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## **2-(2-METHOXYETHOXY)ETHANOL**

CAS-No.: 111-77-3

EINECS-No.: 203-906-6

**Summary risk assessment report**

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### **SUMMARY RISK ASSESSMENT REPORT**

*Final report, July 1999*

The Netherlands

Rapporteur for the risk evaluation of 2-(2-methoxyethoxy)ethanol is the Ministry of Housing, Spatial Planning and the Environment (VROM), in consultation with the Ministry of Social Affairs and Employment (SZW) and the Ministry of Public Health, Welfare and Sport (VWS). Responsible for the risk evaluation and subsequently for the contents of this report is the rapporteur.

The scientific work on this report has been prepared by the Netherlands Organisation for Applied Scientific Research (TNO) and the National Institute of Public Health and Environment (RIVM), by order of the rapporteur.

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## **PREFACE**

This report provides a short summary with conclusions of the risk assessment report of the substance 2-(2-methoxyethoxy)ethanol that has been prepared by the Netherlands 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 original risk assessment report that can be obtained from the European Chemicals Bureau<sup>1</sup>. The present summary report should preferably not be used for citation purposes.

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<sup>1</sup> <http://ecb.ei.jrc.it>



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# 1 GENERAL SUBSTANCE INFORMATION

## Identification of the substance

CAS-No.: 111-77-3  
EINECS-No.: 203-906-6  
IUPAC name: 2-(2-methoxyethoxy)ethanol  
Synonyms: DEGME  
diethylene glycol methyl ether  
diglycol monomethyl ether  
3,6-Dioxa-1-heptanol  
Dowanol DM  
ethanol, 2,2'oxybis-, monomethyl ether  
ethanol, 2-(2-methoxyethoxy)- (6CI, 8CI, 9CI)  
Emkanol MDG  
ethylene diglycol monomethyl ether  
1-hydroxy-3,6-dioxaheptan  
beta-Methoxy-beta'-hydroxydiethyl ether  
methoxydiglycol  
methyl carbitol  
methyldiethoxol  
methyldiglykol  
methyl diglycol ether  
methyl dioxitol  
Poly-Solv DM

Molecular formula: C<sub>5</sub> H<sub>12</sub> O<sub>3</sub>  
Structural formula: CH<sub>3</sub>-O-CH<sub>2</sub>-CH<sub>2</sub>-O-CH<sub>2</sub>-CH<sub>2</sub>-OH  
Molecular weight: 120.2

## Purity/impurities, additives

Purity: 99-100%  
Impurity: ethane-1,2-diol (0-0.5%); water (0-0.1%); 2-methoxyethanol (0-0.4%);  
2(2-(2-methoxyethoxy)ethoxy)ethanol (0-0.2%)  
Additives: 2,6-di-tert-butyl-p-cresol or butylated hydroxytoluene as anti-oxidant (50-150 ppm)(added only to FSII grades)

## Physico-chemical properties

Physical state: liquid  
Melting point: -65 °C  
Boiling point: 190-196 °C  
Relative density: 1.018-1.022 g/cm<sup>3</sup>  
Vapour pressure: ≤ 0.3 (20 °C); 0.24 (25°C) hPa  
Surface tension: 34.8 mN/m at 25 °C  
Water solubility: miscible  
Partition coefficient  
n-octanol/water: -0.682 (log value)  
Granulometry: not relevant  
Conversion factors

(101 kPa, 20°C): 1 ppm = 5.01 mg/m<sup>3</sup>; 1 mg/m<sup>3</sup> = 0.20 ppm  
Flammability: none, based on flashpoint (88-91 °C), autoflammability temperature (215 °C) and structural formula and thermodynamic properties  
Explosive propert.: none, based on structural formula and thermodynamic properties  
Oxidising propert.: none, based on structural formula and thermodynamic properties

**Classification**

Classification and labelling according to the 25<sup>th</sup> ATP of Directive 67/548/EEC:

Classification: Repr. Cat 3; R 63

Labelling: Xn R63 S(2-)36/37

## 2 GENERAL INFORMATION ON EXPOSURE

The substance 2-(2-methoxyethoxy)ethanol (hereafter referred to as DEGME) belongs to the group of glycol ethers, which are mainly used as co-solvents. During 1990-1993 the annual production of DEGME in Europe was 20,000 tonnes. The annual tonnage put on the European market was about 9000 tonnes. The remaining 11,000 tonnes is exported outside the EU. No data on import are given. The EU production larger than 1,000 tonnes per year was located at six different sites. DEGME is produced by the reaction of ethylene oxide and methanol with an alkalic katalysator.

The main use of DEGME is as an anti-icing agent in jet fuel. DEGME is further used as chemical intermediate, basic chemical (processing solvent) and solvent in paints and varnishes, paint strippers, cleaning agents, self-shining emulsions, floor sealants, windscreen washer liquids, skin-cleaning products (soap) and skin-care products. Industrial and use categories are shown in **Table 2.1**. Quantitative estimates indicate that around 75% is used as anti-icing agent in jet fuel, 15% is divided over various use categories and the remaining 10% is used as chemical intermediate. More detailed figures on other categories than the anti-icing agent and chemical intermediate are currently not available.

**Table 2.1** Industrial and use categories of DEGME.

Industrial category	IC no.	Use category	UC no.
-Fuel industry	9	Fuel additive (jet fuel anti-icing agent)	28
		Fuel additives (e.g. diluent for hydraulic brake fluids)	28
-Chemical industry: chemicals used in synthesis	3	Intermediates	33
-Chemical industry: basic chemicals	2	Solvents (e.g. processing solvent for manufacturing of pharmaceuticals)	48
-Paints, lacquers and varnishes industry	14	Solvents (e.g. diluent for metal salt dryers added to oil based paints)	48
-Others	15	Cleaning/washing agents and disinfectants (e.g. solvent in aqueous floor polish)	9

## 3 ENVIRONMENT

### 3.1 EXPOSURE

DEGME may be released into the environment during its production and other life cycle steps. Emission to water is expected to be the most important entry route of DEGME. General characteristics of DEGME which are relevant for the exposure assessment are: no hydrolysis, an estimated atmospheric half-life of 16 hours (reaction with OH-radicals), ready biodegradability (but failing 10 days-window), a low Henry's law constant (i.e. low volatilisation from surface waters), a low  $K_{oc}$  (i.e. low adsorption to organic matter) and, based on a  $\log K_{ow}$  of -0.68, no bioaccumulation is expected in the environment.

For the environmental exposure assessment of DEGME both site-specific and generic emission scenarios are used for calculating the Predicted Environmental Concentrations (PECs) in the various compartments. Site-specific scenarios are based on actual data from industry on emission patterns etc., whereas generic scenarios are primarily based on model calculations. Generic scenarios are used if no data were obtained from either industry or other bodies. For the releases of DEGME during production, two site-specific and two generic scenarios are used. Releases during processing and formulation are subdivided in three subscenarios: 1. formulation as anti-icing agent in jet-fuel, 2. use as basic chemical and 3. use as chemical intermediate. The exposure assessment is based on the EU-Technical Guidance Document (TGD 1996) applying the European Union System for the Evaluation of Substances EUSES (EC 1996). Predicted Environmental Concentrations (PECs) are calculated for the various environmental compartments.

#### 3.1.1 PECs at production, processing, formulation and private use

Local PEC values for the sewage treatment plant range from 0.5 to 554 mg/l. Local PEC values for surface water range from 0.1 to 11 mg/l. Local soil concentrations in the range of 0.0004-0.2 mg/kg are estimated for the terrestrial compartment. Estimated concentrations in the air near the emission sources range from 4.8 mg/m<sup>3</sup> to less than 0.05 µg/m<sup>3</sup>. Concentrations of DEGME in worm and fish were calculated to be 0.001-0.1 mg/kg and 0.02-2.9 mg/kg, respectively.

### 3.2 EFFECTS

Short-term toxicity data are available for fish, daphnia and algae and micro-organisms. The PNEC for the aquatic compartment is extrapolated from the EC50 for Daphnia (1192 mg/l). In the case of DEGME, there are a number of reasons to deviate from the factor of 1,000 and to use a factor of 100. This extrapolation results in a PNEC of **12 mg/l** for the aquatic environment.

The PNEC for micro-organisms is extrapolated from the NOEC for *P. putida* (>10,000 mg/l) using an extrapolation factor of 10. This leads to a PNEC of **1,000 mg/l**.

Since there are no data available for directly deriving a PNEC for the terrestrial compartment the PNEC-terrestrial was estimated from the PNEC for aquatic organisms using the equilibrium partitioning approach. This results in a PNEC<sub>terrestrial</sub> of **1.4 mg/kg**.

The PNEC predators of **90 mg/kg** was estimated from the overall NOAEL of 900 mg/kg b.w./d.

### 3.3 RISK CHARACTERISATION

The environmental risk characterisation, i.e. the comparison of the PECs with the corresponding PNECs, revealed that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied (**conclusion ii**).

The local PECs in a STP and for surface water for the various environmental exposure scenarios are presented in **Table 3.1**

**Table 3.1** PEC/PNEC ratios for micro-organisms and aquatic organisms.

Scenario	PEC/PNEC <sub>micro-organisms</sub>	ratio PEC/PNEC <sub>aquatic</sub>
Specific scenario A -production	not applicable	0.2
Specific scenario B -production/processing	0.0005	0.001
Generic scenario C -production	0.008	0.07
Generic scenario D -production	0.004	0.04
Generic scenario E1 (Anti-icing agent) -formulation	0.001	0.01
Generic scenario E2 (Basic chemicals) -processing	0.6	0.9
Generic scenario E3 (Chemical intermediate) -processing	0.01	0.1

In none of the emission scenarios the PEC soil exceeds the PNEC for the terrestrial compartment (**conclusion ii**). All PEC/PNEC ratios are <0.2. In all scenarios the ratio of the PEC in fish/worm and the PNEC for predators is < 1 (**conclusion ii**). Finally, all PECs calculated for the regional scale do not exceed the corresponding PNECs (**conclusion ii**).

## 4 HUMAN HEALTH

### 4.1 EXPOSURE

The human population may be exposed to DEGME at 1) the workplace, 2) from use of consumer products and 3) indirectly via the environment.

#### 4.1.1 Workplace exposure

Dermal and inhalatory exposure is estimated for the following occupational exposure scenarios: 1. production of DEGME, including quality control sampling and drumming, cleaning of production equipment; 2. production of products containing DEGME, including transferral, mixing, quality control sampling and drumming, cleaning of mixing equipment; 3. automated application of products containing DEGME, including printing (automated application); and 4. manual application of products containing DEGME, such as spray application, brushing, rolling, cleaning (including manual transferral and mixing of such products). The exposure assessment is based on measured data (limited), analogy approach, the EPA transfer model, and the EASE model (inhalation and dermal exposure assessment). Worst case estimates for full-shift inhalation exposure vary from 2.5 mg/m<sup>3</sup> (automated application) to 21 mg/m<sup>3</sup> (production of products). The estimated skin exposure levels are between 42 mg/day (automated application) and 1950 mg/day (manual application). The conclusions on occupational exposure estimates are presented in **Table 4.1**

**Table 4.1** Conclusion on occupational exposure estimates

Scenario	Exposure		Estimated inhalation exposure level (mg/m <sup>3</sup> )						Estimated skin exposure level (mg/day) <sup>A)</sup>
	Duration (hr/day)	Frequency (day/year)	Full-shift				Short-term		
			Typical	Method <sup>B)</sup>	Worst-case	Method <sup>B)</sup>	Level	Method <sup>B)</sup>	
1: production of DEGME	6-8	100-200	2.6	Expert	5.2	EPA-LEV	10.4	Expert	210
2: production of products containing DEGME	6-8 or less	100-200	11	EPA	21	Expert	42	Expert	420
3: automated application of products containing DEGME	6-8 inhal. 0-2 skin	100-200	< 1	Analogues	2.5	EASE	12.5	Analogues	42
4: manual application of products containing DEGME	6-8	100-200	5	Analogues	10	Analogues	100	Analogues	1950

A) Skin exposure levels estimated by EASE model

B) Final result largely derived from measured = measured data from DEGME; Expert = Expert judgement considering other data; EPA-LEV = EPA transfer model considering efficient LEV; EPA = EPA transfer model without LEV; Analogues = measured data from analogues; EASE = EASE model.

### 4.1.2 Consumer exposure

DEGME is used in several products (see chapter 2), some of which are available to consumers. With respect to indicated principal consumer uses of DEGME and the availability of information especially about the concentration of DEGME in the consumer products, three exposure scenarios are considered: 1. paints, 2. paint stripper and 3. windscreen washer liquid. The CONSEXPO model, version 1.04, is used for the estimation of the exposure. CONSEXPO contains a number of models for the estimation of exposure and uptake (during use) of substances via the inhalatory, dermal and oral routes.

Results CONSEXPO model:

**1. Paints.** Assuming the use of paints 1/month for 3 hours with 5 kg/event results in an average inhalatory exposure concentration per event of  $4.1 \text{ mg/m}^3$ . The dermal exposure from vapours, was estimated to be  $55 \text{ mg/cm}^3$ . These routes simultaneously result in a total internal dose rate of  $0.56 \text{ mg/kg b.w./day}$  (yearly average) after inhalation and dermal exposure, assuming 75% and 100% absorption, respectively.

#### **2. Paint stripper/remover**

Assuming the use of paint stripper for 3 hours with 1 kg/event results in an average inhalatory exposure concentration of  $148 \text{ mg/m}^3$ . The dermal exposure from vapours was estimated to be  $300 \text{ mg/cm}^3$ . These figures may result in an internal dose rate of  $0.37 \text{ mg/kg b.w./day}$  (yearly average) after inhalatory and dermal exposure, assuming 75% and 100% absorption, respectively.

#### **3. Windscreen washer liquid**

Assuming the use of windscreen washer liquid 3/day for 3 min. with 500 mg/event results in an inhalatory exposure concentration of  $2.2 \text{ mg/m}^3$ . Dermal exposure occurring via air was negligible. This results in a total internal dose rate of  $0.02 \text{ mg/kg b.w./day}$  (yearly average) assuming 75% absorption for the inhalatory route.

### 4.1.3 Man exposed indirectly via the environment

Man can be exposed indirectly to DEGME via the emissions to the environment from production, formulation/processing and use of the substance. Estimated concentrations in the air near the emission sources for the various exposure scenarios ranged from  $4.8 \text{ mg/m}^3$  to less than  $0.05 \text{ } \mu\text{g/m}^3$ . With the EUSES program total daily human intake via air, drinking water and food are calculated for the emission scenarios. Levels ranged from 0.008 to  $0.383 \text{ mg/kg/day}$  for the various exposure scenarios. The intake via drinking water and via the leaf of crops were found to be the major routes of exposure, followed by the intake via air and fish.

## 4.2 EFFECTS

In the toxicity data set for DEGME animal and only one human study (sensitisation) were available. Most of the studies were not performed according to current standards, and were in some cases not suitable for the overall assessment.

The majority of the acute toxicity studies have not been performed to current guidelines. Based on the available data DEGME has a low acute oral and dermal toxicity,  $\text{LD}_{50}$ 's being  $\geq 5500 \text{ mg/kg b.w. (rat)}$  and  $\geq 6540 \text{ mg/kg b.w. (rabbit)}$ , respectively. No death occurred in the available inhalation studies with rats.

Based on the available skin and eye irritation studies DEGME need not to be classified as an irritant to the skin and eye. Classification as sensitising agent is not indicated.

With respect to repeated dose toxicity the available data set for oral toxicity revealed an overall NOAEL of 900 mg/kg b.w./d. In the available inhalation study no effects were observed in rats at the highest administered dose of 1060 mg/m<sup>3</sup> for 6 hour/day, 5 days/week for 90 days. In a dermal study with guinea pigs DEGME related effects were seen at all dose groups. Decreased spleen weight was observed at doses of  $\geq 200$  mg/kg b.w./d. and slight histopathological changes in the liver and elevated urinary calcium levels were seen at  $\geq 40$  mg/kg b.w./d. A marginal effect level of 40 mg/kg b.w./d. is established, however it should be noted that the size of the margins of safety and assessment factors should be judged in the light of the fact that there is no firm evidence that the observed fatty changes in the liver are an adverse effect.

DEGME is considered to be not mutagenic. Data on carcinogenicity are not available.

In fertility studies with mice and rats DEGME caused no effects in mice and rats at 4000 mg/kg b.w. in drinking water or  $\approx 610$  mg/kg b.w./d. by gavage, respectively. However, in the 6 week repeated dose study with rats the testes weight was decreased and testicular atrophy and altered sperm production was observed at 3600 mg/kg b.w./d.

In oral developmental studies no embryotoxic or teratogenic effects were observed at a dose of 200 mg/kg b.w./d. At high doses ( $\geq 1800$  mg/kg b.w./d.) visceral malformations, especially of the cardiovascular system, were observed. In the available dermal developmental study a NOAEL of 50 mg/kg b.w./d is established.

### 4.3 RISK CHARACTERISATION

#### 4.3.1 Workplace

Given the effects observed in the acute toxicity studies, the skin and eye irritation studies, the sensitisation studies, and the mutagenicity tests, and the anticipated exposure levels, it is concluded that DEGME is of no concern for workers with regard to these effects (**conclusion ii**). There are no reasons for concern with regard to carcinogenicity.

Quantitative risk characterisation is possible for the end-points repeated dose toxicity and reproduction toxicity. Conclusions are based on comparison of the estimated exposure levels and the LOAELs/NOAELs, taking into account interspecies differences, intraspecies differences, differences between experimental conditions and exposure pattern of the worker, type of critical effects, dose-response curve and confidence of the database. Given the estimated frequency of exposure (100-200 days/year) chronic exposure is assumed for risk characterisation

##### Repeated dose toxicity

Starting-point for the risk assessment for workers exposed by skin contact is the marginal LOAEL (40 mg/kg bw/d) from the semichronic dermal study in guinea pigs. The margin of safety between the marginal LOAEL and the regarding dermal exposure levels varies between 1.5 and 67, and it is concluded that DEGME introduces a risk for workers dermally exposed during production of DEGME (margin of safety 13), during production of products containing DEGME (margin of safety 7) and manual application of products containing DEGME (margin of safety 1). Risk reduction measures are indicated for these scenarios (**conclusion iii**).

Starting-point for the risk assessment for workers exposed by inhalation is the NOAEL from the semichronic inhalation study with rats (1060 mg/m<sup>3</sup>, i.e. the highest dose level tested). The margin of safety between the NOAEL and the regarding inhalation exposure levels varies between 50 and 1767, and it is concluded that no health risks due to occupational inhalation exposure are to be expected (**conclusion ii**).

Given the margin of safety from risk estimates after inhalation and after contact with the skin, it is assumed that internal exposure of the worker as result from uptake via inhalation will not significantly contribute to the risk as estimated for dermal exposure.

#### Reproductive toxicity

With respect to reproductive toxicity the risk for workers dermally exposed to DEGME is estimated starting with the NOAEL (50 mg/kg bw/d) from the dermal developmental study in rabbits. The margin of safety between the NOAEL and the regarding dermal exposure levels varies between 2 and 83, and it is concluded that developmental effects due to occupational skin contact cannot be excluded during production of products containing DEGME (margin of safety 8) and during manual application of these products (margin of safety 2) (**conclusion iii**). There are neither reproduction toxicity studies by inhalation available nor sufficient data to perform a quantitative route-to-route extrapolation (e.g. absorption data are lacking). It is expected that the margin of safety for reproduction effects after inhalation exposure will be sufficiently high because (1) comparison of the risk estimates for dermal repeated dose toxicity and dermal reproduction toxicity indicates that reproduction effects may occur at higher dose levels than the critical effects as observed in the repeated dose studies, and (2) margin of safety for chronic inhalation exposure is high (**conclusion ii**).

### 4.3.2 Consumers

Starting point for the risk characterisation are the inhalatory LC<sub>50</sub>-rat (200 mg/l), the marginal effect level (40 mg/kg b.w.) from the semichronic dermal guinea pig study (repeated dose toxicity) and the NOAEL (50 mg/kg b.w.) from the dermal developmental study in rabbits (reproductive toxicity).

#### *Scenario I Paint:*

For the use of DEGME as solvent in aqueous paint an inhalatory exposure concentration per event of 4.1 mg/m<sup>3</sup> has estimated by the CONSEXPO model in an acute scenario. The margin of safety between the 1hr inhalatory LC<sub>50</sub>-rat value of 200 mg/l and the estimated inhalatory concentration/event has been calculated to be 4.8E+4. Taken into account all data available, this margin of safety is judged to be sufficient (**conclusion ii**).

#### Repeated dose toxicity:

The margin of safety between the marginal LOAEL of 40 mg/kg b.w./day (uptake basis assuming the bioavailability via the dermal route is 100%) from the semichronic dermal study in guinea pigs and the estimated total daily uptake has been calculated to be about 70. Taken into account intra- and inter- species variation and the use of a marginal subchronic marginal effect level, it is indicated that there is concern for consumers (**conclusion iii**).

#### Reproductive toxicity

The margin of safety between the NOAEL from the dermal developmental study in rabbits (50 mg/kg b.w.) and the estimated total daily uptake has been calculated to be about 90. Taken into account intra- and inter-species variation and the occurrence of visceral malformations of the cardiovascular system at very high doses, concern for developmental effects cannot be excluded (**conclusion iii**).

#### *Scenario II Paint stripper:*

The inhalatory exposure concentration when using DEGME containing paint stripper was 148 mg/m<sup>3</sup> as calculated by the CONSEXPO model in an acute scenario. The margin of safety between the 1 hr inhalatory LC<sub>50</sub>-rat value of 200 mg/l and the estimated inhalatory concentration/event has been calculated to be about 1300 which is judged to be sufficient (**conclusion ii**).

#### Repeated dose toxicity:

The margin of safety between the marginal LOAEL of 40 mg/kg b.w./day (uptake basis assuming the bioavailability via the dermal route is 100%) and the estimated total daily uptake has been calculated to be about 100, indicating that there is concern for consumers (**conclusion iii**).

#### Reproductive toxicity:

The margin of safety between the NOAEL from the dermal developmental study in rabbits (50 mg/kg b.w., uptake basis assuming the bioavailability via the dermal route is 100%) and the estimated total daily uptake has been calculated to be about 133, indicating that concern for developmental effects cannot be excluded (**conclusion iii**).

#### *Scenario III Windscreen washer liquid:*

##### Repeated dose toxicity and reproductive toxicity

For the use of DEGME as a cleaning agent in windscreen washer liquid an inhalatory exposure concentration of 2.2 mg/m<sup>3</sup> is calculated. The total calculated internal dose (yearly average) is 20 µg/kg b.w./day. The margins of safety between the marginal effect level of 40 mg/kg b.w./day in the semi-chronic guinea pig study and reproductive dermal NOAEL of 50 mg/kg b.w. and the estimated total daily uptake have been calculated to be ≥2000. These margins of safety are judged to be sufficient (**conclusion ii**).

### **4.3.3 Man indirectly exposed via the environment**

#### a. Inhalation

##### *Repeated dose toxicity*

For the risk characterisation for humans indirectly exposed by inhalation the concentration estimates in air are compared with the observed NOAEL of ≥ 1060 mg/m<sup>3</sup> (189 mg/m<sup>3</sup> corrected for continuous exposure) from the 90-day rat study.

The margins of safety are ranging from 9.2E+3 - 9E+6 indicating no concern for human safety (**conclusion ii**).

##### *Reproductive toxicity*

There are neither reproduction toxicity studies by inhalation available nor sufficient data to perform a quantitative route-to-route extrapolation (e.g. absorption data are lacking). From the available oral repeated dose toxicity study (NOAEL 900 mg/kg b.w.) and the oral embryotoxicity study (NOAEL 200 mg/kg b.w.) it may be concluded that reproduction effects may occur at lower dose levels than the critical effects as observed in the oral repeated dose studies. However since the above calculated margins of safety for exposure by inhalation are ≥7000 it is considered unlikely that reproductive effects due to inhalation exposure will occur (**conclusion ii**).

#### b. Intake via drinking water and total intake

##### *Repeated dose toxicity*

For the risk characterisation the total daily intakes are compared with the overall oral NOAEL of 900 mg/kg b.w. from the 6-week rat study. The calculated margins of safety for all scenarios are ranging from 2400 - 2.05 E+6 indicating no concern for human safety following indirect exposure to DEGME (**conclusion ii**).

##### *Reproductive toxicity*

Starting point for the risk characterisation is the NOAEL from the oral developmental study in rats of 200 mg/kg b.w. and the total daily intakes. It is calculated that the margin of safety for the generic scenario processing of basic chemicals is 522. It is concluded that this margin of is sufficient (**conclusion ii**). The margins of safety (all ≥ 1000) for the other scenarios are also indicating no concern for developmental effects in humans following indirect exposure to DEGME (**conclusion ii**).

## **5 RESULTS OF THE RISK ASSESSMENT**

### **Environment**

- (X) ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied

### **Consumers**

- (X) iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account

Conclusion (iii) is reached because:

- health risk for the consumer are expected to occur due to the use of paint or paint stripper containing the substance.

### **Workers**

- (X) iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account

Conclusion (iii) is reached because:

- based on the information available with respect to anticipated effects after occupational dermal exposure (repeated dose studies) risk reducing measures should be taken for occupational exposure scenarios 1 (production), 2 (production of products containing DEGME) and 4 (manual application containing DEGME).
- based on the information available with respect to anticipated effects after occupational dermal exposure (developmental effects) risk reducing measures should be taken for occupational exposure scenario 2 (production of products containing DEGME) and 4 (manual application of products containing DEGME).

It might be possible that in some industrial premises these worker protection measures are already applied.

