

Please find below the Commission Communication and the Commission Recommendation for substance

Dibutylphthalate

CAS 84-74-2

EINECS: 201-557-4

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Commission Communication on the results of the risk evaluation and the risk reduction strategies for the substances: Dibutylphthalate; 3,4-Dichloroaniline; Di-'isodecyl' phthalate; 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich; Di-'isononyl' phthalate; 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; Ethylenediaminetetraacetate; Methyl acetate; Monochloroacetic acid; n-Pentane; Tetrasodium ethylenediaminetetraacetate

(2006/C 90/04)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ involves the data reporting, priority setting, risk evaluation and, where necessary, development of strategies for limiting the risks of existing substances.

In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulations (EC) No 1179/94 ⁽²⁾, (EC) No 2268/95 ⁽³⁾ and (EC) No 143/97 ⁽⁴⁾ respectively concerning the first, second and third list of priority substances as foreseen under Regulation (EEC) No 793/93:

- Dibutylphthalate,
- 3,4-Dichloroaniline,
- Ethylenediaminetetraacetate,
- Methyl acetate,
- Tetrasodium ethylenediaminetetraacetate,
- Di-'isodecyl' phthalate,
- 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich,
- Di-'isononyl' phthalate,
- 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich,
- n-Pentane,
- Monochloroacetic acid.

The rapporteur States designated pursuant to those Regulations have completed the risk evaluation activities with regard to man and the environment for those substances 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 ⁽⁵⁾ and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued an opinion with respect to the risk evaluations carried out by the rapporteurs. These opinions can be found on the website of the Scientific Committee.

Article 11(2) of Regulation (EEC) No 793/93 stipulates that the results of the risk evaluation and the recommended strategy for limiting the risks shall be adopted at Community level and published by the Commission. This Communication, together with the corresponding Commission Recommendation ⁽⁶⁾, provides the results of risk evaluations ⁽⁷⁾ and strategies for limiting the risks for the above mentioned substances.

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJ L 131, 26.5.94, p. 3.

⁽³⁾ OJ L 231, 28.9.1995, p. 18.

⁽⁴⁾ OJ L 25, 28.1.1997, p. 13.

⁽⁵⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁶⁾ OJ L 104, 13.4.2006.

⁽⁷⁾ 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 results of the risk evaluation and strategies for limiting the risks provided for in this communication are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93.

PART 1

CAS-NO. 84-74-2

Einecs-No. 201-557-4

Structural Formula: C₆H₄ — (COOC₄H₉)₂

Einecs Name: **Dibutylphthalate**

IUPAC Name: Dibutylphthalate

Rapporteur: Netherlands

Classification (⁸): Repr. Cat. 2: R61

Repr. Cat. 3: R62

N: R50

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 (⁹). The conclusion for the atmosphere is the result of further testing and is described in the addendum to the Risk Assessment Report.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a plasticiser in resins and polymers. Other uses are in printing inks, adhesives, sealants/grouting agents, nitrocellulose paints, film coatings and glass fibres and cosmetic 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.

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 repeated dermal exposure arising from aerosol forming activities.
- concerns for adverse local effects in the respiratory tract as a consequence of repeated inhalation exposure in all occupational exposure scenarios.

The conclusions of the evaluation of the risks to

⁽⁸⁾ 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.

⁽⁹⁾ The comprehensive Risk Assessment Report and its addendum, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>

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 ⁽¹⁰⁾.

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 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

ATMOSPHERE

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

- the anticipated risk for plants due to atmospheric exposure at local scale from processing in polymers, formulation in adhesives, use of printing inks and processing in glass fibres.

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.

⁽¹⁰⁾ Commission Decision 1999/815/EC pursuant to article 9 of Council Directive 92/59/EEC (OJ L 315, 9.12.1999) and its subsequent prolongations.

Within this framework it is recommended

- to establish at community level occupational exposure limit values for dibutylphthalate according to Directive 98/24/EC ⁽¹⁾.

for CONSUMER

- to consider at Community level restrictions in Council Directive 76/769/EEC ⁽²⁾ (Marketing and Use Directive) for the use of dibutylphthalate in toys and childcare articles due to the classification of dibutylphthalate at a category 2 substance toxic to reproduction and to prevent the use of dibutylphthalate as a replacement for other plasticisers for this application. As regards other uses the existing legislative measures for consumer protection, in particular the provisions under Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances, are considered sufficient to address risks identified to consumers.

for the ENVIRONMENT

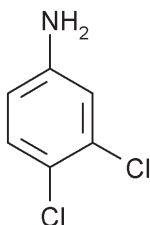
- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) dibutylphthalate should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

PART 2

CAS-NO. 95-76-1

Einecs-No. 202-448-4

Structural Formula:



Einecs Name: **3,4-Dichloroaniline (3,4-DCA)**

IUPAC Name: 1-Amino-3,4-dichlorobenzene

Rapporteur: Germany

Classification ⁽³⁾: T: R23/24/25

Xi: R41, R43

N: R50-53

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 ⁽⁴⁾.

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ OJ L 262, 27.9.1976, p. 201.

⁽³⁾ Commission Directive 2004/73/EC of 29 April 2004, adapting to technical progress for the 29th 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 152, 30.4.2004, p. 1-311

⁽⁴⁾ 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 has, based on the available information, determined that in the European Community the substance is mainly used as a chemical intermediate in production of phenylurea and phenylcarbamate herbicides. Other uses reported are in the production of azo disperse dyes for polyester fibres, and in the production of trichlorocarbanilide which is used as bactericide in household 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 metabolite from its subsequent products, e.g. the plant protection agents diuron, linuron and propanil, and the bactericide trichlorocarbanilide (TCC). The assessment of the risks arising from these exposures are considered in the risk assessment. Environmental emissions of 3,4-dichloroaniline from the use of diuron as antifouling agent and as algicide in the construction sector have to be expected. These releases could not be taken into account in the risk characterisation, but may be assessed in due time under the Biocides Directive (98/8/EC) ⁽¹⁵⁾.

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 skin sensitisation as a consequence of dermal exposure arising from cleaning, maintenance and repair work in the production and further processing of 3,4-dichloroaniline.

The conclusion of the assessment of the risks to

CONSUMERS, HUMANS EXPOSED VIA THE ENVIRONMENT and 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

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.

⁽¹⁵⁾ OJ L 123, 24.4.1998, p. 1

The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM

are:

1. that there is a need for specific measures to limit the risks. The conclusion is reached because of:
 - concerns for effects for the environmental sphere mentioned above as a consequence of exposure arising from the non-agricultural use of diuron as total herbicide on sealed areas.

and

2. 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 risks to the aquatic ecosystem arising from the release from non-agricultural use of diuron on sealed areas as total herbicide.

The information and/or test requirements are:

- long term test on sediment organism *Hyalella azteca*.

However, this requirement for further testing was awaiting the outcome of the risk reduction strategy for the aquatic compartment. Because the measures recommended are expected to sufficiently reduce concentrations in the aquatic compartment, the test is now no longer deemed necessary.

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 are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

TOP PREDATORS VIA ACCUMULATION UP THE FOOD CHAIN

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.

PART 3

CAS-NO. 26761-40-0

Einecs-No. 247-977-1

Structural Formula:

Einecs Name: **di- 'isodecyl' phthalate (DIDP)**

IUPAC Name:

Rapporteur: France

Classification: Not classified.

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 Reports as 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 plasticiser in PVC applications. Other uses are polymer related or as constituents of inks and paints and sealing compounds.

RISK ASSESSMENT**A. Human health**

The conclusion of the assessment of the risks to

WORKERS, 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 applied are considered sufficient ⁽¹⁷⁾.

If the substance would be used as a plasticiser in PVC used for toys and childcare articles, then there would be a need for specific measures to limit the risks. The conclusion would be reached because of:

- concerns for infants and new born babies for general systemic toxicity as a consequence of oral exposure from toys and childcare articles containing 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. Risk reduction measures already being applied are considered sufficient.

⁽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/>

⁽¹⁷⁾ Commission Decision 1999/815/EC pursuant to article 9 of Council Directive 92/59/EEC (OJ L 315, 9.12.1999) and its subsequent prolongations.

B. Environment

The conclusion of the assessment of the risks to the

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 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 THE RISKS

for CONSUMERS

- to consider at Community level restrictions in Council Directive 76/769/EEC ⁽¹⁸⁾ (Marketing and Use Directive) for the use of DIDP in toys and childcare articles.

PART 4

CAS-NO. 68515-49-1

Einecs-No. 271-091-4

Structural Formula:

Einecs Name: **1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich**

IUPAC Name:

Rapporteur: France

Classification: Not classified.

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 Reports as forwarded to the Commission by the Member State Rapporteur ⁽¹⁹⁾.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a plasticiser in PVC applications. Other uses are polymer related or as constituents of inks and paints and sealing compounds.

⁽¹⁸⁾ OJ L 262, 27.9.1976, p. 201

⁽¹⁹⁾ 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, 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 applied are considered sufficient ⁽²⁰⁾.

If the substance would be used as a plasticiser in PVC used for toys and childcare articles, then there would be a need for specific measures to limit the risks. The conclusion would be reached because of:

- concerns for infants and new born babies for general systemic toxicity as a consequence of oral exposure from toys and childcare articles containing 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. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

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 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 THE RISKS

for CONSUMERS

- to consider at Community level restrictions in Council Directive 76/769/EEC ⁽²¹⁾ (Marketing and Use Directive) for the use of the substance in toys and childcare articles.

⁽²⁰⁾ Commission Decision 1999/815/EC pursuant to article 9 of Council Directive 92/59/EEC (OJ L 315, 9.12.1999) and its subsequent prolongations.

⁽²¹⁾ OJ L 262, 27.9.1976, p. 201

PART 5

CAS-NO. 28553-12-0

Einecs-No. 249-079-5

Structural Formula:

Einecs Name: **di-'isononyl' phthalate (DINP)**

IUPAC Name:

Rapporteur: France

Classification: Not classified

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 Reports as forwarded to the Commission by the Member State Rapporteur ⁽²²⁾.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a plasticiser in PVC applications. Other uses are polymer related or as constituents of adhesives, paints, varnishes and sealing compounds.

RISK ASSESSMENT**A. Human Health**

The conclusion of the assessment of the risks to

WORKERS, 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 ⁽²³⁾.

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

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 are not expected. Risk reduction measures already being applied are considered sufficient.

⁽²²⁾ 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/>

⁽²³⁾ Commission Decision 1999/815/EC pursuant to article 9 of Council Directive 92/59/EEC (OJ L 315, 9.12.1999) and its subsequent prolongations.

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 THE RISKS

for CONSUMERS

- In light of the divergent scientific views between the CSTEE ⁽²⁴⁾ and the conclusions of the assessment of the risk for consumers under this Regulation, and taking into account the uncertainties in the evaluation of exposure to DINP from toys and childcare articles, precautionary considerations support the consideration at Community level of proportionate restrictions in Council Directive 76/769/EEC ⁽²⁵⁾ (Marketing and Use Directive) for the use of DINP in toys and childcare articles. Such measures should be reviewed after 3-4 years, in light of further scientific developments.

PART 6

CAS-NO. 68515-48-0

Einecs-No. 271-090-9

Structural Formula:

Einecs Name: **1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich**

IUPAC Name:

Rapporteur: France

Classification: Not classified

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 Reports as forwarded to the Commission by the Member State Rapporteur ⁽²⁶⁾.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a plasticiser in PVC applications. Other uses are polymer related or as constituents of adhesives, paints, varnishes and sealing compounds.

RISK ASSESSMENT

A. Human Health

The conclusion of the assessment of the risks to

WORKERS, 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:

⁽²⁴⁾ Opinion on the results of the risk assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-isononyl phthalate, report version (Human Health Effects), 27th CSTEE plenary meeting, Brussels, 30 October 2001.

⁽²⁵⁾ OJ L 262, 27.9.1976, p. 201

⁽²⁶⁾ 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 shows that risks are not expected. Risk reduction measures already being applied are considered sufficient ⁽²⁷⁾.

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

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 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 THE RISKS

for CONSUMERS

- In light of the divergent scientific views between the CSTEE ⁽²⁸⁾ and the conclusions of the assessment of the risk for consumers under this Regulation, and taking into account the uncertainties in the evaluation of exposure to the substance from toys and childcare articles, precautionary considerations support the consideration at Community level of proportionate restrictions in Council Directive 76/769/EEC ⁽²⁹⁾ (Marketing and Use Directive) for the use of the substance in toys and childcare articles. Such measures should be reviewed after 3-4 years, in light of further scientific developments.

⁽²⁷⁾ Commission Decision 1999/815/EC pursuant to article 9 of Council Directive 92/59/EEC (OJ L 315, 9.12.1999) and its subsequent prolongations.

⁽²⁸⁾ Opinion on the results of the risk assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-isononyl phthalate, report version (Human Health Effects), 27th CSTEE plenary meeting, Brussels, 30 October 2001.

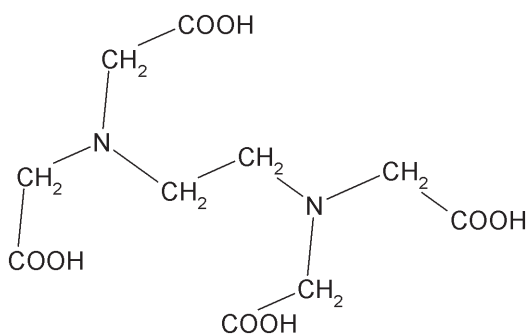
⁽²⁹⁾ OJ L 262, 27.9.1976, p. 201

PART 7

CAS-NO. 60-00-4

Einecs-No. 200-449-4

Structural Formula:



Einecs Name:	Ethylenediaminetetraacetate (EDTA)
IUPAC Name:	{[2-(Bis-carboxymethyl-amino)-ethyl]- carboxymethyl-amino}- acetate
Rapporteur:	Germany
Classification ⁽³⁰⁾ :	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 risk assessment forwarded to the Commission by the Member State Rapporteur.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a complexing agent in many industrial branches, e.g. in cleaning products for industry and skilled trades, photochemicals, agriculture, pulp and paper industry, household laundry and cleaning products, textile industry, electroplating industry, cosmetics and water treatment.

RISK ASSESSMENT**A. Human Health**

The conclusion of the assessment of the risks to

WORKERS

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

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:

⁽³⁰⁾ Commission Directive [...], adapting to technical progress for the 30th 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, to be published.

- 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)

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

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 the

AQUATIC ECOSYSTEM

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

- concerns for environmental effects to environmental spheres mentioned above as a consequence of exposure arising from the use of EDTA in industrial detergents, by paper mills, circuit board producers and releases during recovery of EDTA containing wastes.

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 the ENVIRONMENT

it is recommended:

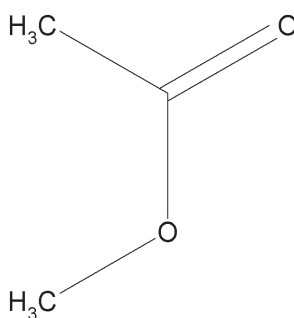
- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control), EDTA should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).
- to take persistent complexing agents into account in the European eco-labelling of paper products and to extend the existing European eco-labelling for cleaners to industrial cleaners under Regulation 1980/2000/EC ⁽³¹⁾.

PART 8

CAS-NO. 79-20-9

Einecs-No. 201-185-2

Structural Formula:



Einecs Name: **Methyl acetate**

IUPAC Name: Methyl acetate

Rapporteur: Germany

Classification ⁽³²⁾: F; R11

Xi; R36

R66, R67

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 risk assessment forwarded to the Commission by the Member State Rapporteur ⁽³³⁾.

The risk assessment has, based on available information, determined that in the European Community the substance is mainly used as a solvent in adhesives, paint systems, cosmetic agents and cleaning products. Furthermore the substance is used as an intermediate in the manufacture of plant protection products, vitamins and as an intermediate for the production of sweeteners. 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.

⁽³¹⁾ OJ L 237, 21.9.2000, p. 1.

⁽³²⁾ Commission Directive [...], adapting to technical progress for the 30th 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, to be published.

⁽³³⁾ 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 acute inhalation exposure arising from flooring works and building trade,
- concerns for local effects in the respiratory tract as a consequence of repeated inhalation exposure arising from manufacture and further processing as a chemical intermediate, production of formulations (paints, lacquers, adhesives, cleanser), metal treatment, electro-engineering, wood treatment, pulp and paper production (paints and adhesives), flooring works, building trade and use of cosmetics,
- concerns for systemic effects as a consequence of repeated inhalation exposure arising from the production of formulations (paints, lacquers, adhesives, cleanser), metal treatment, electro-engineering, wood treatment, pulp and paper production (paints and adhesives), flooring works, building trade
- concerns for developmental toxicity as a consequence of inhalation exposure arising from flooring works and building trade.

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 risk are not expected. Risk reduction measures already being applied are considered to be 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

ATMOSPHERE, AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing and 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 and 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:

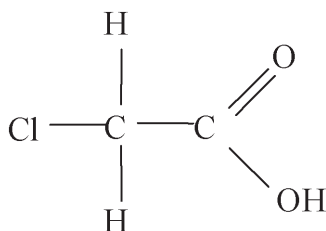
- to establish at community level occupational exposure limit values for methyl acetate according to Directive 98/24/EEC ⁽³⁴⁾.

PART 9

CAS-NO. 79-11-8

Einecs-No. 201-178-4

Structural Formula:



Einecs Name: **Monochloroacetic acid (MCAA)**

IUPAC Name: 2-Chloro-ethanoic acid

Rapporteur: Netherlands

Classification ⁽³⁵⁾: T; R23/24/25

C; R34

N; R50

⁽³⁴⁾ OJ L 131, 5.5.1998, p. 11

⁽³⁵⁾ Commission Directive [...], adapting to technical progress for the 30th 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, to be published.

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 ⁽³⁶⁾.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a chemical intermediate for the synthesis of other products like carboxymethylcellulose (CMC), carboxymethyl starch, crop protection chemicals (like 2,4D and MCPA), plastics, thioglycol acid, sodium salt of MCAA and other products such as esters and amides.

Other uses are as a constituent in acidic paint remover or graffiti remover, can coating for food (i.e. as modifier for resins) escharotic agent, wart remover, anti-microbial additive for food and analytical reagent. However, these are not identified as current or significant consumer uses in the EU, therefore this risk assessment has not identified any risks for consumers.

The risk assessment has identified other sources of exposure to the substance for man and the environment, in particular, the substance can be formed (indirectly) in the atmosphere from industrial chlorinated chemicals. Besides anthropogenic sources, the substance is also expected to be formed *de novo* in the environment, 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 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, which could be used to assess these risks.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

1. is that there is a warning that molten/liquid MCAA is very dangerous for dermal exposure. Following accidental dermal exposure to molten/liquid MCAA, fatal and non-fatal cases of severe acute systemic intoxication have been reported.
2. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for acute toxic effects as a consequence of short-term dermal exposure, arising from the use of MCAA in paint removers;
 - concerns for acute toxic effects as a consequence of short-term inhalation exposure arising from most scenarios (exceptions are the subscenarios: 'Production and cleaning and maintenance in production' and 'Use of solids');
 - concerns for dermal irritation as a consequence of exposure arising from the use of MCAA in paint removers without worker protection measures e.g. PPE;
 - concerns for respiratory (sensory) irritation as a consequence of exposure arising from the production of monochloroacetic acid: transfer of molten monochloroacetic acid and transfer of 80 % monochloroacetic acid;

⁽³⁶⁾ 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/>

- concerns for systemic effects as a consequence of repeated dermal exposure arising from the use of MCAA in paint removers;
- concerns for systemic effects as a consequence of repeated inhalation exposure arising from the production of monochloroacetic acid: transfer of molten monochloroacetic acid and transfer of 80 % monochloroacetic acid and the use of MCAA in paint removers.

3. 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 risks regarding concerns for effects on reproduction as a consequence of exposure to MCAA.

The information and/or test requirement is:

- a developmental toxicity study should be performed, awaiting the opinion of the Scientific Committee on Occupational Exposure Limits (SCOEL) on the necessity of such a study.

The conclusions of the evaluation of the risks to

CONSUMERS

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 risks regarding concerns for effects on reproduction as a consequence of exposure to MCAA.

The information and/or test requirement is:

- a developmental toxicity study should be performed, awaiting the opinion of the Scientific Committee on Occupational Exposure Limits on the necessity of such a study (see workers section).

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

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

- concerns for systemic effects as a consequence of possible repeated exposure to drinking water arising from one local production site.
- concerns for systemic effects as a consequence of possible repeated exposure to leaf crops arising from high emissions to air for one local processing site.

2. 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 risks regarding the effects on reproduction as a consequence of exposure.

The information and/or test requirements are:

- a developmental toxicity study should be performed, awaiting the opinion of the Scientific Committee on Occupational Exposure Limits on the necessity of such a study (see workers section).

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 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 conclusions 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 the local aquatic environmental spheres as a consequence of exposure arising from two production/processing sites of the substance.

The conclusions 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:

there is a need for better information to adequately characterise the risks to the terrestrial environmental spheres regarding the natural and anthropogenic emission sources of background levels of MCAA from unintentional sources.

The information and/or test requirements are

- further data reflecting the relative contributions from natural and anthropogenic emission sources of MCAA.

The conclusions of the evaluation 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 one production/processing site of the substance.

STRATEGY FOR LIMITING RISKS

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 establish at community level occupational exposure limit values for MCAA according to Directive 98/24/EC ⁽³⁷⁾;

for the ENVIRONMENT and HUMANS EXPOSED INDIRECTLY VIA THE ENVIRONMENT

- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) MCAA should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

PART 10

CAS-No. 109-66-0

EINECS-No. 203-692-4

Structural Formula: CH₃-CH₂-CH₂-CH₂-CH₃

EINECS Name: **n-Pentane**

IUPAC Name: n-pentane

Rapporteur: Norway

Classification ⁽³⁸⁾: F+; R12

Xn; R65, R66, R67

N; R51-53

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.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a foaming agent for polystyrene and polyurethane in the polymers industry. It is also used as a solvent in aerosols and as a solvent in polymerisation processes. Other uses include use as a solvent in adhesive formulation and use as a laboratory chemical.

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.

⁽³⁷⁾ OJ L 131, 5.5.1998, p. 11

⁽³⁸⁾ Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25th 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 355, 30.12.1998, p. 1

RISK ASSESSMENT:**A. Human health**

The conclusion of the assessment of the risks to

WORKERS

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

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 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 isolated n-pentane to the formation of ozone in ambient air.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physico-chemical 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

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 isolated n-pentane to the formation of ozone in ambient air.

The conclusion of the assessment of the risks to the

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 are not expected. Risk reduction measures already being applied are considered sufficient.

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 are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for the ENVIRONMENT and HUMANS EXPOSED VIA THE ENVIRONMENT

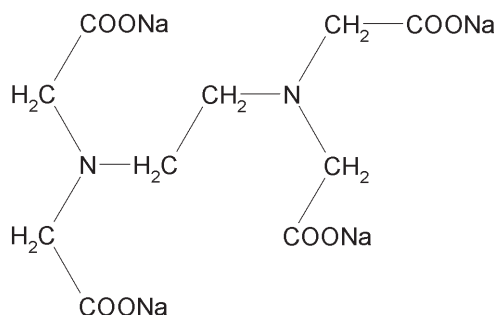
- The legislation currently in force to prevent and reduce harmful effect through pollution by ozone (Directive 2002/3/EC)⁽³⁹⁾ is generally considered to give an adequate framework to limit the risks of n-pentane. The Directive outlines provisions and recommendations for the monitoring of ozone precursors, such as volatile organic compounds (Annex VI to the Directive). The main objectives of such measurements are to analyse any trend in ozone precursors, to check the efficiency of emission reduction strategies, to check the consistency of emission inventories and to help attribute emission sources to pollution concentration. An additional aim is to support the understanding of ozone formation and precursor dispersion processes, as well as the application of photochemical models. The list of VOCs recommended for monitoring in ambient air names more than thirty individual VOCs of which one is n-pentane.

PART 11

CAS-NO. 64-02-8

Einecs-No. 200-573-9

Structural Formula:



Einecs Name:	Tetrasodium ethylenediaminetetraacetate (Na ₄ EDTA)
IUPAC Name:	Tetrasodium {[2-(bis-carboxymethyl-amino)-ethyl]- carboxymethyl-amino}-acetate
Rapporteur:	Germany
Classification ⁽⁴⁰⁾ :	Xn: R22 Xi: R41

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 risk assessment forwarded to the Commission by the Member State Rapporteur.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a complexing agent in many industrial branches, e.g. in cleaning products for industry and skilled trades, photochemicals, agriculture, pulp and paper industry, household laundry and cleaning products, textile industry, electroplating industry, cosmetics and water treatment.

⁽³⁹⁾ OJ L 67, 9.3.2002, p. 14

⁽⁴⁰⁾ Commission Directive [...], adapting to technical progress for the 30th 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, to be published.

RISK ASSESSMENT**A. Human Health**

The conclusion of the assessment of the risks to

WORKERS

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

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)

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

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 the
AQUATIC ECOSYSTEM

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

- concerns for environmental effects to environmental spheres mentioned above as a consequence of exposure arising from the use of Na₄EDTA in industrial detergents, by paper mills, circuit board producers and releases during recovery of Na₄EDTA containing wastes.

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 the ENVIRONMENT

it is recommended:

- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) Na₄EDTA should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).
- to take persistent complexing agents into account in the European eco-labelling of paper products and to extend the existing European eco-labelling for cleaners to industrial cleaners under Regulation 1980/2000/EC ⁽⁴¹⁾.

⁽⁴¹⁾ OJ L 237, 21.09.2000, p. 1

COMMISSION RECOMMENDATION

of 11 April 2006

on risk reduction measures for the substances: Dibutylphthalate; 3,4-Dichloroaniline; Di-'isodecyl' phthalate; 1,2-Benzenedicarboxylic acid, di-C₉₋₁₁-branched alkyl esters, C₁₀-rich; Di-'isononyl' phthalate; 1,2-Benzenedicarboxylic acid, di-C₈₋₁₀-branched alkyl esters, C₉-rich; Ethylenediaminetetraacetate; Methyl acetate; Monochloroacetic acid; n-Pentane; Tetrasodium ethylenediaminetetraacetate

(Text with EEA relevance)

(2006/283/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 Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulations (EC) No 1179/94 ⁽²⁾, (EC) No 2268/95 ⁽³⁾ and (EC) No 143/97 ⁽⁴⁾ respectively concerning the first, second and third list of priority substances as foreseen under Regulation (EEC) No 793/93:

— Dibutylphthalate;

— 3,4-Dichloroaniline;

— Ethylenediaminetetraacetate;

— Methyl acetate;

— Tetrasodium ethylenediaminetetraacetate;

— Di-'isodecyl' phthalate;

— 1,2-Benzenedicarboxylic acid, di-C₉₋₁₁-branched alkyl esters, C₁₀-rich;

— Di-'isononyl' phthalate;

— 1,2-Benzenedicarboxylic acid, di-C₈₋₁₀-branched alkyl esters, C₉-rich;

— n-Pentane;

— Monochloroacetic acid.

(2) The rapporteur States designated pursuant to those Regulations have completed the risk evaluation activities with regard to man and the environment for those substances 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 ⁽⁵⁾ and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

(3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteurs. The opinions have been published on the website of the Scientific Committee.

(4) The results of the risk evaluation and further results of the strategies for limiting the risks are set out in the corresponding Commission Communication ⁽⁶⁾.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances.

(6) The risk reduction measures recommended for workers should be considered within the framework of the legislation for workers protection, which is considered to provide an adequate framework to limit the risks of the relevant substances to the extent needed.

(7) The risk reduction measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93,

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJ L 131, 26.5.1994, p. 3.

⁽³⁾ OJ L 231, 28.9.1995, p. 18.

⁽⁴⁾ OJ L 25, 28.1.1997, p. 13.

⁽⁵⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁶⁾ OJ C 90, 13.4.2006.

HEREBY RECOMMENDS:

Within this framework:

SECTION 1

DIBUTYLPHTHALATE

(CAS No 84-74-2; EINECS No 201-557-4)

Risk reduction measures for the environment (1, 2)

1. The competent authorities in the Member States concerned should lay down, in the permits issued under Council Directive 96/61/EC ⁽¹⁾, conditions, emission limit values or equivalent parameters or technical measures regarding dibutylphthalate, in order for the installations concerned to operate according to the best available techniques (hereinafter BAT) by the end of October 2007, taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
2. Member States should carefully monitor the implementation of BAT regarding dibutylphthalate and report any important developments to the Commission in the framework of the exchange of information on BAT.

SECTION 2

3,4-DICHLOROANILINE

(CAS No 95-76-1; EINECS No 202-448-4)

Risk reduction measures for workers (3) and the environment (4, 5)

3. The employers using 3,4-dichloroaniline in production and further processing for the uses indicated as a concern in the risk assessment should take note of any sector specific guidance for cleaning, maintenance and repair work developed at national level based on the practical non-binding guidance, available from the Commission as provided for in Article 12(2) of Council Directive 98/24/EC ⁽²⁾.

The legislation currently in force at Community level for plant protection products (Council Directive 91/414/EEC ⁽³⁾) and for biocides (Directive 98/8/EC of the European Parliament and of the Council ⁽⁴⁾) is considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

⁽¹⁾ OJ L 257, 10.10.1996, p. 26.

⁽²⁾ OJ L 131, 5.5.1998, p. 11.

⁽³⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁴⁾ OJ L 123, 24.4.1998, p. 1.

4. The information from the risk assessment of 3,4-dichloroaniline released from diuron used as a herbicide on sealed surfaces should be considered.

5. Misuse of diuron in small packages should be prevented.

SECTION 3

ETHYLENEDIAMINETETRAACETATE

(CAS No 60-00-4; EINECS No 200-449-4)

Risk reduction measures for the environment (6, 7, 8, 9)

6. For the river basins where emissions of Ethylenediaminetetraacetate (EDTA) may cause a risk, the relevant Member State should establish Environmental Quality Standards (EQS) and the national pollution reduction measures to achieve those EQS by 2015 should be included in the river basin management plans in line with the provisions of Directive 2000/60/EC of the European Parliament and of the Council ⁽⁵⁾.
7. The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 96/61/EC, conditions, emission limit values or equivalent parameters or technical measures regarding EDTA in order for the installations concerned to operate according to the BAT by the end of October 2007, taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
8. Member States should carefully monitor the implementation of BAT regarding EDTA and report any important developments to the Commission in the framework of the exchange of information on BAT.
9. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

⁽⁵⁾ OJ L 327, 22.12.2000, p. 1.

SECTION 4

METHYL ACETATE

(CAS No 79-20-9; EINECS No 201-185-2)

Risk reduction measures for workers (10)

- Employers using products for flooring works in the building trade containing methyl acetate should take note of any sector specific guidance developed at national level based on the practical non-binding guidance, available from the Commission as provided for in Article 12(2) of Directive 98/24/EC.

SECTION 5

MONOCHLOROACETIC ACID

(CAS No 79-11-8; EINECS No 201-178-4)

Risk reduction measures for workers (11) and the environment (12, 13, 14)

- Employers using Monochloroacetic acid (MCAA) for uses identified as a concern in the risk assessment should take note of any sector specific guidance developed at national level based on the practical non-binding guidance, available from the Commission as provided for in Article 12(2) of Directive 98/24/EC.
- The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 96/61/EC, conditions, emission limit values or equivalent parameters or technical measures regarding MCAA in order for the installations concerned to operate by the end October 2007 according to BAT and taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
- Member States should carefully monitor the implementation of BAT regarding MCAA 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 and man exposed indirectly via the environment is expected.

SECTION 6

TETRASODIUM ETHYLENEDIAMINETETRAACETATE

(CAS No 64-02-8; EINECS No 200-573-9)

Risk reduction measures for the environment (15, 16, 17, 18)

- For the river basins where emissions of Tetrasodium ethylenediaminetetraacetate (Na_4EDTA) may cause a risk, the relevant Member State should establish Environmental Quality Standards (EQS) and the national pollution reduction measures to achieve those EQS in 2015 should be included in the river basin management plans in line with the provisions of Directive 2000/60/EC.
- The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 96/61/EC, conditions, emission limit values or equivalent parameters or technical measures regarding Na_4EDTA in order for the installations concerned to operate by the end October 2007 according to BAT and taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
- Member States should carefully monitor the implementation of BAT regarding Na_4EDTA 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.

SECTION 7

ADDRESSEES

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

Done at Brussels, 11 April 2006.

For the Commission

Stavros DIMAS

Member of the Commission