish parquet do not contained anymore glycol ethers. These observations were confirmed by another French investigation from INERIS [INERIS 2007]. Furthermore, among the 22% of coatings designed to paint a room or varnish parquet still containing glycol ethers, FIPEC indicated that glycol ethers could be present in formulations, either through raw materials used by manufacturers of paints and varnishes, or added by manufacturers to provide specific properties to the product manufactured. We can then find the PGMA, present in the raw materials used by members and found in less than 0,005% of manufactured paints and varnishes at concentrations up to 20% (confirms information provided in the RAR).

Based on the type of effects observed and the uncertainty related to the exposure assessment (restrictive), it seems neither appropriate nor proportional to propose a restriction as the probability that the health effects highlighted in the RAR occurs seems to be negligible.

Anyhow, in order to reduce consumer exposure to solvents based products, we highly recommend Industry to substitute as much as possible dangerous solvents in their products and industry and MS to provide a high degree of information to consumers about the use of these products and to establish a reactive vigilance on solvents based consumer's products.

## C. AVAILABLE INFORMATION ON ALTERNATIVES

To be filed in REACH-IT and used when needed: detailed information on glycol ethers and their alternative can be found in the survey joined to the dossier [[9]].

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## G. STAKEHOLDER CONSULTATION

Stakeholders have been regularly consulted in the frame of the different studies conducted in France.

## REFERENCE LIST


**[1] EUROPEAN UNION RISK ASSESSMENT REPORT: 1-METHOXYPROPAN-2-OL ACETATE (PGMA), FINAL HUMAN HEALTH RISK ASSESSMENT. 67. 28-10-2008.**
**REF TYPE: REPORT**

**[2] EUROPEAN COMMISSION, I.O.H.A.C.P.DG JOINT RESEARCH CENTRE, EUROPEAN CHEMICALS BUREAU. EUROPEAN UNION RISK ASSESSMENT REPORT: 1-METHOXYPROPAN-2-OL ACETATE (PGMA), PART I - ENVIRONMENT. S.J.MUNN, K.ASCHBERGER, O.COSGROVE, S.PAKALIN, A.PAYA-PEREZ, B.SCHWARZ-SCHULZ, AND S.VEGRO. 67. 2006. LUXEMBOURG: OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES. 2006.**
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**REF TYPE: REPORT**

**[4] EUROPEAN UNION RISK ASSESSMENT REPORT: 1-METHOXYPROPAN-2-OL ACETATE (PGMA), FINAL HUMAN HEALTH RISK ASSESSMENT. 67. 28-10-2008.**
**REF TYPE: REPORT**

**[5] EUROPEAN UNION RISK ASSESSMENT REPORT: 1-METHOXYPROPAN-2-OL ACETATE (PGMA), FINAL HUMAN HEALTH RISK ASSESSMENT. 67. 28-10-2008.**
**REF TYPE: REPORT**

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**[8] RISK & POLICY ANALYST LIMITED. ALTERNATIVES TO SPECIFIC GLYCOL ETHERS USED IN CONSUMER AND PROFESSIONAL PRODUCTS**

ANS APPLICATIONS. AFSSET. 2007.
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[9] RISK & POLICY ANALYST LIMITED. ALTERNATIVES TO SPECIFIC GLYCOL ETHERS USED IN CONSUMER AND PROFESSIONAL PRODUCTS ANS APPLICATIONS. AFSSET. 2007.
REF TYPE: REPORT

## ANNEXES