

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION RECOMMENDATION

of 16 September 2002

on the results of the risk evaluation and risk reduction strategy for the substance diphenyl ether, octabromo derivative

(notified under document number C(2002) 3394)

(Text with EEA relevance)

(2002/755/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 diphenyl ether, octabromo derivative has been identified as a priority substance for evaluation in accordance with Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽²⁾. In Regulation (EC) No 1179/94 France and the United Kingdom have been designated as rapporteur Member States for that substance.
- (2) Those rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for diphenyl ether, octabromo derivative ⁽³⁾ and have suggested a strategy for limiting the risks in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 ⁽⁴⁾.
- (3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted with respect to the risk evaluations carried out by the Member State rapporteurs.
- (4) The results of the risk evaluation are contained in the Annex to this recommendation.
- (5) 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,

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJ L 131, 26.5.1994, p. 3.

⁽³⁾ The comprehensive risk assessment report as forwarded to the Commission by the rapporteur Member States is publicly available. A short summary is 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 Ispra, Italy (<http://ecb.jrc.it/regulation-results/>).

⁽⁴⁾ OJ L 161, 29.6.1994, p. 3.

HEREBY RECOMMENDS:

1. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using and disposing or recovering:
 - diphenyl ether, octabromo derivative
CAS No 32536-52-0
EINECS No 251-087-9should take into account the results of the risk evaluation set out in the Annex.
2. The strategy for limiting risks set out in point II of the Annex should be implemented.

Done at Brussels, 16 September 2002.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

Diphenyl ether, octabromo derivative or octabromodiphenyl ether

CAS No: 32536-52-0

EINECS No: 251-087-9

Rapporteurs: France and United Kingdom

Classification: not yet 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 risk assessment forwarded to the Commission by the Member States Rapporteurs.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as flame retardant mostly in applications in the plastics and textile industries.

I. RISK ASSESSMENT

A. Human health

The conclusions of the assessment of the risks to

WORKERS are:

1. that there is a need for further information and/or testing. This conclusion is reached since information is needed on transthyretin-T4 competition with octabromodiphenyl ether as well as information on the extent of excretion of commercial octabromodiphenyl ether into the breast milk and information on the effects of prolonged exposure; and
2. that there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account. This conclusion is reached for manufacture (bagging and cleaning activities) and for compounding and master batching (bag emptying). There are concerns for:
 - systemic effects after inhalation and dermal repeated exposure,
 - local effects in the respiratory tract after inhalation repeated exposure, and
 - effects on female fertility after inhalation and dermal repeated exposure.

The conclusion of the assessment of the risks for

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 already.

This conclusion is reached because consumer exposure is considered negligible.

The conclusion of the assessment of the risks for

HUMANS EXPOSED VIA THE ENVIRONMENT is

that there is a need for further information and/or testing.

This conclusion is reached since further information is needed on emissions into the environment from use or on soil-plant transfer; on the extent of excretion of commercial octabromodiphenyl ether into the breast milk and cow's milk. Depending upon the results submitted by Industry on milk excretion further information might be requested. There is a need for exposure information from local and regional sources on the concentration of octabromodiphenyl ether in cows milk. Information is needed as well on transthyretin-T4 competition with octabromodiphenyl ether and on the effects of prolonged exposure.

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 already.

B. Environment

The conclusions of the assessment of the risks to the

ENVIRONMENT are

1. that there is a need for further information and/or testing. This conclusion applies to the risk of secondary poisoning from all sources of octabromodiphenyl ether. It is possible that the current PEC/PNEC approach for secondary poisoning may not be appropriate in terms of both the PEC and the PNEC, and could underestimate the risk. This issue needs further investigation.

A second aspect of the concern for secondary poisoning is that although the substance is persistent, there is evidence that it can degrade under some conditions to more toxic and bioaccumulative compounds.

There is a high level of uncertainty associated with the suitability of the current risk assessment approach for secondary poisoning and the debromination issue. The combination of uncertainties raises a concern about the possibility of long-term environmental effects that can not easily be predicted. It is not possible to say whether or not on a scientific basis there is a current or future risk to the environment.

This uncertainty is sufficient to warrant risk reduction measures directly based on the information currently provided in the risk assessment;

2. that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already. This conclusion applies to the environmental assessment of risks to the aquatic (surface water, sediment and waste water treatment plants), terrestrial and atmospheric compartments by the conventional PEC/PNEC approach for octabromodiphenyl ether itself from all sources (including the assessment of the hexabromodiphenyl ether component);
3. that there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account. This conclusion applies to the assessment of secondary poisoning via the earthworm route for the hexabromodiphenyl ether component in the commercial octabromodiphenyl ether product from the use in polymer applications.

II. STRATEGY FOR LIMITING RISKS

For HUMANS EXPOSED VIA THE ENVIRONMENT:

While the outcome of the human health risk assessment for exposure via the environment is that further information/testing is required, Member States noted the uncertainties regarding the risk characterisation for infants exposed to commercial octabromodiphenyl ether from human breast or cow's milk. In particular, there was concern that it would take a significant time to gather the information and that the resulting refined risk assessment could then indicate a risk to breast-feeding infants. Any risk reduction measures proposed for the substance must take account of the concern about infants exposed via milk.

For WORKERS:

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

Within this framework it is recommended to develop at Community level occupational exposure limit values for the substance. Until such time as occupational exposure limit values for the substance have been adopted at Community level, exposure in the workplace should be reduced as low as technically feasible. The use of non-inhalable forms (pellets etc.) in place of the powder form should be considered. The need for such measures will be dependent on the outcome of proposals to protect human health and the environment.

For the ENVIRONMENT:

Marketing and use restrictions should be considered at Community level to protect the environment from the use of octabromodiphenyl ether.
