

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

**2,3-Epoxypropyltrimethylammonium chloride**

**CAS No: 3033-77-0  
EINECS No: 221-221-0**

**Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: 2,3-epoxypropyltrimethylammonium chloride (EPTAC), (3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC) and hexachlorocyclopentadiene**

(Text with EEA relevance)

(2008/C 157/02)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances <sup>(1)</sup> 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 143/97 <sup>(2)</sup> and (EC) 2364/2000 <sup>(3)</sup> respectively concerning the third and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

- 2,3-epoxypropyltrimethylammonium chloride (EPTAC),
- (3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC),
- hexachlorocyclopentadiene.

The rapporteur Member 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 <sup>(4)</sup> and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Health and Environmental Risks (SCHER) 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 2008/472/EC <sup>(5)</sup>, provides the results of risk evaluations <sup>(6)</sup> and strategies for limiting the risks for the above mentioned 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.

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<sup>(1)</sup> OJ L 84, 5.4.1993, p. 1.

<sup>(2)</sup> OJ L 25, 28.1.1997, p. 13.

<sup>(3)</sup> OJ L 273, 26.10.2000, p. 1.

<sup>(4)</sup> OJ L 161, 29.6.1994, p. 3.

<sup>(5)</sup> OJ L 162, 20.6.2008.

<sup>(6)</sup> 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/>

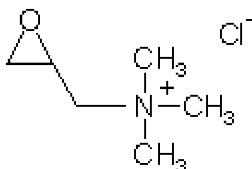
## ANNEX

## PART 1

CAS No: 3033-77-0

Einecs No: 221-221-0

Structural formula:



|                                 |   |
|---------------------------------|---|
| Einecs name:                    | 2,3-epoxypropyltrimethylammonium chloride |
| IUPAC name:                     | 2,3-epoxypropyltrimethylammonium chloride |
| Rapporteur:                     | Finland                                   |
| Classification <sup>(1)</sup> : | None                                      |

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 <sup>(2)</sup>.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a starch cationisation agent in the production of paper.

Other uses are in the quaternisation of guar (used in the manufacture of paper and paperboard for food products and as a flocculant in the mining industry), of cellulose derivatives (added in hair conditioning and emollient cosmetic creams) and of proteins.

## 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 mutagenicity, carcinogenicity and sensitisation as a consequence of exposure arising from all scenarios,
  - concerns for repeated dose toxicity as a consequence of exposure arising from sampling and laboratory work during production of EPTAC.
- 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 reproductive toxicity.

The information requirements are a 2-generation fertility test and a developmental toxicity test.

However, since EPTAC is a genotoxic carcinogen, this property alone is sufficient to lead to the strictest measures for risk management in work places. Therefore, the further information requirements for EPTAC will not be requested.

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 exposure is negligible and thus risks are not expected. Risk reduction measures already being applied are considered sufficient.

<sup>(1)</sup> This chemical substance is currently not included in the Annex I of Directive 67/548/EEC.

<sup>(2)</sup> 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 conclusion of the assessment 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 mutagenicity and carcinogenicity since EPTAC is identified as non-threshold carcinogen. However, the risk assessment indicates that risks are already very 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.
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 reproductive toxicity.

The information requirements are a 2-generation fertility test and a developmental toxicity test.

However, exposure is already very low and since EPTAC is a genotoxic carcinogen, this property alone is sufficient to lead to the strictest measures for risk management. Therefore the further information requirements for EPTAC will not be requested.

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 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 (including marine environment)

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

- concerns for surface water and sediment as a consequence of exposure arising from cationisation of starch with wet process) at local scale for five sites.

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 worker's protection currently in force at Community level, particularly Directive 2004/37/EC of the European Parliament and of the Council <sup>(1)</sup> (the Carcinogens and Mutagens Directive), is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

for HUMANS EXPOSED VIA THE ENVIRONMENT

The risk reduction measures recommended to protect the environment are considered sufficient to protect humans via the environment.

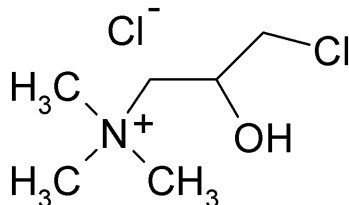
<sup>(1)</sup> OJ L 158, 30.4.2004, p. 50.

## PART 2

CAS No: 3327-22-8

Einecs No: 222-048-3

Structural formula:



Einecs name: (3-chloro-2-hydroxypropyl)trimethylammonium chloride

IUPAC name: (3-chloro-2-hydroxypropyl)trimethylammonium chloride

Rapporteur: Finland

Classification (1): None

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 (2).

The risk assessment has, based on the available information determined that in the European Community the substance is mainly used as a starch cationisation agent in the production of paper.

Other uses are in the quaternisation of guar (used in the manufacture of paper and paperboard for food products and as a flocculant in the mining industry), of cellulose derivatives (added in hair conditioning and emollient cosmetic creams) and of proteins.

Other known applications of CHPTAC are as impregnation agents, as a raw material in the dye industry and in the synthesis of other chemicals, such as carnitine, which is used in nutraceuticals.

## RISK ASSESSMENT

## A. Human health

The conclusion of the assessment of the risks to

## WORKERS

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

- concerns for mutagenicity, carcinogenicity and sensitisation for all use scenarios as a consequence of exposure to EPTAC due to the intentional conversion of CHPTAC to EPTAC during use.

2. is that there is a need for further information. This conclusion is reached because:

- there is a need for better information to adequately characterise the risks regarding the mutagenicity and reproductive toxicity of CHPTAC.

It should be noted, however, that risk reduction measures are being taken already because of the potential exposure to epichlorohydrin in the manufacture of CHPTAC and epichlorohydrin is classified as category 2 carcinogen. Risk reduction measures should be applied also because intentional conversion of CHPTAC to EPTAC occurs in all use scenarios and for EPTAC there is a concern for carcinogenicity which should lead to the strictest measures for risk management. In consideration of the stringent risk management measures required for the above mentioned reasons, the further information requirements for CHPTAC will not be requested.

(1) This chemical substance is currently not included in the Annex I of Directive 67/548/EEC.

(2) 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 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 exposure is negligible and thus 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 further information and/or testing. This conclusion is reached because:

- there is a need for better information to adequately characterise the risks regarding the mutagenicity and reproductive toxicity of CHPTAC.

However, since exposures are estimated to be very low the further information requirements for CHPTAC will not be requested.

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 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 (including marine environment)

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

- concerns for surface water and sediment as a consequence of exposure arising from cationisation of starch with wet process at local scale for four sites.

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

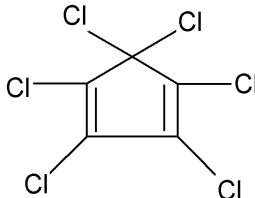
The legislation for worker's protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

## PART 3

CAS No: 77-47-4

Eines No: 201-029-3

Structural formula:



|                     |   |
|---------------------|---|
| Eines name:         | Hexachlorocyclopentadiene                           |
| IUPAC name:         | Hexachlorocyclopentadiene                           |
| Rapporteur:         | Netherlands   |
| Classification (1): | T+; R26<br>T; R24<br>Xn; R22<br>C; R34<br>N; R50/53 |

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 (2).

The risk assessment has, based on the available information, determined that in the European Community hexachlorocyclopentadiene is mainly used as an intermediate in the production of the pesticide endosulfan, and in the synthesis of HET-acid used as a copolymer to produce flame-retardant and corrosion-proof polyesters and alkydresins (e.g. thermoplastics). Minor HCCP applications are its use as an intermediate in the production of a speciality coating, dyes, and pharmaceuticals.

The risk assessment has identified other sources of exposure to the substance to man and the environment, in particular, unintentional formation of hexachlorocyclopentadiene in some semiconductor industrial processes, which do not result from the life-cycle of the substance produced in or imported into the European Community. This source has been assessed, whereas unintentional formation of hexachlorocyclopentadiene in fires has not been assessed.

## 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 effects and ovarian inflammation as a consequence of repeated inhalation exposure arising from production of pesticides and flame retardants, and use of product containing residual HCCP,
- concerns for ovarian inflammation as a consequence of repeated dermal exposure arising from production of pesticides and flame retardants, and unintentional occurrence of HCCP in the semiconductor industry.

(1) The classification of the substance is established by Commission Directive 96/54/EC of 30 July 1996 adapting to technical progress for the 22nd 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 248, 30.9.1996, p. 1).

(2) 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 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 (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, 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 RISKS**

For WORKERS

The legislation for workers' protection currently into 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 HCCP according to Directive 98/24/EC <sup>(1)</sup>.

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<sup>(1)</sup> OJ L 131, 5.5.1998, p. 11.



## COMMISSION RECOMMENDATION

of 30 May 2008

**on risk reduction measures for the substances 2,3-epoxypropyltrimethylammonium chloride (EPTAC), (3-chloro-2-hydroxypropyl) trimethylammonium chloride (CHPTAC) and hexachlorocyclopentadiene**

(notified under document number C(2008) 2316)

(Text with EEA relevance)

(2008/472/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 <sup>(1)</sup> 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 143/97 <sup>(2)</sup> and (EC) No 2364/2000 <sup>(3)</sup> respectively concerning the third and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

- 2,3-epoxypropyltrimethylammonium chloride (EPTAC),
- (3-chloro-2-hydroxypropyl) trimethylammonium chloride (CHPTAC),
- hexachlorocyclopentadiene.

(2) The rapporteur Member 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 in accordance with Council Regulation (EEC) No 793/93 <sup>(4)</sup> and have suggested a strategy for limiting the risks.

(3) The Scientific Committee on Health and Environmental Risks (SCHER) 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 <sup>(5)</sup>.
- (5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances. For the substances which are not specifically listed, there are no recommendations for the addressees of this Recommendation.
- (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,

HEREBY RECOMMENDS:

## SECTION 1

**2,3-EPOXYPROPYLTRIMETHYLAMMONIUM CHLORIDE (EPTAC)**

(CAS No 3033-77-0; Eines No 221-221-0)

**Risk reduction measures for workers (1) and the environment (2)**

1. Employers using EPTAC in manufacturing and as a cationisation agent in the cationisation of starches should take note of any sector specific guidance developed at national level based on the practical non-binding guidelines, drawn up by the Commission pursuant to Article 12(2) of Council Directive 98/24/EC <sup>(6)</sup> (Chemical Agents Directive).

<sup>(1)</sup> OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 25, 28.1.1997, p. 13.

<sup>(3)</sup> OJ L 273, 26.10.2000, p. 5.

<sup>(4)</sup> OJ L 161, 29.6.1994, p. 3.

<sup>(5)</sup> OJ C 157, 21.6.2008, p. 10.

<sup>(6)</sup> OJ L 131, 5.5.1998, p. 11. Directive as modified by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

2. Local emissions to the environment of EPTAC should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

#### SECTION 2

#### **(3-CHLORO-2-HYDROXYPROPYL) TRIMETHYLAMMONIUM CHLORIDE (CHPTAC)**

(CAS No 3327-22-8; Eines No 222-048-3)

#### **Risk reduction measures for workers (3) and the environment (4)**

3. Employers using CHPTAC as a cationisation agent in the cationisation of starches should take note of any sector specific guidance developed at national level based on the practical non-binding guidelines, drawn up by the Commission pursuant to Article 12(2) of Directive 98/24/EC.

4. Local emissions to the environment of CHPTAC should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

#### SECTION 3

#### **ADDRESSEES**

5. 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, 30 May 2008.

*For the Commission*  
Stavros DIMAS  
*Member of the Commission*