

Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: benzyl butyl phthalate (BBP), 2-furaldehyde (furfural), perboric acid, sodium salt

(Text with EEA relevance)

(2008/C 149/04)

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 2268/95 ⁽²⁾ and (EC) No 143/97 ⁽³⁾ respectively concerning the second and third list of priority substances as foreseen under Regulation (EEC) No 793/93:

- benzyl butyl phthalate (BBP),
- 2-furaldehyde (furfural),
- perboric acid, sodium salt.

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 2008/447/EC ⁽⁵⁾, provides the results of risk evaluations ⁽⁶⁾ 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.

⁽¹⁾ OJL 84, 5.4.1993, p. 1.

⁽²⁾ OJL 231, 28.9.1995, p. 18.

⁽³⁾ OJL 25, 28.1.1997, p. 13.

⁽⁴⁾ OJL 161, 29.6.1994, p. 3

⁽⁵⁾ OJL 156, 14.6.2008.

⁽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/>

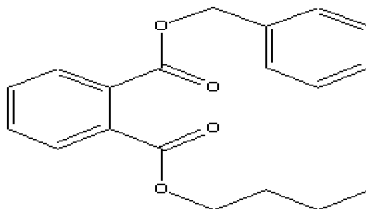
ANNEX

PART 1

CAS No: 85-68-7

Einecs No: 201-622-7

Structural formula:



Einecs name:	Benzyl Butyl Phthalate
IUPAC name:	Benzyl Butyl Phthalate
Rapporteur:	Norway
Classification ⁽¹⁾ :	Repr. Cat. 2; R61 Repr. Cat. 3; R62 N; R50-53

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 (more than 95 %) as a plasticizer of polyvinyl chloride (PVC) or other polymers.

The BBP-plasticized polymeric material has consumer and industrial uses such as in flooring, sealants, paints, textile coating and adhesives. A minor use is in a non-polymeric application and a relatively small but significant use is in the food wrap or food packaging area which has diminished over recent years due to technological developments leading to no further requirement for BBP in one of the food wrap applications (i.e. regenerated cellulose film). Furthermore, BBP has been reported at low concentrations in child-care articles and children's toys; however, in these products BBP probably occurs as by-products/impurities and has not been added intentionally to the products.

Because BBP is not chemically bound to the matrix it can migrate from the polymeric material and become available for emissions to other matrices (environmental or biological). BBP can be released from polymer-based products during their use or after disposal. The rate of emission is dependent on various factors, for example temperature and physical or mechanical handling of the product.

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.

It should be noted that additive effects related to co-exposure with other phthalates has not been evaluated in the risk assessment.

⁽¹⁾ 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. 125).

⁽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

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

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

1. 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 to the aquatic ecosystem.

The information and/or test requirements are

- a long-term fish study on reproductive and endocrine effects;

2. is that there is a need for specific measures to limit the risks. Risk reduction measures which are already being applied shall be taken into account. The conclusion is reached because of:

concerns for the aquatic compartment (including sediment) as a consequence of exposure arising from flooring at large and small sites and non polymer use during processing and formulation.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for specific measures to limit the risks. Risk reduction measures which are already being applied shall be taken into account. The conclusion is reached because of:

- concerns for the terrestrial compartment (including sediment) as a consequence of exposure arising from flooring at large and small sites, PVC coated textiles and non polymer use during processing and formulation. The scenarios that give concern are generic scenarios based on default emission data.

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 protections currently in force at Community level is generally considered to give an adequate framework to limit risks of the substance to the extent needed and shall apply. Within the framework it is recommended:

- to establish at community level occupational exposure limit values for BBP according to Directive 98/24/EC ⁽¹⁾.

For ENVIRONMENT

It is recommended

- in order to facilitate permitting and monitoring under Council Directive 2008/1/EC ⁽²⁾ (Integrated Pollution Prevention and Control) that BBP should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT),

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ OJ L 24, 29.1.2008, p. 8.

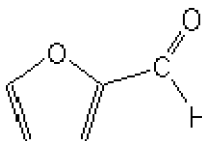
- to consider, within the framework of existing legislative measures under Council Directive 76/769/EEC (Marketing and Use Directive), restrictions for the use of BBP in industrial installations for processing polymers with BBP (formulation and processing of plastisol flooring) and formulation and processing of PVC coated textiles and non polymer uses with BBP, exempting installations with no emission of BBP to the environment as well as installations where BBP emissions are adequately controlled. Adequate control could e.g. be achieved through efficient treatment of exhaust air and aqueous effluents. The efficiency in emissions' reduction should be documented to enable follow up by Member State authorities.

PART 2

CAS No: 98-01-1

Einecs No: 202-627-7

Structural formula:



Molecular formula:	C ₅ H ₄ O ₂
Einecs name:	2-furaldehyde
IUPAC name:	2-furaldehyde
Rapporteur:	Netherlands
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 Rapporteur.

The risk assessment has, based on the available information, determined that in the European Community the substance is used for about 75 % in the production of furan derivatives. The remaining part is mainly used as a selective solvent in refineries. Other reported uses are in manufacturing refractories and pesticides, or use as a chemical tracer in gas-oil (refineries). Furthermore it is used as fragrances in cosmetics, and as a reagent in analytical chemistry. For the UK a different use pattern is present, where approximately 40 % is used in the production of resins, abrasive wheels and refractories.

In addition the risk assessment has identified unintentional sources of exposure which do not result from the life-cycle of the substance produced in or imported into the European Community. In particular, 2-furaldehyde is a natural volatile compound identified in many foods (fruits, vegetables, wine, bread) and in several essential oils of plants; 2-furaldehyde is formed in trace amounts in a number of dietary sources and as a degradation by-product in the refuse of chemical and fuel production. 2-furaldehyde is also a major contaminant from the sulfite pulping processes used in pulp and paper industry, or may be released to the environment via the smoke from burning wood. The risks arising from these unintentional exposures are beyond the scope of this comprehensive Risk Assessment Report, which does however provide information that can be used to assess those risks.

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 systemic effects and local effects on respiratory tract as a consequence of exposure arising from repeated inhalation exposure in all scenarios,
- concerns for systemic effects as a consequence of exposure arising from repeated dermal exposure in cleaning and maintenance during production,
- concerns for developmental effects as a consequence of exposure arising from repeated dermal and inhalation exposure in cleaning and maintenance during production,
- concerns for carcinogenicity as a consequence of exposure arising from repeated dermal and inhalation exposure in all exposure scenarios.

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

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 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. This conclusion is reached because:

- given the intrinsic properties of the substance, risks from physicochemical properties are not expected.

B. Environment

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 the

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 toxic effects of 2-furaldehyde to the terrestrial ecosystems. The PEC_{soil} exceeds the PNEC_{soil} in the scenarios 'formulation for manufacturing refractories' and 'use as intermediate in pesticide manufacture'. The terrestrial PNEC is derived through the equilibrium partitioning method and there is therefore scope to refine this PNEC through testing,
- however, no testing is proposed for the terrestrial compartment since risk reduction measures are proposed for the local aquatic compartment which should cover the conclusions for the terrestrial compartment.

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 the aquatic compartment as a consequence of exposure arising from formulation of chemical tracer in mineral oil and fuel industry, formulation for manufacturing refractories and use as intermediate in pesticide manufacture.

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.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for 2-furaldehyde according to Directive 98/24/EEC ⁽¹⁾.

For ENVIRONMENT

- it is recommended in order to facilitate permitting and monitoring under Directive 2008/1/EC ⁽²⁾ (Integrated Pollution Prevention and Control) that 2-furaldehyde should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

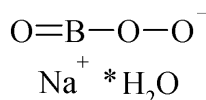
PART 3

CAS No: 11138-47-9

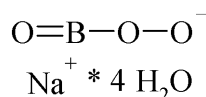
Einecs No: 234-390-0

Number for the anhydrous form which covers the mono- and tetrahydrate

Structural formulas:



BHO₃ · H₂O · Na (monohydrate)



BHO₃ · 4H₂O · Na (tetrahydrate)

Einecs name:

Perboric acid, sodium salt

IUPAC name:

Sodium perborate

Rapporteur:

Austria

Classification ⁽³⁾:

None

The risk assessment ⁽⁴⁾ 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.

The risk assessment assesses the risk arising from sodium perborate and its degradation product, hydrogen peroxide. The risk of the degradation product boric acid has not been assessed in the comprehensive Risk Assessment Report.

The risk assessment has, based on the available information, determined that in the European Community sodium perborate mono- and tetrahydrate are mainly used as oxidizing and bleaching agents in detergents (household detergents as well as detergents for institutional uses) and also in cleaning (e.g. automatic dishwashers, stain removers in form of bleach booster tablets) and cosmetic preparations (denture cleansers). In laundry washing applications, perborates are used in regular and compact heavy-duty powders.

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 local effects on the upper airways and for developmental effects as a consequence of inhalation exposure in the production of sodium perborate.

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ OJ L 24, 29.1.2008, p. 8.

⁽³⁾ This chemical substance is currently not included in the Annex I of Directive 67/548/EEC.

⁽⁴⁾ 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.
