II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: trichloroethylene, benzene, 2-methoxy-2-methylbutane (TAME)

(Text with EEA relevance)

(2008/C 157/01)

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 2364/2000 ([3]) respectively concerning the first and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

— trichloroethylene,

— benzene,

— 2-methoxy-2-methylbutane (TAME).

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) 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, together with the corresponding Commission Recommendation 2008/471/EC ([5]), provides the results of risk evaluations ([6]) and strategies for limiting the risks for the above mentioned substances.

([1]) OJ L 84, 5.4.1993, p. 1.
([2]) OJ L 131, 26.5.1994, p. 3.
([3]) OJ L 273, 26.10.2000, p. 1.
([4]) OJ L 161, 29.6.1994, p. 3.
([5]) OJ L 162, 20.6.2008.
([6]) 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.

ANNEX

PART 1

CAS No: 79-01-6	Einecs No: 201-167-4

Structural formula:	$HClC = CCl_2$
Einecs name:	Trichloroethylene
IUPAC name:	Trichloroethylene
Rapporteur:	United Kingdom
Classification [1]:	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xi; R36/38 R67 R52-53

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 the substance is mainly used for metal cleaning. Other uses are in adhesives and as an intermediate for synthesis of other chemicals. 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.

It is not possible to draw clear conclusions in relation to developmental neurotoxicity and consequently the risk assessment does not evaluate the risks to any population for this endpoint. However, further testing has not been required, as the substance has been identified as a non-threshold carcinogen.

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 kidney toxicity following repeated exposure, mutagenicity and carcinogenicity, as a consequence of exposure arising from all workers scenarios,

— concerns for acute central nervous system depression and repeated exposure central nervous system functional disturbances as a consequence of exposure arising from metal cleaning, adhesive manufacture and adhesive use.

The conclusions of the evaluation 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 mutagenicity and carcinogenicity, as a consequence of exposure arising from consumer products containing the substance.

[1] Commission Directive 2001/59/EC of 6 August 2001, 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).

[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 conclusions of the evaluation of the risks to man for

HUMANS EXPOSED VIA THE ENVIRONMENT

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

— risks can not be excluded, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already 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.

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

ATMOSPHERE

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

— concerns for effects on plants from air emissions of trichloroethylene from production, processing as an intermediate, formulation for solvent use, and use in metal degreasing.

The conclusion of the assessment of the risks 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

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. However, for metal cleaning, particularly in premises using less than 1 tonne/year, this needs to be supplemented by further action:

— to establish at Community level occupational exposure limit values for trichloroethylene according to Directive 98/24/EC ([1]) or Directive 2004/37/EC ([2]) as appropriate,

([1]) OJ L 131, 5.5.1998, p. 11.
([2]) OJ L 158, 30.4.2004, p. 50.

— in parallel with a Voluntary Agreement between the European Chlorinated Solvents Association on behalf of European producers of the substance, their distributors and customer (Commission Recommendation 2008/471/EC [1]), if monitoring reveals that there is insufficient compliance with the voluntary agreement, and that standards are not improving, to consider Restrictions at Community level for the use of trichloroethylene in metal cleaning in systems other than sealed or enclosed systems, as defined in Part 4 of European Standard EN 12921.

For CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

The existing legislative measures for consumer protection and humans exposed via the environment, in particular the provisions under Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances and Directive 2008/1/EC of the European Parliament and of the Council [2] (Integrated Pollution Prevention and Control), are considered sufficient to address the identified risks.

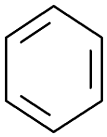
For ENVIRONMENT

The existing legislative measures for environmental protection, in particular Council Directive 1999/13/EC [3] (Solvent Emissions Directive) and Directive 2008/1/EC (Integrated Pollution Prevention and Control), are considered sufficient to address the risks identified.

PART 2

CAS No: 71-43-2	Einecs No: 200-753-7

Structural formula:



Einecs name:	Benzene
IUPAC name:	Benzene
Rapporteur:	Germany
Classification [4]:	F; R11 Carc. Cat. 1; R45 Muta. Cat. 2; R46 T; R48/23/24/25 Xn; R65 Xi; R36/38 S53-45

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 [5].

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the manufacture of plastics, synthetic rubber, dyestuffs, resins, raw materials for detergents, and plant protection agents.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular from non-isolated benzene e.g. in petrol and other refinery 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 Report as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

(1) OJ L 162, 20.6.2008.
(2) OJ L 24, 29.1.2008, p. 8.
(3) OJ L 85, 29.3.1999, p. 1.
(4) The classification of the substance is established by 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, amended by OJ L 216, 16.6.2004, 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/

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 and carcinogenicity as a consequence of dermal and inhalation exposure arising from all worker scenarios,

— concerns for acute toxicity as a consequence of inhalation exposure during production of perfumes (use of benzene) and cleaning of crude benzene and gasoline tanks,

— concerns for repeated dose toxicity and developmental toxicity as a consequence of inhalation exposure during production of perfumes (use of benzene), cleaning of crude benzene and gasoline tanks, recovery of benzene in coking plants, distribution of gasoline (without vapour recovery) foundries (without local exhaust ventialtion) and production, further processing and refinery,

— concerns for fertility as a consequence of inhalation exposure during production of perfumes (use of benzene), cleaning of crude benzene and gasoline tanks and recovery of benzene in coking plants.

Benzene is easily absorbed after inhalation and skin contact. Internal body burdens after demal exposure are generally low because of rapid evaporation of benzene and only prolonged exposure might pose a risk. For prolonged dermal exposure and inhalation exposure at levels below 1 ppm (3,2 mg/m^3) the only concerns are for mutagenicity and carcinogenicity.

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 due to mutagenic and carcinogenic effects by inhalation exposure from use of contaminated paints and from car interior accessories.

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 due to repeated dose toxicity, mutagenicity and carcinogenicity.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physico-chemical properties)

is that there is at present no need for further 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 benzene to the formation of ozone and other harmful substances, i.e. smog formation.

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. This conclusion is reached because of:

— concerns for effects on local aquatic ecosystems as a consequence of exposure arising from the production and processing of the substance.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is at present no need for further 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 a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for effects on microorganisms in industrial waste water treatment plants at 23 production, production and processing or mere processing sites of the substance.

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:

— the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) review the new information contained in the risk assessment report and recommend whether there is a need to revise the current community OEL,

— to consider at Community level restrictions of the use of benzene as an extracting agent in the perfume industry in Council Directive 76/768/EEC relating to cosmetic products ([1]).

For CONSUMERS

The existing legislative measures for the protection of consumers, in particular the provisions under Directive 76/769/EEC as regards CMR substances, Directive 2001/95/EC of the European Parliament and of the Council as regards products, are considered sufficient to address identified risks to consumers.

For ENVIRONMENT

The risk assessment has identified other sources of benzene emissions (from non isolated benzene, e.g. in petrol and other refinery products), than those from the produced or imported chemical. The need to consider if additional risk management is needed can best be considered under Directives 98/70/EC ([2]) (quality of petrol and diesel fuels), 1999/13/EC ([3]) (VOC emissions from organic solvents), 2000/69/EC ([4]) (limit values in ambient air), 2001/81/EC ([5]) (national emission ceilings for air pollutants) and 2002/3/EC ([6]) (ozone in ambient air) using the information in the comprehensive risk assessment report.

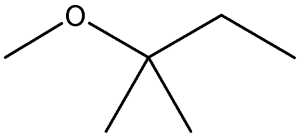
The existing legislative measures for the protection of the environment are considered sufficient to address the risks identified for the atmosphere and the aquatic environment, in particular the provisions under the Directives 1999/13/EC (VOC emissions from organic solvents), 2000/69/EC (limit values in ambient air), 2001/81/EC (national emission ceilings for air pollutants), 2002/3/EC (ozone in ambient air) and 2000/60/EC ([7]) (Water Framework Directive with benzene as a priority substance).

([1]) OJ L 262, 27.9.1976, p. 169.
([2]) OJ L 84, 5.4.1993, p. 1; OJ L 262, 27.9.1976, p. 201; OJ L 11, 15.1.2002, p. 4; OJ L 143, 30.4.2004, p. 87; OJ L 350, 28.12.1989, p. 58.
([3]) OJ L 85, 29.3.1999, p. 1.
([4]) OJ L 313, 13.12.2000, p. 12.
([5]) OJ L 309, 27.11.2001, p. 22.
([6]) OJ L 67, 9.3.2002, p. 14.
([7]) OJ L 327, 22.12.2000, p. 1.

PART 3

CAS No: 994-05-8	Einecs No: 213-611-4

Structural formula:



Einecs name:	2-methoxy-2-methylbutane
IUPAC name:	2-methoxy-2-methylbutane
Rapporteur:	Finland

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 blending component of standard unleaded petrol.

Other uses are as on-site intermediate in neat form.

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)

(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 the potability of drinking water in respect of taste and odour as a consequence of exposure arising from leaking underground storage tanks and spillage from overfilling of the storage tanks.

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 the aquatic ecosystem as a consequence of exposure arising from intermittent and continuous releases to surface water at terminal sites mainly from storage tank bottom waters but also other sources related to operation on terminal.

The conclusion of the assessment of the risks to the

GROUNDWATER

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

— concerns for the potability of ground water in respect of taste and odour as a consequence of exposure arising from leaking underground storage tanks and spillage from overfilling of the storage tanks.

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.