

COMMISSION RECOMMENDATION**of 29 April 2004**

**on the results of the risk evaluation and the risk reduction strategies for the substances:
Acetonitrile; Acrylamide; Acrylonitrile; Acrylic acid; Butadiene; Hydrogen fluoride;
Hydrogen peroxide; Methacrylic acid; Methyl methacrylate; Toluene; Trichlorobenzene**

(notified under document number C(2004) 1446)

(Text with EEA relevance)

(2004/394/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ and in particular Article 11(2) thereof,

Whereas:

- (1) In the framework of Council Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽²⁾, which also designates for those substances the following rapporteur Member States:
- Acetonitrile, rapporteur Member State: Spain,
 - Acrylamide, rapporteur Member State: the United Kingdom,
 - Acrylonitrile, rapporteur Member State: Ireland,
 - Acrylic acid, rapporteur Member State: Germany,
 - Butadiene, rapporteur Member State: the United Kingdom,
 - Hydrogen fluoride, rapporteur Member State: the Netherlands,
 - Methacrylic acid, rapporteur Member State: Germany,

¹ OJ L 84, 5.4.1993, p. 1.

² OJ L 131, 26.5.94, p. 3.

- Methyl methacrylate, rapporteur Member State: Germany.
- (2) In the framework of Council Regulation (EEC) No 793/93 the following substances have been identified as a priority substances for evaluation in accordance with Commission Regulation (EC) No 2268/95 of 28 September 1995 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽³⁾, which also designates for those substances the following rapporteur Member States:
- Hydrogen peroxide, rapporteur Member State: Finland;
 - Toluene, rapporteur Member State: Denmark;
 - Trichlorobenzene, rapporteur Member State: Denmark;
- (3) Those rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for those substances and have suggested a strategy for limiting the risks in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 ⁽⁴⁾.
- (4) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted and has issued an opinion with respect to the risk evaluations carried out by the Member States rapporteurs.
- (5) The results of the risk evaluation are set out in the Annex.
- (6) On the basis of the measures recommended by the rapporteur, the Member States and the interested sector should where appropriate take into account the agreed risk evaluation and implement the relevant recommendations, to ensure risk to human health and the environment is controlled for each of the substances for which a risk assessment has been carried out. The Commission has also listed community legislative measures to which priority should be given.
- (7) The measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15 of Regulation (EEC) No 793/93,

HEREBY RECOMMENDS:

1. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substances:
 - (1) Acetonitrile;
CAS No 75-05-8
Einecs No 200-835-2

³ OJ L 231, 28.9.1995, p. 18.

⁴ OJ L 161, 29.6.1994, p. 3.

- (2) Acrylamide;
CAS No 79-06-1
Einecs No 201-173-7
- (3) Acrylonitrile;
CAS No 107-13-1
Einecs No 203-466-5
- (4) Acrylic acid;
CAS No 79-10-7
Einecs No 201-177-9
- (5) Butadiene;
CAS No 106-99-0
Einecs No 203-450-8
- (6) Hydrogen fluoride;
CAS No 7664-39-3
Einecs No 231-634-8
- (7) Hydrogen peroxide;
CAS No 7722-84-1
Einecs No 231-765-0
- (8) Methacrylic acid;
CAS No 79-41-4
Einecs No 201-204-4
- (9) Methyl methacrylate;
CAS No 80-62-6
Einecs No 201-297-1
- (10) Toluene;
CAS No 108-88-3
Einecs No 203-625-9
- (11) Trichlorobenzene;
CAS No 120-82-1
Einecs No 204-428-0

should take into account the results of the risk evaluation set out in the Section Risk assessment of parts 1 to 11 of the Annex for each of the substances mentioned.

2. The strategy for limiting risks set out in the Section Strategy for limiting risks of Parts 1 to 11 of the Annex to this recommendation should be implemented. Where it is considered that no risks are expected, the information should be used to ensure the current risk reduction measures are maintained.

This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substances and to the Member States.

Done at Brussels, 29 April 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

PART ONE

CAS-NO. 75-05-8

Einecs-No. 200-835-2

Structural Formula: **CH₃-C ≡ N**

Einecs Name: Acetonitrile

IUPAC Name: **Acetonitrile**

Rapporteur: Spain

Classification ⁵:
F: R11
Xn: R20/21/22
Xi: R36

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur ⁶. The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of industrial chemicals, pharmaceuticals and pesticides, and in the manufacturing of photographic film. Other uses include as a solvent in various extraction processes and in research and analytical laboratories. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, the substance is produced during biomass burning and is present in automobile exhaust, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment. The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information about these risks.

⁵ The classification of the substances is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 136, 8.6..2000, p. 1).

⁶ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity as a consequence of dermal exposure arising from use as a solvent and as an intermediate.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

The conclusions of the evaluation of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

is that there is a need for specific measure to limit the risks. The conclusion is reached because of:

- concerns for the aquatic and terrestrial ecosystems as a consequence of exposure arising from use of the substance in the pharmaceutical industry.

The conclusions of the evaluation of the risks to the environment for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on sewage treatment plants as a consequence of exposure arising from the use of the substance in the pharmaceutical industry.

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of acetonitrile emissions (eg burning of fossil fuels). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

The legislation for workers protection currently in force at Community level is considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to consider revising the current occupational exposure limit value adopted under Commission Directive 91/322/EEC⁷ to provide an indication that dermal exposure can make a contribution to the worker body burden.

for ENVIRONMENT

- that the European Commission should consider the inclusion of acetonitrile in the priority list of Annex X to Council and Parliament Directive 2000/60/EC⁸ (Water Framework Directive) during the next review of this Annex.

⁷ Commission Directive 91/322/EEC on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (OJ L 177, 5.7.1991, p. 22).

⁸ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, (OJ L 327, 22.12.2000, p. 1).

- to facilitate permitting under Council Directive 96/61/EC⁹ (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

⁹ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26).

ANNEX

PART TWO

CAS-NO. 79-06-1

Einecs-No. 201-173-7

Structural Formula: **CH₂ = CH-CONH₂**Einecs Name: **Acrylamide**

IUPAC Name: 2-propenamide

Rapporteur: United Kingdom

Classification ¹⁰:
Carc.Cat.2:R45
Muta.Cat.2:R46
Repro.Cat.3:R62
T:R25
T:R48/23/24/25
Xn:R20/21
Xi:R36/38
R43

The risk assessment is based on current practices related to the life-cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur ¹¹.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the chemical industry for the production of polyacrylamide. Other uses are as on-site preparation of polyacrylamide gels and as grouting agents. The main uses of polyacrylamide are in waste water treatment, paper and pulp processing and mineral processing; minor uses include as cosmetic additives and as soil conditioners. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore some uses may exist which are not covered by this risk assessment.

¹⁰ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to 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).

¹¹ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for mutagenicity and carcinogenicity as a consequence of exposure arising from production of the substance, use as an intermediate in the chemical industry for the production of polyacrylamide, use of polyacrylamide, use of polyacrylamide gels for electrophoresis and use of acrylamide based grouts (small and large scale applications).
- concerns for neurotoxicity and reproductive toxicity as a consequence of exposure arising from the small and large scale use of acrylamide based grouts.

The conclusions of the evaluation of the risks to

CONSUMERS

- is that risks can not be excluded at any exposure, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for neurotoxicity, reproductive toxicity, mutagenicity and carcinogenicity as a consequence of exposure resulting from the use of acrylamide based grouts in large scale construction applications.

In addition to the conclusion given above, risks cannot be excluded considering the remaining uses, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for the aquatic ecosystem as a consequence of exposure arising from the use of acrylamide based grouts in construction applications, and to indirect exposure of other organisms through contaminated water from the same use.

The conclusion of the assessment of the risks to the

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for further information and/or testing. This conclusion is reached because of:

- concerns for use of acrylamide-based grouts in construction applications. The information and/or testing requirement is:
- information to refine the risk evaluation for the environment.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

The conclusion of the assessment of the risks to the

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for HUMAN HEALTH and the ENVIRONMENT

It is recommended:

- to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC¹² for the use of acrylamide¹³ in grouts for small and large-scale applications.
- Further work may be necessary to determine if derogations can be justified
- The marketing and use restrictions proposed will eliminate the need for more information to refine the risk evaluation for the environment

for WORKERS

The legislation for worker 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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for acrylamide.

for CONSUMERS

- The existing legislative measures for consumer protection, in particular the provisions under Directive 76/769/EEC (Marketing and Use Directive) as regards substances that are carcinogenic, mutagenic and toxic to reproduction (CMR

¹² OJ L 262, 27.9.1976, p. 201.

¹³ N-methylolacrylamide-based grouts are also a potential source of free acrylamide in the grouting process and consideration should be given to examining the risks from this chemical.

substances), and Council Directive 2001/95/EC (General Product Safety) ¹⁴ as regards products are considered sufficient to address the risks identified.

¹⁴ OJ L 11, 15.1.2002, p. 4.

ANNEX

PART THREE

CAS-NO. 107-13-1

Einecs-No.203-466-5

Structural Formula: $\text{CH}_2 = \text{CH} - \text{C} \equiv \text{N}$ Einecs Name: **Acrylonitrile**

IUPAC Name: 2-propenenitrile

Rapporteur: Ireland

Classification ¹⁵
F:R11
Carc.Cat.2:R45
T:R23/24/25
Xi:R37/38
R41
R43
N:R51/53

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ¹⁶.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a monomer in the production of polymeric materials, primarily acrylic and modacrylic fibres, acrylonitrile-butadiene-styrene plastics and styrene-acrylonitrile plastics. Other uses are as a monomer in the synthesis of novel polymeric materials, production of acrylamide, adiponitrile, fatty amines and fatty alcohols.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, which do not result from the life cycle of the substance produced in or imported into the European Community, in particular, the substance is produced during combustion of fossil fuels. The assessment of the risks arising from these exposures are not part of this risk assessment. The comprehensive Risk Assessment Report, as forwarded to the

¹⁵ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 136, 8.6.2000, p.1).

¹⁶ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

Commission by the Member State Rapporteur, does however provide information which could be used to assess these risks.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic effects and carcinogenicity as a consequence of exposure arising during the production and processing of the substance.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

are that there is a need for specific measures to limit the risks. This conclusion is reached because :

- Risks can not be excluded for all exposure scenarios, as the substance is currently regarded as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measure to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic sphere as a consequence of exposure arising from production of acrylic fibres at a particular site.

The conclusion of the assessment of the risks to the
ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental sphere mentioned above are not expected. Risk reduction measures already being applied are considered sufficient

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of acrylonitrile emissions (e.g. burning of fossil fuels). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for Acrylonitrile

for CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- The existing legislative measures for the protection of consumers and humans exposed via the environment, in particular the provisions under the Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances, Council Directive 2001/95/EC (General Product Safety) as regards products, and Council Directive 96/61/EC (Integrated Pollution Prevention and Control) are considered sufficient to address the risks identified.

for the ENVIRONMENT

- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to

develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.

- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART FOUR

CAS NO. 79-10-7

Einecs-No.201-177-9

Structural Formula: **CH₂ = CH-COOH**Einecs Name: **Acrylic Acid**

IUPAC Name: 2-propenoic acid

Rapporteur: Germany

Classification ¹⁷
C:R35
Xn:R20/21/22
R10
N:R50

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ¹⁸.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the production of polyacrylates. Other uses are as an ingredient in adhesives and its occurrence as a residual monomer in adhesives, paints, binding agents, printing inks, sanitary towels, panty-liners and nappy pants. Polyacrylates are mainly used as co-builders in phosphate free washing agents, in flocculating agents and for treatment of drinking and waste water. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular, during the use of acrylate based grouting agents, as a decomposition product during the production of printed circuit boards and during the removal of paints using gas flames, which do not result from the life-cycle of the substance produced

¹⁷ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 136, 8.6.2000, p.1).

¹⁸ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for respiratory tract irritation and corrosivity as a consequence of single inhalation exposure arising from production and processing, production of adhesives containing the substance and use of adhesives containing the substance,
- concerns for local effects as a consequence of repeated inhalation exposure arising from production of adhesives containing the substance and use of adhesives containing the substance,
- concerns for general systemic toxicity as a consequence of repeated inhalation exposure arising from production and use of adhesives containing the substance.

The conclusion of the assessment of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic ecosystem as a consequence of exposure arising from wet polymerisation processes including wet production of super absorber polymers and the use of acrylate based grouts.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for further information and/or testing. This conclusion is reached because

- there is a need for better information to adequately characterise the risk to municipal waste water treatment plants as a consequence of exposure from the use of the substance for wet polymerisation including the production of super absorber polymers.

The information and/or test requirements are

- Further data reflecting integrity of native ciliate populations in sewage.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for acrylic acid.
- that employers using adhesives containing acrylic acid should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Council Directive 98/24/EC¹⁹ (Chemical Agents Directive),

¹⁹ OJ L 131, 5.5.1998, p. 11.

and of any sector specific guidance developed at national level based on this guidance.

for ENVIRONMENT

it is recommended that:

- for Acrylic Acid released from chemical grouts:
- to establish a harmonised European testing and assessment scheme for chemical grouts.
- to regulate general conditions for use of chemical grouts at EU level, including requirements on comprehensive training of planners and field personnel, whereas local aspects should be considered by the respective local supervisory authorities.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
- for Acrylic Acid used in wet polymerisation processes at downstream user sites (processing capacity > 500 t/a) and in SAP production:
- that the European Commission should consider the inclusion of acrylic acid in the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex and should consider measures such as harmonised requirements for prior authorisation of discharges and emissions into water for the respective plants.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART FIVE

CAS-NO. 106-99-0

Einecs-No. 203-450-8

Structural Formula: **CH₂ = CH – CH = CH₂**Einecs Name: **Butadiene**

IUPAC Name: 1,3-Butadiene

Rapporteur: UK

Classification²⁰
F+:R12
Carc.Cat.1:R45
Muta.Cat.2:R46

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur²¹

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the polymer industry. The major uses of 1,3-butadiene are in the manufacture of synthetic rubber such as styrene-butadiene rubber (SBR) and polybutadiene rubber, thermoplastic resins such as acrylonitrile-butadiene-styrene (ABS), and styrene-butadiene latex. It is also used as a chemical intermediate in the production of neoprene for automotive and industrial rubber goods, in the production of methylmethacrylate-butadiene-styrene (MBS) polymer, which is used as a polyvinyl chloride (PVC) reinforcing agent, and for producing adiponitrile, a nylon precursor. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

²⁰ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to 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).

²¹ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for mutagenicity and carcinogenicity as a consequence of exposure arising from production and use as an intermediate in the polymer industry.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need to limit the risks. This conclusion is reached because:

- Risks can not be excluded for all exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.
- The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE, AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the evaluation of the risks to the environment for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for butadiene .

for CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- the existing legislative measures for the protection of consumers and humans exposed via the environment, in particular the provisions under the Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances, Council Directive 2001/95/EC (General Product Safety) as regards products, and Council Directive 96/61/EC (Integrated Pollution Prevention and Control) are considered sufficient to address the risks identified.

ANNEX

PART SIX

CAS-NO. 7664-39-3

Einecs-No.231-634-8

Structural Formula:	HF
Einecs Name:	Hydrofluoric acid , anhydrous hydrofluoric acid
IUPAC Name:	Hydrogen fluoride
Rapporteur:	Netherlands
Classification ²²	T+:R26/27/28 C: R34

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ²³.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the chemical industry for the synthesis of organofluoride compounds and inorganic fluorides. Other uses are as a pickling agent for metal surfaces, an etching agent for glass surfaces and surface cleaning. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, releases of hydrogen fluoride from iron/steel and aluminium industry, glass, ceramic and brick industry, power plants and phosphate chemical producers, which does not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment. The risk assessment forwarded to the Commission by the Member State Rapporteur does however provide information which could be used to assess these risks.

²² The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000, adapting to technical progress for the 26th 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 136, 8.6.2000, p. 1).

²³ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin, eye and respiratory tract irritation and/or corrosivity, depending on the concentration, as a consequence of repeated exposure to gaseous hydrogen fluoride at production and use as an intermediate in the chemical industry and use of aqueous solutions of the substance,
- concerns for general systemic toxicity as a consequence of repeated inhalatory exposure arising from the use of aqueous solutions of the substance,
- concerns for skin irritation and/or corrosivity, depending on concentration, as a consequence of single exposure to the hydrogen fluoride liquid arising from the use of aqueous solutions of the substance,
- concerns for respiratory tract irritation and/or corrosivity, depending on concentration, as a consequence of single exposure to gaseous hydrogen fluoride at production and use as an intermediate in the chemical industry and at the use of aqueous solutions of the substance.

The conclusion of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin irritation and/or corrosivity, depending on concentration, as a consequence of single and repeated exposure to the hydrogen fluoride liquid arising from the consumer use of preparations containing the substance.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity due to repeated inhalatory exposure in the vicinity of production and processing sites of the substance.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected although concerns for risks related to the violent behaviour of the concentrated substance on contact with water and the potential formation of hydrogen on reaction of less than 65 % solutions of the substance with metals have been raised.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and ATMOSPHERE

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on local aquatic and atmospheric environmental spheres as a consequence of exposure arising from some production and use sites of the substance.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended:

- to consider at the Community level prohibition of the use in building surface cleaning (including floors) at work of hydrogen fluoride by including it in Annex III of Directive 98/24/EC (Chemical Agents Directive);
- that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) review the new information contained in the risk assessment report and recommend whether there is a need to revise the current occupational exposure limit (OEL).

for CONSUMERS

It is recommended:

- to remove hydrogen fluoride preparations classified as corrosive or toxic from the consumer market ²⁴These products do not comply with the general safety requirement of the Directive 92/59/EEC on General Product Safety ²⁵and should be immediately withdrawn. Member States should carry out an active and effective market surveillance of the situation in their territories concerning the presence of hydrogen fluoride containing consumer products, to remove these products from the market as being unsafe under the general safety obligation provisions of the Directive 92/59/EEC (General Product Safety) and to notify the Commission through the Rapid Alert System of Directive 92/59/EEC.

²⁴ Minutes of the meeting of 2 April 2003 of the Emergencies Committee of Directive 92/59/EEC (General Product Safety).

²⁵ OJ L 228, 11.8.1992, p. 24.

for the ENVIRONMENT

- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART SEVEN

CAS-NO. 7722-84-1

Einecs-No. 231-765-0

Structural Formula: **H₂O₂**

Einecs Name: **Hydrogen peroxide**

IUPAC Name: Hydrogen peroxide

Rapporteur: Finland

Classification ²⁶ O:R8
C:R35

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report as forwarded to the Commission by the Member State Rapporteur ²⁷.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as in pulp bleaching and chemicals manufacture. Other uses are in textile bleaching, disinfection in the foods processing industry, etching in the electronics industry, metal plating, degrading of proteins, tooth bleaching, professional hair dyeing and bleaching, treatment of drinking water and waste water, in numerous consumer products for hair dyeing and bleaching, household textile bleaching products, cleaning agents, contact lens disinfection, and tooth bleaching products.

²⁶ The classification of the substance is established by Commission Directive 91/325/EEC of 1 March 1991, adapting to technical progress for the 12th 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 L180, 8. 7. 1991, p. 1).

²⁷ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin, eye and respiratory tract irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from loading operations.
- concerns for skin and eye irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from bleaching of textiles (batch process), aseptic packaging (old types of immersion bath machines), peracetic acid use in breweries, etching of circuit boards (old process), metal plating, degrading of proteins.
- concerns for eye irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from hairdresser's work.
- concerns for repeated inhalation toxicity in loading operations and aseptic packaging (all machines types), etching of circuit boards (old process) and waste water treatment.

The conclusions of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for eye irritation as a consequence of exposure arising from hair dyeing and bleaching and concerns for eye irritation/corrosivity in use of textile bleaches and cleaning agents, if the actual concentration of hydrogen peroxide is >5 %.
- concerns for specific adverse effects on tooth pulp and teeth as a consequence of exposure arising from tooth bleaching with 35% of hydrogen peroxide by a dentist.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is a need for specific measures to limit the risks (applies to the workers and to the consumers) This conclusion is reached because:

- concerns for the risk of fire hazard caused by spills of the more concentrated (>25 %) hydrogen peroxide solutions on combustible materials.

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on aquatic ecosystem as a consequence of exposure arising from four production sites and use in manufacture of other chemicals.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended that:

- employers review any risk assessments produced according to Directive 98/24/EC (Chemical Agents Directive) to take into account the information contained in the risk assessment and risk reduction strategy for hydrogen peroxide produced under Regulation (EEC) 739/93, and take any necessary measures that are required.
- employers using hydrogen peroxide for the uses identified as a concern in the risk assessment (part I) should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Directive 98/24/EC, and of any sector specific guidance developed at national level based on this guidance.

for CONSUMERS

It is recommended that:

- in the framework of Commission Directive (EC) 2003/83²⁸ regarding the maximum acceptable percentage of hydrogen peroxide for tooth bleaching products used under supervision of a dentist, a concentration limit of up to 6 % hydrogen peroxide should be considered, provided appropriate conditions of use and warning are printed on the label.
- textile bleaching agents and cleaning agents which contain ≥ 5 % of hydrogen peroxide should be formulated so that the risk of eye irritation/corrosivity is diminished (e.g. viscous suspensions, cream). In the instructions, the risk of eye irritation/corrosivity should be emphasised and the percentage of H₂O₂ in the product should be indicated. For hair dyes/bleaches the above mentioned recommendations, including the percentage limit, should be considered within the framework of Community legislation on cosmetic products.
- the requirement for child-resistant fastenings in the Directive 1999/45/EC (Dangerous Preparations Directive) should be extended to all household chemicals, which may be accessible to children and contain hydrogen peroxide.

for ENVIRONMENT

It is recommended that:

- to facilitate permitting under Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.

²⁸ OJ L 238 25.9.2003, p. 27.

ANNEX

PART EIGHT

CAS-NO.79-41-4

Einecs-No. 201-204-4

Structural Formula: **CH₂ = C(CH₃)-COOH**

Einecs Name: **Methacrylic acid (MAA)**

IUPAC Name: 2-Propenoic acid, 2-methyl

Rapporteur: Germany

Classification ²⁹: C: R35
Xn: R21/22

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ³⁰

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an internal and external intermediate in the chemical industry for the production of methacrylic acid esters and as co-monomer in different kinds of polymers. Other uses are as an ingredient in adhesives and its occurrence as a residual monomer in paints and products for textile processing. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular during the use of methacrylate based grouts, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

²⁹ The classification of the substance is established by Commission Directive 2001/59/EC of 19 August 2001 adapting to 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).

³⁰ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. 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.

The conclusion of the assessment of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The 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.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for Methacrylic acid.
- that employers using adhesives containing methacrylic acid should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Directive 98/24/EC (Chemical Agents Directive) and of any sector specific guidance developed at national level based on this guidance .

for ENVIRONMENT

For methacrylic acid released from chemical grouts it is recommended:

- to establish a harmonised European testing and assessment scheme for chemical grouts.
- to regulate general conditions for use of chemical grouts at EU level, including requirements on comprehensive training of planners and field personnel, whereas local aspects should be considered by the respective local supervisory authorities.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART NINE

CAS-NO.80-62-6

Einecs-No.201-297-1

Structural Formula:	CH₂ = C(CH₃) – COOCH₃
Einecs Name:	Methyl methacrylate (MMA)
IUPAC Name:	2-methyl-propenoic acid, methyl ester
Rapporteur:	Germany
Classification ³¹	F:R11 Xi:R37/38 R43

The risk assessment is based on current practices related to the lifecycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur ³².

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in production of polymers, copolymers, adhesives, reactive resins, in transesterification and in cast sheet production. Other uses are in the production of emulsion, dispersion and solvent polymers, acrylic sheet type polymers, as an ingredient in reactive adhesives and embedding resins, floor coatings, casting resins used for dental and medical applications and the substance occurs as residual monomer in paints, as well as in other polymers used for consumer products. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular, as a decomposition product during the thermal processing of polymethyl methacrylate (PMMA), which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

³¹ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 136, 8.6.2000, p. 1).

³² The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for respiratory tract irritation and corrosivity as a consequence of inhalation exposure arising from cast sheet production, production of reactive resins, production and use of adhesives, production of paints, skilled trade area: floor coating, use of casting resins in medical applications and in orthopaedic workshops, dental laboratories and surgeries as well as in ornamental decoration,
- concerns for skin sensitisation as a consequence of dermal exposure arising from production of methyl methacrylate, polymethyl methacrylate, transesterification, cast sheet production, production of adhesives and reactive resins in chemical industry, production of adhesives, casting resins and floor coating materials, production of paints and varnishes, use of adhesives in plastics, electronics and glass industry, use of adhesives and floor coating in skilled trade area, use of casting resins in medical applications, orthopaedic workshops, dental laboratories and surgeries, manufacturing of lenses and ornamental decoration,
- concerns for local effects as a consequence of repeated inhalation exposure arising from cast sheet production, production of reactive resins, production and use of adhesives and as well as production of paints, use of casting resins in orthopaedic workshops and dental laboratories and surgeries,
- concerns for general systemic effects as a consequence of inhalation exposure arising from cast sheet production, production of adhesives, production of paints, skilled trade area: floor coating, use of casting resins in orthopaedic workshops and in ornamental decoration.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic ecosystem as a consequence of exposure arising from wet polymerisation processes.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for methyl methacrylate
- that employers using methyl methacrylate for the uses identified as a concern in the risk assessment (part I) should take note of the practical non-binding guidance to be developed by the Commission as foreseen under Article 12(2) of 98/24/EC (Chemical Agents Directive), and of any sector specific guidance developed at national level based on this guidance.

for ENVIRONMENT

for Methyl methacrylate used in wet polymerisation processes at downstream user sites (processing capacity > 5000 t/a) it is recommended:

- that the European Commission should consider whether to include methyl methacrylate on the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex and should consider measures such as harmonised requirements for prior authorisation of discharges and emissions into water for the respective plants.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART TEN

CAS-NO. 108-88-3

Einecs-No. 203-625-9

Structural Formula: **C₆H₅ – CH₃**Einecs Name: **Toluene**

IUPAC Name: Toluene

Rapporteur: Denmark

Classification³³
F:R11
Xn:R20

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur³⁴.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of other chemicals, in solvents, and adhesives, paints, lacquers, varnishes and in the mineral oil, fuel and polymer industries. Other uses reported are in the pulp, paper and board industry, textile industry, agricultural industry and electrical and electronic industry.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular the use and combustion of petroleum products, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures is not part of this risk assessment. The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

³³ The classification of the substance is established by Commission Directive 91/325/EEC of 1 March 1991, adapting to technical progress for the 12th 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 180, 8. 7. 1991, p. 1).

³⁴ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for acute toxicity as a consequence of dermal exposure arising from spraying painting or the use of adhesives,
- concerns for acute toxicity (headache, dizziness, feeling of intoxication, sleepiness and impaired functional performance) as a consequence of inhalation exposure arising from production and use as an intermediate, production of products containing the substance and use of products containing the substance,
- concerns for eye irritation as a consequence of exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for general systemic toxicity as a consequence of inhalation exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for general systemic toxicity as a consequence of dermal exposure arising from use of products containing the substance in the sectors of manual cleaning, use of adhesives and spray painting,
- concerns for general systemic toxicity as a consequence of the combined dermal and inhalatory exposure arising the use of products containing the substance in the sectors of manual painting,
- concerns for specific organ toxicity (auditory system toxicity) as a consequence of inhalation exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for fertility and developmental effects and spontaneous abortions as a consequence of inhalation exposure arising from production of products and use of toluene containing products in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating).

The conclusions of the evaluation of the risks to

CONSUMERS

1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for acute toxicity (headache, dizziness, feeling of intoxication, sleepiness and impaired functional performance) and eye irritation as a consequence of inhalation exposure or eye exposure to vapours arising from spray painting and carpet laying.
2. is that there is a need for further information and/or testing. This conclusion is reached because
 - concerns for effects on reproduction as a consequence of inhalation exposure.

The information and/or test requirement is:

- information on the relationship between the observed effects on reproduction and the duration of the exposure leading to these effects.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on humans due to the contribution of commercial product toluene to the formation of ozone and other harmful substances, i.e., smog formation.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the aquatic ecosystem as a consequence of exposure arising from some sites of production and combined production and processing of the substance, as well as exposure arising from processing and the use sectors of basic chemicals (including processing aid, “extraction” agent and solvent), processing and formulation, mineral oil and fuel formulation, formulation of polymers, formulation of paints and textile processing.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for terrestrial ecosystem as a consequence of exposure arising from processing as well as exposure arising from the use sectors of basic chemicals (including processing aid, “extraction” agent and solvent), processing and formulation, mineral oil and fuel formulation, formulation of polymers, formulation of paints and textile processing.

The conclusion of the assessment of the risks for

ATMOSPHERE

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the contribution of the commercial product toluene to the formation of ozone and other harmful substances, i.e. smog formation.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for sewage treatment plants as a consequence of exposure arising from processing of the substance as well as in the use sectors of industry use as basic chemicals.

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of toluene emissions (e.g. gasoline and crude oil). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

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.

Within this framework it is recommended:

- that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) review the new information contained in the risk assessment report and recommend whether there is a need to revise the current OEL.

for CONSUMERS

It is recommended:

- to consider at Community level marketing and use restrictions in Directive 76/769/EEC for the substance as such or in preparations for use in adhesives and spray paint.
- The marketing and use restrictions proposed will eliminate the need for more information on reproduction as a consequence of inhalation exposure.

for ENVIRONMENT and HUMANS EXPOSED VIA THE ENVIRONMENT

It is recommended:

- that the European Commission should consider the inclusion of toluene in the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex but that, in the meantime, toluene should be considered as a relevant List II substance in Council Directive 76/464/EEC³⁵ on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, thus requiring the establishment of national quality objectives, monitoring and eventual reduction measures, as to ensure that concentrations in surface water systems do not exceed the quality objective.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) that this substance is included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

³⁵

OJ L 129, 18.5.1976, p 23.

The proposal from the Commission to limit the content of solvents in certain products would further limit the risk from toluene to man via the environment³⁶

³⁶ Proposal for a Directive on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (COM(2002) 750 final).

ANNEX

PART ELEVEN

CAS-NO. 120-82-1

Einecs-No. 204-428-0

Structural Formula:	C₆H₃Cl₃
Einecs Name:	1,2,4-Trichlorobenzene (TCB)
IUPAC Name:	1,2,4-Trichlorobenzene
Rapporteur:	Denmark
Classification ³⁷	Xn:R22 Xi:R38 N:50-53

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ³⁸.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of herbicides and as a process solvent in closed systems. Other uses reported include as a solvent, dye carrier in textile industry, additive in dielectric fluids and corrosion inhibitor. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, from certain 1,2,4-trichlorobenzene containing dielectric fluids still in use in existing electrical equipment and environmental formation of 1,2,4-trichlorobenzene as a decomposition product of other, more complex organo-chlorine compounds, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment.

The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

³⁷ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to 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. 30).

³⁸ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

The risk assessment indicates that it should be further investigated if the substance should be considered in relation to national or international programmes addressing persistent organic pollutants.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for further information and/or testing. This conclusion is reached because:

- concerns for effects as a consequence exposure

The information and/or test requirements are

- information on occupational exposure during the use of the substance as a dye carrier and as a process solvent, during production of products containing the substance in the sector of production of dielectric fluids and during the use of products containing the substance in the sector of production of wire and cabling.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity as a consequence of repeated inhalation exposure arising from drumming activities in the production of the substance, from the production of products containing the substance in the sector of pigment production and from the use of products containing the substance in the sector of spray painting,
- concerns for eye and respiratory tract irritation as a consequence of repeated exposure to the vapour of the substance arising from the production of products containing the substance in the sector of pigment production and from the use of products containing the substance in the sector of production of plastic pellets,
- concerns for general systemic toxicity and local dermal effects as a consequence of repeated dermal exposure arising from the use of the products containing the substance in the sectors of spray painting, dismantling transformers and polishing,

The conclusions of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for eye and respiratory tract irritation as a consequence of repeated exposure to vapours and general systemic toxicity as a consequence of repeated inhalation and dermal exposure arising from spray painting and car polishing.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for indirect exposure as calculated exposures can exceed WHO TDIs, and WHO guideline values in drinking water for local use scenarios.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the aquatic ecosystem and terrestrial ecosystem as a consequence of exposure arising from the use of the substance as a dye carrier and other uses (including as a process solvent, additive in dielectric fluids and a corrosion inhibitor).

The conclusion of the assessment of the risks to the

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for sewage treatment plants as a consequence of exposure arising from use as an intermediate, as well as from the use sectors of basic chemicals as a solvent, textile industry as dye carrier and other downstream uses.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level and in particular the provisions under Commission Directive 2000/39/EC³⁹ establishing a first list of indicative exposure limit values are generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

The marketing and use restrictions proposed for the environment will also reduce the risk for human health (workers) and eliminate the need for more information on the occupational exposure scenarios.

for CONSUMERS, the ENVIRONMENT and HUMANS EXPOSED VIA THE ENVIRONMENT

It is recommended:

- to consider marketing and use restrictions at Community level in Council Directive 76/769/EEC for all uses of TCB except as an intermediate to protect the environment and to reduce the indirect exposure via the environment. Where appropriate, marketing and use restrictions of articles containing TCB should also be considered.

³⁹ OJ L 142, 16.6.2000, p. 47.