

COMMISSION RECOMMENDATION

of 5 March 2001

**on the results of the risk evaluation and the risk reduction strategies for the substances:
diphenylether/pentabromo derivative and cumene**

(notified under document number C(2001) 439)

(Text with EEA relevance)

(2001/194/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) Article 10 of Regulation (EEC) No 793/93 establishes the procedure to be followed for the risk evaluation of the substances on the priority lists at the level of the Member State designated as rapporteur.

(2) Commission Regulation (EC) No 1488/94 ⁽²⁾ outlines the principles for the assessment of risks to man and the environment of existing substances in accordance with Regulation (EEC) No 793/93.

(3) The Member State rapporteur, after evaluating the risk of a given priority substance to man and the environment, should suggest, where appropriate, a strategy for limiting the risk, including control measures and/or surveillance programmes.

(4) Article 11 of Regulation (EEC) No 793/93 provides that the results of the risk evaluation and the recommended strategy for limiting risks in respect to substances on the priority lists should be adopted at Community level in accordance with the procedure laid down in Article 15 and be published by the Commission.

(5) Article 1 of Regulation (EEC) No 793/93 provides that that Regulation should apply without prejudice to Community legislation on the protection of consumers and on safety and protection of health of workers at

work, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽³⁾.

(6) A first priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 1179/94 ⁽⁴⁾. This priority list provides, among other substances, for the evaluation of the following:

— cumene.

(7) A second priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 2268/95 ⁽⁵⁾. This second priority list provides, among other substances, for the evaluation of the following:

— diphenylether, pentabromo derivative.

(8) The rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for the above two substances ⁽⁶⁾ and where appropriate, have suggested strategies for limiting the risks.

(9) The results of the risk evaluation of the two substances and the recommended risk reduction strategies for one of the two substances concerned should be adopted at the Community level.

(10) In accordance with Article 11(3) of Regulation (EEC) No 793/93, the Commission will consider the results of the risk evaluation and the recommended strategy for limiting the risks, when proposing Community measures in the framework of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, Regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations ⁽⁷⁾ and in the framework of Directive 89/391/EEC, as well as in the framework of other relevant existing Community instruments.

(11) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted and has issued an opinion with respect to the risk assessment reports referred to in this recommendation.

⁽³⁾ OJ L 183, 29.6.1989, p. 1.

⁽⁴⁾ OJ L 131, 26.5.1994, p. 3.

⁽⁵⁾ OJ L 231, 28.9.1995, p. 18.

⁽⁶⁾ The comprehensive risk assessment reports as forwarded to the Commission by the rapporteur Member States are publicly available. Short summaries are also available. Both can be found on the Internet site of the European Chemicals Bureau, Institute for Health and Consumer protection of the Joint Research Centre in Inpsra, Italy (<http://ecb.ei.jrc.it/existing-chemicals/>).

⁽⁷⁾ OJ L 262, 27.9.1976, p. 201.

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJ L 161, 29.6.1994, p. 3.

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

HEREBY RECOMMENDS:

1. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using disposing or recovering the following substance:

- diphenylether, pentabromo derivative
CAS No 32534-81-9
Eines No 251-084-2

should take into account the results of the risk evaluation as summarised in Section I (human health/environment) of Annex I. These results were formulated in the light of the opinions delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) ⁽¹⁾.

2. The risk reduction strategies described in Section II (strategy for limiting risks) of Annex I should be implemented.

3. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substance:

- Cumene
CAS No 98-82-8
Eines No 202-704-5

should take into account the results of the risk evaluation as summarised in Section I (human health/environment) of Annex II. These results were formulated in the light of the opinion delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) ⁽²⁾.

Done at Brussels, 5 March 2001.

For the Commission

Margot WALLSTRÖM

Member of the Commission

⁽¹⁾ The environment risk assessment report was peer-reviewed by the CSTEE and its opinion was expressed at the 13th plenary meeting held in Brussels on 4 February 2000 and the human health risk assessment report was peer-reviewed by the CSTEE and its opinion was expressed at the 16th plenary meeting held in Brussels on 19 June 2000. The CSTEE opinions can be found on the Internet site: (http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html).

⁽²⁾ The risk assessment report was peer-reviewed by the CSTEE and its opinion was expressed at the 15th plenary meeting held in Brussels on 5 May 2000. The CSTEE opinions can be found on the Internet site: (http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html).

ANNEX I

CAS-No 32534-81-9

EINECS-No 251-084-2

 $C_{12}H_5Br_5O$

Einecs name: diphenylether, pentabromo derivative

IUPAC name: pentabromodiphenyl ether

Rapporteur: United Kingdom

Classification (*): Xn; R48/21/22
R64
N; R50-53

(*) The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 136, 8.6.2000, p. 1).

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 used as a flame retardant additive in the manufacture of polyurethane foam in applications such as furniture and upholstery. Use as a flame retardant additive in epoxy resins, phenolic resins, unsaturated polyesters and textiles has been quoted in other reviews but has not been known of by industry supplying to the EU for more than 20 years. 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.

I. RISK ASSESSMENT**A. HUMAN HEALTH**

The conclusion of the assessment of the risks to

WORKERS

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 lifetime exposure to the substance.

The information requirements are:

- dermal exposure data on workers,
- the extent of dermal absorption (quantitative data) should be clarified by the conduct of an appropriate dermal absorption study; depending upon the outcome of this study (i.e. an indication of significant skin absorption) then it may be necessary to undertake an oral toxicokinetic study in order to provide adequate comparative information for interpretation of the oral dosing toxicity studies available,
- health surveillance data are required to investigate signs of chloracne in workers,
- risk characterisation methodology for bioaccumulative substance (lifetime exposure); this may involve the conduct of a lifetime study in rodents depending upon the way in which the methodology for assessing lifetime exposure is developed and any data requirements that may be indicated for such a methodology.

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 conclusions of the assessment of the risks to

MAN EXPOSED VIA THE ENVIRONMENT

are 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 lifetime exposure to the substance.

The information requirements are:

- risk characterisation methodology for bioaccumulative substance (lifetime exposure); this may involve the conduct of a lifetime study in rodents depending upon the way in which the methodology for assessing lifetime exposure is developed and any data requirements that may be indicated for such a methodology,
- actual measured exposure data from local sources.

The conclusion of the assessment of the risks to

INFANTS EXPOSED VIA MILK

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 exposure of infants to the substance via breast milk and cows' milk.

The information requirements are:

- information on the toxicokinetics of the substance with respect to breast milk including uptake from breast milk into the infant, the time course of the excretion via breast milk during lactation in humans and the future trends in levels in human breast milk,
- information on the relative toxicity to the liver of the substance in young (neonatal) and adult animals,
- further studies on potential effects on behaviour following neonatal dosing in order to determine the reproducibility of effects, the effects of repeated dosing and the significance of the effects to human development,
- a multi-generation reproduction study in order to investigate whether or not other effects might be observed through exposure to breast milk. Designed correctly, such a study could address the issue of whether or not the young animal is more sensitive to liver effects and whether or not differences in behaviour are produced,
- exposure estimates from local and regional sources on the concentration of the substance in cows' milk.

However, the strategy for limiting risks for the environment in Part II of Annex I will eliminate the need for further information requirements.

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 environment for

ATMOSPHERE

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

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

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

AQUATIC ECOSYSTEM AND TERRESTRIAL ECOSYSTEM

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

- concerns for effects on the local aquatic (sediment) and terrestrial environment as a consequence of exposure arising from polyurethane foam production,
- concerns for secondary poisoning to the environmental spheres mentioned above both locally and regionally as a consequence of exposure arising from production and/or use of polyurethane foams.

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

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for better information to adequately characterise the risk to micro-organisms in the sewage treatment plant;

— a test on sewage treatment plant micro-organisms would be required if this data gap is to be filled.

However, the strategy for limiting risks for the environment in Part II of Annex I will eliminate the need for further information requirements.

II. STRATEGY FOR LIMITING RISKS

For HUMAN HEALTH

While the formal outcome of the human health risk assessment of the substance is that further information/testing is required, Member States noted the uncertainties regarding the risk characterisation for infants exposed to the substance from milk. In particular, there was concern about whether the concentration in human breast milk might increase during the time it would take to obtain the information needed to refine the risk characterisation and to remove some of the uncertainties. Any risk reduction measures proposed for the substance must take account of the concerns about infants exposed via milk.

For THE ENVIRONMENT

Marketing and use restrictions should be considered at Community level for the substance, and articles containing the substance, for controlling secondary poisoning risks arising from the production and use of polyurethane foams ⁽¹⁾.

The measures identified to protect the environment will also reduce human exposure to the substance.

Any future use of the substance should be monitored.

Consideration should be given to the monitoring of imports of articles from outside the EU.

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⁽¹⁾ Whereas the risk assessment and risk reduction strategy only identified the production and use of the substance in polyurethane foams, all other uses resulting in emissions, discharges and losses to the environment would be unacceptable.

ANNEX II

CAS-No. 98-82-8

EINECS-No. 202-704-5

 C_9H_{12}

Einecs name:	cumene
Rapporteur:	Spain
Classification (*)	R10 Xn; R65 Xi; R37 N; R51-53

(*) The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 136, 8.6.2000, p. 1).

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 an intermediate in chemical industry for the production of phenol and acetone. Other uses are as a starting material for detergent production, in the synthesis of α -methylstyrene, acetophenone and di-isopropylbenzene and as a catalyst for acrylic polyester-type resins. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, in petroleum products, which does not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment. The 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.

I. RISK ASSESSMENT**A. HUMAN HEALTH**

The conclusion of the evaluation of the risks to

WORKERS, CONSUMERS and MAN 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 ⁽¹⁾.

B. ENVIRONMENT

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

ATMOSPHERE, AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

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

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

⁽¹⁾ These measures include the use of occupational exposure limit values established at Community level for the protection of workers from chemical risks. Cumene is included in the Annex to Commission Directive 2000/39/EC of 8 June 2000 (OJ L 142, 16.6.2000, p. 47), establishing a first list of indicative occupational exposure limit values, pursuant to Council Directive 98/24/EC (OJ L 131, 5.5.1998, p. 11) on the protection of the health and safety of workers from the risks related to chemical agents at work.

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

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

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

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

II. STRATEGY FOR LIMITING RISKS

None
