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METHACRYLIC ACID

CAS No: 79-41-4

EINECS No: 201-204-4

Summary Risk Assessment Report

2002 **Special Publication I.01.63**

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2002

Germany

The risk assessment of methacrylic acid (MAA) has been prepared by Germany on behalf of the European Union.

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Date of Last Literature Search :	**1995**
Review of report by MS Technical Experts finalised:	**1999**
Final report:	**2002**

(The last full literature survey was carried out in 1995 - targeted searches (for example on grouting) were carried out subsequently, and information found through scanning certain sources has also been included).

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance methacrylic acid that has been prepared by Germany 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

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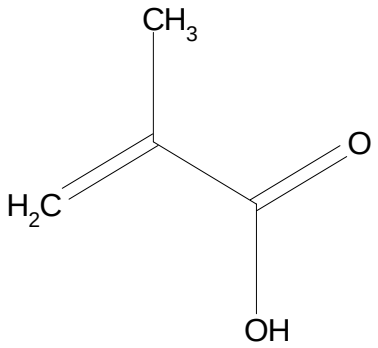
1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS-No.:	79-41-4
EINECS-No.:	201-204-4
IUPAC name:	2-propenoic acid, 2-methyl
Synonyms:	methacrylic acid (MAA)
Molecular weight:	86.09 g/mol
Molecular formula:	$C_4H_6O_2$
Structural formula:	



1.2 PURITY/IMPURITIES, ADDITIVES

Purity:	> 99% w/w
Impurity:	≤ 0.3% w/w distilled water ≤ 1.5% w/w various ester adducts α-hydroxyisobutyrate (traces)
Additives:	≤ 270 ppm hydrochinone and hydrochinone methyl ether (stabilisers)

Table 1.1 Physico-chemical properties

Physical state	liquid at 20°C
Melting point	14 - 16°C
Boiling point	159 - 163°C at 1,013 hPa
Relative density	1.015 at 20°C
Vapour pressure	0.9 hPa at 20°C
Surface tension	65.9 mN/m
Water solubility	89 g/l at 25°C
Dissociation constant	pKa = 4.66
Partition coefficient	log Pow 0.93 at 22°C log Pow 0.99
Flash point	77°C (open cup)
Flammability	365°C
Explosive properties	not explosive
Oxidizing properties	no oxidizing properties
Henry's law constant	0.087 ± 0.003 Pa · m^3 · mol^{-1}

1.3 CLASSIFICATION

Classification according to Annex I of directive 67/548/EEC[2]:

Classification:	Xn; R21/22	Harmful in contact with skin and if swallowed
	C; R35 Note D	Corrosive; Causes severe burns
Labelling:	C R: 21/22-35	S: (1/2-)26-36/37/39-45

Concentration limits: $C \geq 25\%$; C; R21/22-35
$10\% \leq C < 25\%$; C; R35
$5\% \leq C < 10\%$; C; R34
$1\% \leq C < 5\%$; Xi; R36/37/38

According to the data presented below and to the criteria of the Directive 92/21/EEC, methacrylic acid has not to be classified as dangerous to the environment.

[2] The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adapting to the technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p.1).

2 GENERAL INFORMATION ON EXPOSURE

At six sites in the European Union methacrylic acid (hereafter referred to as MAA) is produced at tonnages of > 1,000 t/a, i.e. the maximum production volumes per site are between 5,000 up to 50,000 t/a.

Taking into account the actual production volumes or production capacities provided by four producers and the upper value of the ranges given by the remaining companies in IUCLID, a total production volume of 40,000 tons is calculated. As up to 5,000 t/a are known to be imported to the EU, 45,000 t/a are assumed to be available in the European market.

MAA is used as an internal and external intermediate in the chemical industry for the production of methacrylic acid esters and as a co-monomer in different kinds of polymers. One main use of MAA is in the preparation of ethyl methacrylate and higher homologues by direct esterification. About 50 to 60 % of the MAA produced is converted into different types of esters (industrial category: chemical industry = IC 3). Most of these esters are used for the production of polymers, as it is the case for the free acid (industrial category: polymers industry = IC 11). MAA is used as a monomer in the preparation of carboxylated polymers and emulsion polymers for paints, adhesives and textile applications.

Approximately 2/3 of the total production quantity is sold to customers and not processed at the production sites.

MAA is predominantly produced via the acetone cyanohydrine route involving hydrolysis of methacrylamide sulphate. In another less important production process ethylene is used as feed stock producing MAA through an oxosynthesis by reaction of ethylene with formaldehyde and oxygen.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

Releases of MAA into the environment are to be expected during production and processing with wastewater and, to a lesser extent, exhaust gases. Regarding the formulation step relevant releases may occur during the formulation of polymer dispersions.

Further releases are expected through residual monomeric MAA contents in the final products. The residual monomer content of polymers manufactured from MAA and other monomers is expected to be between 0.001 and 0.4%.

From the use of a grouting agent containing hydroxyethylmethacrylate releases of MAA to the hydrosphere occur via drainage water.

Direct releases to agricultural or natural soil are not expected.

The environmental behaviour of MAA is determined by the following characteristics:

- the estimated atmospheric half-life is approximately 11 hours,
- MAA is readily biodegradable and stable to hydrolysis,
- evaporation from surface water is not an important fate process,
- the average K_p value of 0.5 l/kg indicates no relevant adsorption onto sediment or soil.

Based on the physico-chemical properties of MAA, the hydrosphere is the preferred target compartment and neither relevant bioaccumulation nor geoaccumulation is expected. In wastewater treatment plants (WWTPs) 87.4% of the substance is estimated to be removed predominantly by biodegradation.

Predicted Environmental Concentrations (PECs) are calculated for the local aquatic environments of the production and processing sites using all site-specific information available. Data gaps are filled with the default values proposed in the Technical Guidance Document (TGD). The resulting concentrations are in the range of 0.3 to 4 µg/l with the exception of one production site where no wastewater treatment plant is installed. For this site realistic worst-case PEC calculations of 80 to 220 µg/l are performed on the basis of measured effluent concentrations and estimated site-specific dilution factors.

MAA is also used as an external intermediate, i.e. considerable quantities are sold within the EU to non-producers/importers for processing at sites different from those considered above. A default calculation for external esterification at a fictitious site gives a PEC of 2.8 µg/l.

Besides the ester production the manufacturing of polymers is the main application area for MAA. From dry polymerisation no relevant releases with wastewater into the aquatic compartment have to be assumed. For wet polymerisation a default calculation according to the TGD results in a PEC of 66 µg/l.

Due to actual data provided by Industry it is possible to supplement the generic scenario by specific information on this downstream use. The volumes of MAA applied for wet polymerization were provided for 28 European sites covering a total annual amount of 8,120 t MAA. For four sites covering a total amount of approximately 775 t/a, zero release to the hydrosphere had been confirmed as a wastewater reutilization/recycling system is employed.

For all remaining sites where more than 100 t MAA are known to be annually handled, the calculated PECs based on the site-specific volumes, site-specific information on wastewater treatment and dilution, as far as available, and default release factors are in the range of 0.2 to 147 µg/l.

Additional exposure assessments are performed for the formulation of paints and for paper recycling, because the polymer emulsions and the paper coatings may contain residual monomeric MAA. For both scenarios PEC values of around 1 µg/l are calculated.

The private use of paints seems not to be a relevant path of exposure because only small amounts of residual monomeric MAA (at maximum 6 t/a) are handled annually for this kind of wide dispersive use. Therefore a quantitative local exposure assessment is not performed.

No monitoring data in the aquatic environment are available.

MAA measurements had been performed in the drainage water from a tunnel construction site during the application of a grouting agent containing hydroxyethylmethacrylate. High concentrations of MAA were found in the drainage water during injection of the product and the resulting PEC in the local aquatic environment is estimated to be up to 204 µg/l based on the measured concentration in the drainage water and site-specific dilution factors.

For the sediment compartment no PEC-estimation is performed, because relevant adsorption of MAA onto sediment is not expected.

For the atmosphere one generic PEC estimation representing a realistic worst case for production and external processing as well as for dry and wet polymerisation processes by downstream users is performed. A local release amount of 1 t/a is estimated using the respective emission factors proposed in the TGD and this results in a concentration in air in the vicinity of the site of 0.9 µg/m^3.

Local exposure of the atmosphere from the manufacturing, formulation and use of polymers is expected to be significantly below the generic emissions calculated above for the handling of the monomer and therefore additional quantification is not necessary.

The release of MAA to soil is expected to occur through atmospheric deposition after local release to the atmosphere. The input through sludge application on agricultural soil is considered negligible, as MAA does not partition to a significant extent to sewage sludge in the WWTP.

From the total annual deposition in the vicinity of the generic site the maximum equilibrium concentration in soil is calculated according to the procedure proposed in the TGD. The resulting bulk concentration in soil (natural soil and agricultural soil) is 0.12 µg/kg ww, the respective porewater concentration is 0.2 µg/l.

The regional background concentrations calculated according to EUSES are low and do not contribute to a significant extent to the local concentrations. The values are:

$PEC_{regional_{aquatic}}$	**=**	**0.14 µg/l**
$PEC_{regional_{air}}$	**=**	**0.1 ng/m^3**
$PEC_{regional_{agr\ soil}}$	**=**	**3 ng/kg ww**
$PEC_{regional_{agr\ soil\ porewater}}$	**=**	**5 ng/l**

3.2 EFFECTS ASSESSMENT

For fish only results from acute test are currently available, the most sensitive value, a 96-h LC_{50} of 85 mg/l is recorded for *Oncorhynchus mykiss*.

For invertebrates acute and long-term studies on *Daphnia magna* had been conducted and the most relevant value is a 21-d NOEC of 53 mg/l.

Conflicting test results are available for MAA algae toxicity with *Selenastrum capricornutum*: in a study conducted in 1990 according to US-EPA/ASTM protocols, an EC_{50} of 0.59 mg/l and a NOEC of 0.38 mg/l were derived for reduction of biomass after 96 hours test duration. A more recent and well documented investigation from 1999 according to OECD testing guideline 201 revealed about 25-fold higher effect concentrations. After careful evaluation it is concluded, that some unknown experimental particulars of the older study are regarded as a cause for considerably increased MAA toxicity. Since these experimental particulars could neither be identified nor be reproduced, the results are not used for PNEC derivation on a weight of evidence basis. From the number of EC values reported for the various test runs of the recent study from 1999 an $E_{growthrate}C_{10}$ of 8.2 mg/l from the closed vessel test run is considered as most relevant.

For the determination of the Predicted No Effect Concentration (PNEC) this EC_{10} is regarded as a long-term NOEC test result, according to the TGD. An assessment factor of 50 is proposed for a data basis like the one available for MAA and a $PNEC_{aqua}$ of 164 µg/l is derived.

For microorganisms a cell multiplication inhibition test (German standard guideline) was performed with *Pseudomonas putida*. In a neutralized medium an EC_{50} value of 270 mg/l and an EC_{10} of 100 mg/l (nominal) were measured after 16.5 hours. According to the TGD to determine the $PNEC_{microorganisms}$ an assessment factor of 1 is applied to the NOEC-value for specific bacteria and therefore the $PNEC_{microorganisms}$ is set at 100 mg/l.

There are no experimental results with benthic organisms available and there is no need for performing an indicative quantitative risk assessment for the sediment compartment, because MAA shows no relevant adsorption and there are no monitoring data on MAA-concentrations in sediment available.

It is not possible to derive a PNEC for the atmospheric compartment due to the lack of experimental data.

Data on effects to terrestrial organisms are not available. In an indicative risk assessment for the soil compartment, the aquatic PNEC of 164 µg/l can be used and compared to the concentration in soil pore water.

3.3 RISK CHARACTERISATION

The possible risks to microorganisms in wastewater treatment plants are evaluated for municipal and industrial facilities. For all considered scenarios the PEC/PNEC ratios are below one and a risk to microorganisms in the WWTPs is not expected (**conclusion (ii)**).

For surface waters, a comparison between PEC and PNEC for all relevant exposure scenarios is performed. Only for one production site a risk for the local aquatic environment is identified on the basis of measured effluent concentrations from 1998 and estimated site-specific dilution factors. The company indicated that further emission reducing measures are under way and effluent measurements are continued. From the available monitoring results for 1999 (January to October) it can be seen that effluent concentrations leading to PECs higher than the PNEC were only measured during two weeks in 1999. Therefore, it can be assumed that the identified risk is adequately handled and the indicated improvements of the emission situation at this site are further monitored (**conclusion (ii)**).

During the use of a grouting agent containing hydroxyethylmethacrylate high concentrations of MAA are released via the drainage water and a risk for the local aquatic environment has to be deduced. The exposure assessment was based on measured concentration at a tunnel construction site leading to a PEC/PNEC-ratio slightly above 1. A quantitative extrapolation to other construction sites seems not possible, but similar conditions might be anticipated. Data improvement is not the proposed option, because an environmentally safe handling of the grouting agent has to be achieved independent of the local circumstances. Therefore, risk reduction measures at Community level are recommended (**conclusion (iii)**).

From the current manufacturing and use of MAA no risk for the sediment compartment is expected (**conclusion (ii)**).

Due to the fast atmospheric photooxidation and the low resulting concentrations in air, adverse effects on organisms and abiotic effects upon the atmosphere, like global warming and ozone depletion are not expected from MAA **(conclusion (ii)**).

From an indicative risk assessment for the soil compartment no risk is deduced for the present data configuration and there is no need for further testing and/or gathering of exposure information (**conclusion (ii)**).

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure Assessment

4.1.1.1 Occupational Exposure

Methacrylic acid (MAA) is primarily used as a chemical intermediate which is further processed to methacrylic esters, homo- and copolymers. Moreover the substance is used in reactive adhesive preparations (one (anaerobic)- and two-package polymerization adhesives).

The occupational exposure limit for methacrylic acid is 70 mg/m^3 (20 ml/m^3) in Denmark, Belgium, France, Norway, Sweden, the UK, the USA and Australia. In Sweden, the short-term exposure limit is 100 mg/m^3 (30 ml/m^3) and in the UK 140 mg/m^3 (40 ml/m^3).

Occupational exposure scenarios in the chemical industry, in the industrial area and in skilled trade have to be considered.

The exposure assessment is based on measured data (limited), expert judgement and estimations according to the EASE model.

With regard to exposure via inhalation, exposure to methacrylic acid in vapour form has to be considered. Concerning dermal exposure immediate skin contact with the corrosive substance and with corrosive preparations (≥ 5 % MAA) is only assumed by single contacts. During handling of non-corrosive preparations (< 5 % MAA) frequent immediate contact has to be taken into consideration.

For tunnelling and sewer processes the use of methacrylate ester compounds as grouting agents is known. MAA is assumed to be formed from the hydroxyethylesters in alkaline milieu. Taking into account the available information exposure via inhalation to mist and vapour and dermal exposure are regarded to be of minor relevance for workers.

The results for the different scenarios are summarised in **Table 4.1**.

Table 4.1 Summary of exposure data

Area of production and use	Duration and frequency	Inhalative exposure Exposure level shift average [mg/m³]	Dermal exposure Exposure level [mg/cm²/day]	Exposed area [cm²]	Shift average [mg/p/day]
Chemical industry					
1) Production and further processing as a chemical intermediate	shift length / daily	5.6 [1]	low	---	low [1]
	single contacts	---	0 - 0.1	420 (palms of 2 hands)	0 – 42 [2]
	short term / not daily	23 [3] (short term)	---	---	---
2) Manufacture of adhesives (up to 12% MAA)	assumed 2h / daily	0.5 – 2.75 [4]	low	---	low [1]
	single contacts	---	0 - 0.1	420 (palms of 2 hands)	0 – 42 [2]
Industrial area: production of preparations					
3) Manufacture of adhesives (up to 12% MAA)	assumed 2 h / daily	0.5 – 2.75 [4] 9 – 45 [5]	low	---	low [1]
	single contacts	---	0 - 0.1	420 (palms of 2 hands)	0 – 42 [2]
Industrial area: use					
4) Use of adhesives (up to 12% MAA)					
a) ≥ 5% methacrylic acid (proposed labelling as corrosive)	assumed shift length, daily	2 – 11 [4] 36 [5]	low		low [1]
	single contacts	---	0 – 0.01	210 (fingers)	0 –2.1 [2]
b) <5% methacrylic acid (not labelled as corrosive)	contact level intermittent / assumed shift length, daily	2 – 11 [4] 36 [5]	0.005 – 0.05	210 (fingers)	1 – 10.5 [2]
Skilled trade					
5) Use of adhesives (up to 12% MAA)					
a) ≥ 5% methacrylic acid (proposed labelling as corrosive)	assumed shorter than shift length, not daily	< 36 [1]	low	---	low [1]
	single contacts	---	0 - 0.01	210 (fingers)	0 - 2.1 [2]
b) < 5% methacrylic acid (not labelled as corrosive)	contact level intermittent, assumed shorter than shift length, not daily	< 36 [1]	0.005 - 0.05	210 (fingers)	1 - 10.5 [2]

1) expert judgement
2) EASE
3) workplace management
4) EASE with LEV
5) EASE without LEV

4.1.1.2 Consumer exposure

Polymers manufactured with methacrylic acid as co-monomer are used in consumer products. Using dispersion paints, lacquers and 2-component adhesives consumers may be exposed only to residual monomers.

Dispersion paints

Assuming the use of dispersion paints 6 events/year with 13.6 kg/event results in an average inhalation concentration per event of 0.5 mg/m^3. The dermal exposure via skin (~ 0.07mg/event) and from vapours (~ 0.13 µg/event) is considered to be negligible. Thus, the total internal dose rate was calculated to be 0.0012 mg/kg bw/d (yearly average) after exposure via inhalation.

Lacquers

Assuming the use of solvent-based paints 6 events/year with 6.7 kg/event results in an average inhalation concentration per event of 1.0 mg/m^3 using the SCIES model calculations. An internal dose rate of 0.017 mg/kg bw/d was estimated as a yearly average.

2-component adhesives

Assuming the appropriate use of the adhesive (1 g of product for 1 hour, 4 events per year) a maximum concentration of 0.0125 mg/m^3 was estimated using the SCIES model. Taking into consideration that most of the methacrylic acid monomer will polymerize during the use, the residual monomer available for inhalation is much lower. Thus, an acute exposure by inhalation can be neglected.

4.1.1.3 Humans exposed via the Environment

Man can be exposed indirectly to methacrylic acid via the environment mainly by drinking water. An intake of a total daily dose of 0.15 µg/kg bw/d is calculated for the local scenario and of 4 ng/kg bw/d for the regional scenario, respectively.

4.1.1.4 Combined exposure

A person who is exposed indirectly to MAA through the environment may also be exposed through different applications via inhalation as well as via the dermal route. However, in such cases the sum of all types of exposure will be expected to amount to 1-10 µg/kg bw/d.

4.1.2 Effects Assessment

Methacrylic acid (MAA) is rapidly absorbed in rats after oral and inhalation administration. In an inhalation study deposition efficiency of 95% was measured in the surgically isolated upper respiratory tract of anaesthetised rats. However, the degree of penetration to underlying cells could not be derived from this experiment. There are no studies which specifically address the metabolism of exogenously applied methacrylic acid.

Human data on acute toxicity of MAA are not available. The main clinical sign in animal tests on acute toxicity of methacrylic acid is severe irritancy at the site of contact. The substance exhibits a potent chemical reactivity at the site of application. Oral LD_{50} values of 1,320-2,260 mg/kg for rats and a dermal LD_{50} value between 500 and 1,000 mg/kg for rabbits were determined. On the basis of these acute toxicity data, methacrylic acid will be labelled with "R 21/22 (Harmful in contact with skin and if swallowed)".

Human data on local irritation or corrosion caused by methacrylic acid are not available. The substance causes adverse effects at the site of application, depending on the concentration and frequency or time of exposure. The undiluted acid causes skin and eye corrosion and respiratory tract lesions and will therefore be classified "C, Corrosive" and labelled as "R 35, Causes severe burns".

Methacrylic acid is not sensitising as demonstrated by human experience and by animal tests.

The main effect of methacrylic acid identified in subchronic animal studies is irritation/corrosivity at the site of contact. In repeated dose inhalation studies the relevant toxic effect was irritation of the nasal mucosa. Rhinitis was observed in rats >20 ppm (71.4 mg/m³) and mice at 300 ppm (1,071 mg/m³) when animals were exposed for 90 days. Additionally, in mice degenerative lesions of the olfactory epithelium occurred at doses from 100 ppm (357 mg/m³). A NOAEL for the local effects of 20 ppm (71.4 mg/m³) was derived from a study in mice. MAA reduced body growth in mice at 300 ppm. The NOAEC for systemic toxic effects was identified to be 100 ppm in mice and 300 ppm in rats. Toxic effects after dermal or oral application routes are unknown. Due to the very low systemic availability of methacrylic acid, and the assessed exposure scenario for the consumer, there is no cause for concern on systemic toxic effects.

Methacrylic acid is negative in a bacterial gene mutation test. Further testing on methacrylic acid is lacking. However, taking into consideration the data on the structurally related substance methyl methacrylate (methyl ester of methacrylic acid) - which indicate that this substance does not express a genotoxic potential *in vivo* - there is no need for further testing.

No cancer studies on methacrylic acid are available. Focal hyperplasia of the respiratory epithelium or lymphatic hyperplasia of mandibular lymph nodes as seen in the 90-day inhalation study were not interpreted as a preneoplastic lesion; this lesions were considered to represent reactive or inflammatory processes to the irritant effect of the test substance. With respect to methyl methacrylate data, there is no concern on carcinogenic properties of methacrylic acid.

There are no data on reproductive toxicity of methacrylic acid. However, data from studies concerning the methyl ester of methacrylic acid can be taken into consideration as an alternative due to a rapid ester cleavage. On the basis of these findings, there is no concern in relation to reproductive toxicity.

4.1.3 Risk Characterisation

4.1.3.1 Workers

For the purpose of the risk assessment it is assumed that inhalation of vapour and skin exposure are the main routes of exposure.

This summary concentrates on the main points of concern with regard to the risk characterisation at workplaces.

Irritation/Corrosivity

Inhalation

A threshold for acute respiratory irritation is not described. With reference to the passage on repeated dose toxicity, it is anticipated, that the respiratory tract irritation threshold for single (8 h) exposure does not significantly differ from that for repeated (8 h) exposure. This consideration implies that the chronic irritation threshold of slightly below 20 ppm (72 mg/m³) (see "Repeated dose toxicity") may be used for the assessment of single (8 h) exposure as well. Experimental data concerning different exposure duration per day are not available. As a pragmatic, but cautious approach, it is assumed that the irritation threshold of about 20 ppm is also appropriate to assess short-term (<8 h) exposure.

In addition to the critical scenarios due to chronic inhalation exposure data on short-term exposure in the chemical industry (MOS: 3.1) and the (intermittent) use of adhesives in the skilled trade sector (MOS: > 2) are evaluated as being of (weak) concern (**conclusion (iii)**).

Repeated dose toxicity

Inhalation (local effects)

Vapours of methacrylic acid are irritant to the upper respiratory tract. The assessment of local irritation potency particularly relies on the findings of the 90-day rat and mice inhalation studies.

A NAEC for both species slightly below 20 ppm (72 mg/m^3) is assumed as a basis for occupational risk considerations.

For chronic risk assessment it may be assumed that the nasal irritation threshold for methacrylic acid will not substantially change with longer duration of exposure.

The main problem in methacrylic acid risk assessment is species extrapolation from rodents to humans. Rodents show a nasal anatomy and respiratory physiology different from man. These species differences will influence toxicokinetics of substances in the upper respiratory tract.

A CFD/PBPK model was constructed for interspecies (rat, mouse, humans) extrapolation of methacrylic acid tissue dose in the olfactory region of the nasal cavity. However, this model is not considered valid enough to account quantitatively for potential interspecies variation. Thus, for the time being, it is proposed to rely occupational risk assessment for methacrylic acid on the experimental results in the animal tests.

In conclusion, occupational risk assessment is based on an anticipated human NAEC of about 20 ppm (72 mg/m^3).

For the different exposure scenarios MOS values from 2 to 144 (lowest and highest value) are calculated. Principally, for MOS values below 1 (the exposure level exceeds the anticipated human NAEC) chronic respiratory irritation is anticipated to occur. For methacrylic acid, there are no scenarios with MOS values lower than 1. However, because of remaining uncertainties concerning the human dose-response relationship (no clear-cut experimental NOAEC, no chronic toxicity data, limited validity of the PBPK model) exposure scenarios including a MOS range of up to about 2 to 3 are considered of concern (**conclusion (iii)**).

Table 4.2 Results of the occupational risk assessment

Area of production and use	Irritation/ Corrosivity (inhal.)	Repeated dose toxicity local, inhal., MOS - conclusion
Chemical industry		
(1) Production and further processing as a chemical intermediate	iii	ii
(2) Manufacture of adhesives	ii	ii
Industrial area		
(3) Manufacture of adhesives (a) with LEV (b) without LEV	 ii iii	 ii 2 - 8 iii
(4) Use of adhesives (a) with LEV (b) without LEV	 ii iii	 ii 2 iii
Skilled trade		
(5a,b) Use of adhesives	iii	ii

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

4.1.3.2 Consumers

Repeated dose toxicity

Following the exposure assessment, the consumer may be exposed to MAA via inhalation, whereas oral and dermal exposure can be neglected. The described human exposure scenarios (dispersion paints, lacquers and 2-component adhesives) do not represent real chronic scenarios. The NOAEC for local effects of 20 ppm (71.4 mg/m^3) used for the margin of safety is derived from a 90-day inhalation study in mice. Because MAA acts primarily at the nasal cavity, systemic effects have not been considered. Taking into account the worst-case exposure scenarios (no real chronic exposure) the margin of safety is judged to be sufficient **(conclusion (ii))**.

Reproductive toxicity

Following the exposure assessment, there is no evidence for relevant exposure to methacrylic acid. There are no experimental data on reproductive toxicity of methacrylic acid available. The available data from studies with methyl methacrylate (methyl ester of methacrylic acid) did not give evidence for adverse effects on reproductive organs. Also in developmental toxicity studies with methyl methacrylate a specific teratogenic, embryo- or fetotoxic potential could not be revealed. Thus it can be concluded that there is no concern for consumers (**conclusion (ii)**).

4.1.3.3 Humans exposed via the environment

Repeated dose toxicity

For the risk characterisation the total daily intakes for the local scenario and the regional one are compared with an oral NOAEL of 167 mg/kg bw/d which was converted from the NOAEC for systemic effects (100 ppm; 0.357 mg/l) from the 90-day inhalation mouse study. The margins of safety expressed by the magnitude between the calculated exposures and the NOAEL is considered to be sufficient for both scenarios. Thus, the substance is of no concern in relation to indirect exposure via the environment (**conclusion (ii)**).

Reproductive toxicity

Following the exposure assessment, there is no evidence for relevant exposure to methacrylic acid. There are no experimental data on reproductive toxicity of methacrylic acid available. The available data from studies with methyl methacrylate (methyl ester of methacrylic acid) did not give evidence for adverse effects on reproductive organs. Also in developmental toxicity studies with methyl methacrylate a specific teratogenic, embryo- or fetotoxic potential could not be revealed. Thus it can be concluded that there is no concern in relation to indirect exposure via the environment (**conclusion (ii)**).

4.1.3.4 Combined exposure

Taking into account the sum of all types of exposure the combined exposure was estimated to amount to 1-10 µg/kg bw/d.

The margin of safety expressed by the magnitude between the estimated exposure and the NOAEL is very low. Thus, the substance is considered of no concern in relation to combined exposure (**conclusion (ii)**).

5 RESULTS

5.1 ENVIRONMENT

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

This conclusion applies to all environmental spheres regarded for the production and processing of methacrylic acid and the use of polymeric products made from methacrylic acid.

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

This conclusion is reached because of concerns for effects on the aquatic ecosystem as a consequence of exposure arising from the use of acrylate based grouting agents.

During the use of a grouting agent containing hydroxyethylmethacrylate high concentrations of methacrylic acid are released via the drainage water. The exposure assessment was based on measured concentration at a tunnel construction site. A quantitative extrapolation to other construction sites seems not possible, but similar conditions might be anticipated. Data improvement is not the proposed option, because an environmentally safe handling of the grouting agent has to be achieved independent of the local circumstances. Therefore, risk reduction measures at Community level are recommended.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

Workers

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

This conclusion is reached because of

- concerns for respiratory tract irritation as a consequence of short term inhalation exposure arising from the production, further processing as a chemical intermediate in the chemical industry, the manufacture of adhesives in the industrial area and the industrial and skilled trade use of adhesives,

- concerns for local respiratory effects as a consequence of repeated inhalation exposure arising from manufacture and use of adhesives.

Consumers

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

Humans exposed via the environment

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

Combined exposure

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

5.2.2 Human health (risks from physico-chemical properties)

MAA has no explosive or oxidising properties due to structural reasons and is not highly flammable. Therefore with regard to the physico-chemical properties and with regard to the occupational exposure and consumer exposure, MAA is not expected to cause specific concern relevant to human health.

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