Communication from the Commission on the results of the risk evaluation of chlorodifluoromethane, bis(pentabromophenyl)ether and methenamine and on the risk reduction strategy for the substance methenamine

(Text with EEA relevance)

(2008/C 131/04)

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]) and (EC) No 2268/95 ([3]) respectively concerning the first and the second list of priority substances as foreseen under Regulation (EEC) No 793/93:

— chlorodifluoromethane,

— bis(pentabromophenyl)ether,

— methenamine.

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 ([4]) 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) and the Scientific Committee on Health and Environmental Risks (SCHER) respectively have been consulted and have 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 Committees.

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 provides the results of risk evaluations ([5]) of chlorodifluoromethane, bis (pentabromophenyl)ether and methenamine and the strategy for limiting the risks for methenamine.

The results of the risk evaluation and the strategy for limiting the risks set out 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.

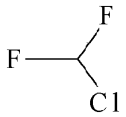
([1]) OJ L 84, 5.4.1993, p. 1.
([2]) OJ L 131, 26.5.1994, p. 3.
([3]) OJ L 231, 28.9.1995, p. 18.
([4]) OJ L 161, 29.6.1994, p. 3.
([5]) The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the Internet site of the European Chemicals Bureau:
http://ecb.jrc.it/existing-substances/

ANNEX

PART 1

CAS No: 75-45-6	Einecs No: 200-871-9

Structural formula:



Einecs name:	Chlorodifluoromethane
IUPAC name:	Chlorodifluoromethane
Rapporteur:	Italy
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.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as raw material feedstock for other chemicals such as fluoropolymers and as end product predominantly as working fluid in vapour compression refrigeration cycles.

Other uses are foam blowing with HCFC-22 which has been banned since 1 January 2004 ([2]). Emissions deriving from this use are not considered in the risk assessment.

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.

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.

([1]) This chemical substance is currently not included in the Annex I of Directive 67/548/EEC.
([2]) Regulation (EC) No 2037/2000 on substances that deplete the ozone layer.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

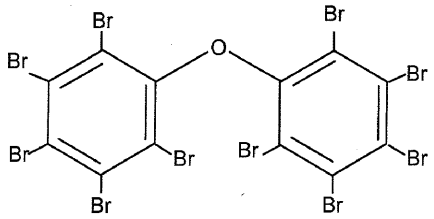
is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

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

PART 2

CAS No: 1163-19-5	Einecs No: 214-604-9

Structural formula:



Einecs name:	Bis(pentabromophenyl)ether
IUPAC name:	Bis(pentabromophenyl)ether
Rapporteur:	France (Human Health) and United Kingdom (Environment)
Classification:	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 Rapporteurs ([1]).

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a flame retardant additive in the manufacture of polymers, mainly for use in electrical equipment, and drapery and upholstery textiles. Other minor uses reported are as a flame retardant additive in styrenic rubbers, polycarbonates, polyamides and terephthalates and in hot melt adhesives.

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 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 developmental neurotoxic effects of the substance.

The information requirements are:

— a further developmental neurotoxicity study in mice or rats.

([1]) 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 already.

This conclusion was reached in the risk assessment report because consumer exposure was considered negligible. While recent information indicates that consumers may be exposed to bis(pentabromophenyl)ether released from consumer products, this exposure has not yet been quantified and considered in the risk assessment based on the current hazard profile available.

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 human exposure and the risks regarding developmental neurotoxic effects of the substance.

The information requirements are:

— a suitable human bio-monitoring programme, including breast milk and blood, and the need for a trend analysis with annual reporting over a ten year time period,

— further developmental neurotoxicity study in mice or rats.

The conclusion of the assessment of the risks to

HUMANS 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

AQUATIC AND 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 concerns regarding the persistent, bioaccumulative and toxic properties of the substance.

The information requirements are:

— environmental monitoring, programme including birds, sewage sludge, sediment, and air to establish the trends in levels of contamination for the substance and its more toxic and bioaccumulative degradation products, with annual reporting over a 10 year time period.

The conclusion of the assessment of the risks to the

ATMOSPHERE

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

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

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

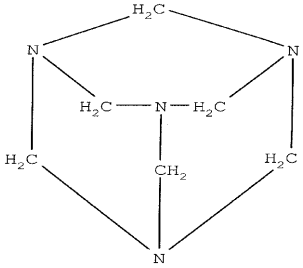
is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

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

PART 3

CAS No: 100-97-0	Einecs No: 202-905-8

Structural formula:



Molecular formula:	$C_6H_{12}N_4$
Einecs name:	Methenamine
IUPAC name:	1,3,5,7-tetraazatricyclo(3.3.1.1 ^{3,7})decane
Rapporteur:	Germany
Classification ([1]):	F; R11
	R42/43

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 to produce resins and rubber. Other minor uses include fuel tablets for camping stoves.

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 in all scenarios,

— concerns for systemic toxicity as a consequence of repeated dermal exposure arising from formulation of phenolic resin systems,

— concerns for developmental toxicity as a consequence of repeated dermal exposure arising from formulation of phenolic resin systems, from production of fuel tablets, and from production of formulations used in corrosion prevention and as photo chemicals.

([1]) 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. 3).

([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 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 cosmetics, even at low concentrations, and from application (handling/breaking) of solid fuel tablets.

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 (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, the AQUATIC and TERRESTRIAL ECOSYSTEMS

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

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

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

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

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

STRATEGY FOR LIMITING RISKS

For WORKERS

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

For CONSUMERS

The existing legislative measures for the protection of consumers, in particular the provisions under Council Directive 76/768/EEC ([1]) as regards cosmetics and Directive 2001/95/EC as regards products, are considered sufficient to address identified risks to consumers.

([1]) A Commission Proposal for a recast of the Directive 76/768/EEC was adopted on 5 February 2008.