Please find below the Commission Communication and the Commission Recommendation for substance

5-tert-butyl-2,4,6-trinitro-m-xylene

CAS 81-15-2
EINECS: 201-329-4

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Commission communication on the results of the risk evaluation and the risk reduction strategies for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene

Text with EEA relevance

(2008/C 34/01)

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]), (EC) No 2268/95 ([3]) and (EC) No 143/97 ([4]) respectively concerning the first, second and third list of priority substances as foreseen under Regulation (EEC) No 793/93:

— Piperazine;

— Cyclohexane;

— Methylenediphenyl diisocyanate;

— But-2yne-1,4-diol;

— Methyloxirane;

— Aniline;

— 2-Ethylhexylacrylate;

— 1,4-Dichlorobenzene;

— 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone;

— Di-(2-ethylhexyl)phthalate;

— Phenol;

— 5-tert-butyl-2,4,6-trinitro-m-xylene.

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 ([5]) 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) or the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have

([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 25, 28.1.1997, p. 13.
([5]) OJ L 161, 29.6.1994, p. 3.

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 ([6]), provides the results of risk evaluations ([7]) 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.

([6]) OJ L 33, 7.2.2008.

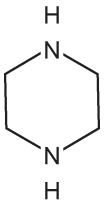
([7]) The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: http://ecb.jrc.it/existing-substances/

ANNEX

PART 1

CAS No 110-85-0	Einecs No 203-808-3

Structural formula:



Einecs name:	Piperazine
IUPAC name:	Piperazine
Rapporteur:	Sweden
Classification ([1]):	C; R34
	R42/43
	R52/53
	Proposed classification (to replace C & L from 22nd ATP after 30th ATP is published) ([2])
	Repr. Cat. 3; R62-63
	C; R34
	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 ([3]).

The risk assessment has, based on the available information, determined that in the European Community, piperazine as such or as salts, is mainly used as an intermediate in the chemical industry including the production of pharmaceuticals. Piperazine as such or as salts, is also used for human and veterinary medicinal drugs, as formulation in gas-washing (scrubbers), and as a catalyst in urethane production. The described scenarios represent the main use of piperazine.

Note: The use of piperazine in veterinary medicines is not addressed under this legislation, it is covered by Council Regulation (EEC) No 2377/90 ([4]) (Maximum residue limits in foodstuff of animal origin).

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 the scenarios handling piperazine salts (i.e. final handling during production and loading activities during formulation);

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

([2]) Commission Directive adapting to technical progress for the 30th 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 (not yet published).

([3]) 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/

([4]) OJ L 224, 18.8.1990, p. 1.

— concerns for asthma as a consequence of inhalation exposure arising from all occupational scenarios;

— concerns for neurotoxicity and reproductive toxicity as a consequence of repeated exposure to piperazine salts in the scenarios final handling during production and loading activities during formulation.

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 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

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

— concerns for aquatic ecosystem as a consequence of exposure arising at one production site and one formulation site and for industrial use of gas washer formulations with piperazine at 21 sites.

The conclusion of the assessment of the risks to the

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

— concerns for micro-organisms in sewage treatment plants as a consequence of exposure arising from the majority of local gaswasher scenarios.

STRATEGY FOR LIMITING RISKS

For WORKERS

— to consider at Community level a harmonised classification under Council Directive 67/548/EEC ([5]) of the salts of piperazine.

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:

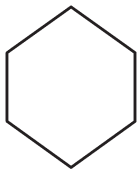
— to establish at Community level occupational exposure limit values for the salts of piperazine according to Council Directive 98/24/EC ([6]).

([5]) OJ 196, 16.8.1967, p.1.
([6]) OJ L 131, 5.5.1998, p. 11.

PART 2

CAS No 110-82-7	Einecs No 203-806-2

Structural formula:



Einecs name:	Cyclohexane
IUPAC name:	
Rapporteur:	France
Classification ([1]):	F; R11
	Xn; R65
	Xi; R38
	R67
	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.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as intermediate in chemical industry. Other uses reported are as a solvent in chemical production process and in adhesives and coatings.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular from crude oil and plants, combustion products (tobacco smoke, volcanic emissions) and petroleum derived fuels (gasoline vapours), 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 are not part of this risk assessment. The comprehensive Risk Assessment Report ([2]), as forwarded to the Commission by the Member State Rapporteur, does however provide information which could be used to assess these 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 acute toxicity (neurobehavioural effects) and general systemic toxicity (hepatic effects) as a consequence of inhalation exposure arising from formulation and industrial use of products containing the substance as well as from use of products containing the substance in craft industries.

([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, corrected by OJ L 216, 16.6.2004, 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 acute toxicity (neurobehavioral effects) as a consequence of exposure arising from use of products containing the substance.

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, 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 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.

For CONSUMERS

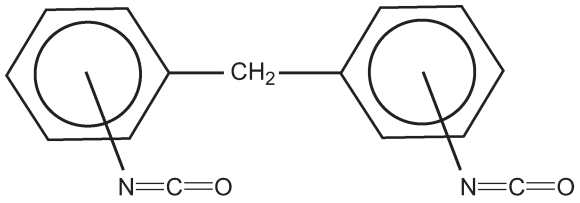
To consider at Community level marketing and use restrictions in Council Directive 76/769/EEC ([3]) (marketing and use Directive) for the use of cyclohexane in neoprene based adhesives.

([3]) OJ L 262, 27.9.1976, p. 201.

PART 3

CAS No 26447-40-5	Einecs No 247-714-0

Structural formula:



Einecs name:	1,1'-methylenebis (isocyanatobenzene)
IUPAC name:	Methylenediphenyl diisocyanate
	Methylenebis (phenyl isocyanate)
Rapporteur:	Belgium
Classification:	Xn; R20
	Xi; R36/37/38
	R42/43
	Proposed classification (to replace C&L from 28th ATP after 30th ATP is published) ([1])
	Carc. Cat. 3; R40
	Xn; R20-48/20
	Xi; R36/37/38
	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 in the industrial production of rigid polyurethane foams. Many other uses are in the fields of wood binders, Coatings, Adhesives, Sealants and Elastomers (CASE), (semi) flexible and thermoplastic polyurethane foams and fibres. A limited but not negligible use is within consumer products, such as adhesives and one component foams (OCFs).

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

WORKERS

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 characterize the risks regarding the toxicity for fertility because the current database does not adequately cover this endpoint. The collection of additional information should, however, not delay the implementation of appropriate control measures needed to address the concerns related to other endpoints.

([1]) Commission Directive, adapting to technical progress for the 30th 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 (not yet published).

([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/

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

— concerns for skin and eye irritation for workers on building sites, as in this case occupational hygiene standards are often low and PPE might not be worn;

— concerns for respiratory tract irritation as a consequence of inhalation exposure arising from all investigated occupational exposure scenarios;

— concerns for skin and respiratory sensitization as a consequence of dermal and inhalation exposures arising from all investigated occupational exposure scenarios;

— concerns for respiratory toxicity as a consequence of repeated inhalation exposure arising from all investigated occupational exposure scenarios.

The conclusion of the assessment of the risks to

CONSUMERS

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 characterize the risks regarding the toxicity for fertility because the current database does not adequately cover this endpoint. The collection of additional information should, however, not delay the implementation of appropriate control measures needed to address the concerns related to other endpoints.

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

— concerns for skin and eye irritation as a consequence of exposure arising from the use of all types of MDI-containing consumer products;

— concerns for respiratory tract irritation as a consequence of inhalation exposure arising from the use of MDI-containing one component foams (OCFs) and hot melt adhesives;

— concerns for skin and respiratory sensitisation as a consequence of inhalation and dermal exposures arising from the use of all types of MDI-containing consumer products;

— concerns for lung effects as a consequence of inhalation by short-term repeated exposure arising from the use of MDI-containing one component foams (OCFs) and hot melt adhesives.

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, AQUATIC ECOSYSTEM, TERRESTRIAL ECOSYSTEM, MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT and NON ECOSYSTEM-SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN

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 the extent needed and shall apply.

Within this framework it is recommended:

— to establish at Community level occupational exposure limit values for MDI according to Council Directive 98/24/EC ([3]).

For CONSUMERS

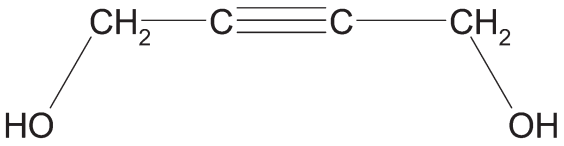
To consider at Community level marketing and use restrictions in Council Directive 76/769/EEC ([4]) for the use of MDI in consumer's products.

([3]) OJ L 131, 5.5.1998, p. 11.
([4]) OJ L 262, 27.9.1976, p. 201.

PART 4

CAS No 110-65-6	Einecs No 203-788-6

Structural formula:



Einecs name:	But-2-yne-1,4-diol
IUPAC name:	But-2-yne-1,4-diol
Rapporteur:	Germany
Classification:	C; R34
	T; R23/25
	Xn; R21-48/22
	R43

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 Reports as forwarded to the Commission by the Member State Rapporteur ([1]).

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 chemical industry for the production of butanediol and butenediol. Other professional uses include its use as an intermediate for the synthesis of polyols, insecticides, pharmaceuticals and auxiliaries for the paint and textile industry. The substance is directly used as a corrosion inhibitor in pickling solutions in technical cleaning products for metal surface treatment, as a brightener in galvanic baths and in organic paint removers. In consumer products it is used in cleaning agents and sanitary disinfectants.

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 respiratory tract irritation as a consequence of single inhalation exposure arising from production and further processing of the solid substance (flakes) in the large scale chemical industry.

— concerns for local respiratory tract irritation as a consequence of repeated exposure arising from manufacturing and further processing of the solid substance (flakes) in the large scale chemical industry and in the preparation of formulations (in the absence of local exhaust ventilation).

— concerns for sensitisation as a consequence of dermal exposure arising from production and further processing of the substance in the large scale chemical industry, in the preparation of formulations and its use in organic paint removers.

([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. 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 (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 conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM, 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 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

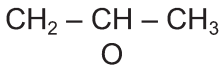
For WORKERS

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 and shall apply.

PART 5

CAS No 75-56-9	Einecs No 200-879-2

Structural formula:



Einecs name:	Methyloxirane
IUPAC name:	Propylene oxide
Rapporteur:	United Kingdom
Classification:	F+; R12
	Carc. Cat. 2; R45
	Muta. Cat. 2; R46
	Xn; R20/21/22
	Xi; R36/37/38

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 Reports as forwarded to the Commission by the Member State Rapporteur ([1]).

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a monomer in polymer production and as an intermediate in the synthesis of other substances. Other uses are as a stabiliser in dichloromethane and as an anti-corrosion additive. 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.

This substance has not been adequately tested for sensitisation and consequently the risk assessment does not evaluate the risks to any population of this end point. This test has not been required, as the substance has been identified as a non-threshold carcinogen.

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

WORKERS, CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that the risk assessment shows that risks cannot be excluded for all exposure scenarios, as the substance is identified as a non-threshold carcinogen, 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 (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.

([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/

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 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.

For CONSUMERS AND HUMANS EXPOSED VIA THE ENVIRONMENT

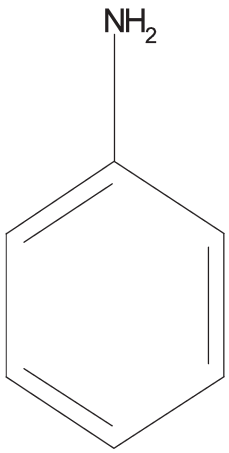
The existing legislative measures for the protection of consumers and humans exposed via the environment, in particular the provisions under the Council Directive 76/769/EEC ([2]) (marketing and use Directive) as regards CMR substances, Directive 2001/95/EC of the European Parliament and of the Council ([3]) (general product safety) as regards products, and Council Directive 96/61/EC ([4]) (integrated pollution prevention and control) are considered sufficient to address the risks identified.

([2]) OL L 262, 27.9.1976, p. 201.
([3]) OJ L 11, 15.1.2002, p. 4.
([4]) OJ L 257, 10.10.1996, p. 26.

PART 6

CAS No 62-53-3	Einecs No 200-539-3

Structural formula: C_6H_7N



Einecs name:	Aniline
IUPAC name:	Aminobenzene
Rapporteur:	Germany
Classification ([1]):	Carc. Cat. 3; R40
	Muta. Cat. 3; R68
	T; R23/24/25-48/23/24/25
	Xi; R41 R43
	N; R50

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 ([2]).

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 chemical industry, to produce methylenedianiline or rubber. Other uses are processing to dyes, pesticides, pharmaceuticals, fibres, etc.

Releases of aniline can occur during these production and processing scenarios. In addition, aniline is a residual component of dyes and adhesives.

The risk assessment has identified other sources of exposure to the substance to humans and the environment, in particular via microbial reduction of nitrobenzene, and from the coal and oil industry. The assessment of the risks arising from these exposures, which do not result from the life-cycle of the substance produced in or imported into the European Community 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 those risks.

([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, as corrected by OJ L 216, 16.6.2004, p. 3).

([2]) The comprehensive Risk Assessment Report can be found on the internet site of the European Chemicals Bureau: http://ecb.jrc.it/existing-substances/

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusions 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 acute toxicity as a consequence of:

  — inhalation exposure and/or dermal contact in case of unsuitable gloves arising from production and further processing in the large-scale chemical industry;

  — inhalation exposure arising from thermal degradation of plastics in iron, steel and aluminium foundries;

  — dermal exposure arising from the use of dyes containing residual aniline;

— concerns for skin sensitisation as a consequence of dermal exposure arising from production and further processing in the large-scale chemical industry (in case of unsuitable gloves), and the use of dyes with residual aniline;

— concerns for systemic toxic effects as a consequence of:

  — inhalation exposure and/or dermal contact in case of unsuitable gloves arising from production and further processing in the large-scale chemical industry;

  — inhalation exposure arising from vulcanisation of rubber chemicals, and from thermal degradation of plastics in iron, steel and aluminium foundries;

  — dermal exposure arising from the use of dyes containing residual aniline;

— concerns for mutagenicity and carcinogenicity in all workplace scenarios, as the substance is identified as a non-threshold carcinogen. However, for the following specific working scenarios risks are already low:

  — Release of aniline as a decomposition products in different industrial sectors (e.g. plastics processing, electrical engineering);

  — Use of products with residual aniline (e.g. adhesives, engineering, device and tool construction industries).

This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures;

— concerns for developmental toxicity as a consequence of dermal exposure in case of unsuitable gloves arising from production and further processing in the large-scale chemical industry.

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 mutagenicity and carcinogenicity as a consequence of exposure arising from use of products containing the substance, as aniline is identified as a non-threshold carcinogen.

The conclusions 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 for systemic toxic effects, developmental toxicity, mutagenicity and carcinogenicity as a consequence of exposure arising from point sources,

— concerns for mutagenicity and carcinogenicity as a consequence of possible exposures at a regional level, as aniline is identified as a non-threshold carcinogen. However, exposures are already very low and 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 of:

— 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 ECOSYSTEM and MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

1. is that there is a need for further information and/or testing. This conclusion is reached because of:

   — the need for better information to adequately characterise the risks for the aquatic ecosystem as a consequence of exposure arising from rubber production sites.

   The information and/or test requirements are:

   — data about the formation of aniline from rubber chemicals, the releases into the waste water and waste water treatment processes which are representative for the European rubber industry;

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. This conclusion is reached because of:

   — concerns for effects on the aquatic environmental spheres including sediment as a consequence of exposure arising from aniline production and further processing (4,4'-methylenedianiline and rubber chemicals) sites.

The conclusion of the assessment of the risks to the

ATMOSPHERE

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 atmosphere.

   The information and/or test requirements are:

   — data about releases into the atmosphere and the applied exhaust air purification techniques which are representative for the European rubber industry;

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. This conclusion is reached because of:

   — concerns for effects on plants as a consequence of exposure via the air compartment arising from one aniline production site.

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 risks to agricultural soils from aniline as a degradation product of phenylurea and carbamate derivatives used as plant protection products.

The information and/or test requirements are:

— long term tests with plants, earthworms and micro-organisms.

However, since the risk to soil from the breakdown of plant protection agents is not covered by Council Regulation (EEC) No 793/93 ([3]) it is proposed that this be considered within the frame of Council Directive 91/414/EEC ([4]).

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:

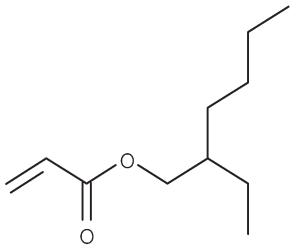
— to establish at community level occupational exposure limit values for Aniline according to Council Directive 98/24/EC ([5]), taking the dermal uptake into account.

([3]) OJ L 84, 5.4.1993.
([4]) OJ L 230, 19.8.1991.
([5]) OJ L 131, 5.5.1998, p. 11.

PART 7

CAS No 103-11-7	Einecs No 203-080-7

Structural formula:



EINECS name:	2-ethylhexyl acrylate
IUPAC name:	2-ethylhexyl acrylate
Rapporteur:	Germany
Classification: ([1])	Xi; R37/38 R43

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 as a monomer in the chemical industry for the production of polymers and copolymers, which are mainly processed further to aqueous polymer dispersions. The polymers and polymer dispersions are used in adhesives and as binders for paints. Other applications include coatings raw materials and uses in the plastics and textiles industries. In addition, 2-ethylhexyl acrylate is used as a monomer in construction-industry, chemicals (e.g. floor coatings, road-marking 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 local effects as a consequence of repeated inhalation exposure arising during the formulation of preparations containing 2-ethylhexyl acrylate.

— concerns for skin sensitisation as a consequence of dermal exposure arising during the production of 2-ethylhexyl acrylate and polymerisation, the formulation of preparations and the use of formulations containing monomeric 2-ethylhexyl acrylate in the building trade.

The conclusions of the assessment of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

are 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]) 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, corrected by OJ L 216, 16.6.2004, 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

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 conclusions of the assessment of the risks to the

ATMOSPHERE, AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

are 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

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 THE RISK

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-ethylhexyl acrylate according to Council Directive 98/24/EEC ([3]).

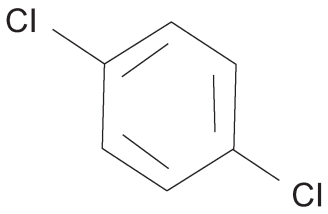
Existing controls are considered to be sufficient to limit the risks of skin sensitisation.

([3]) OJ L 131, 5.5.1998, p. 11.

PART 8

CAS No 106-46-7	Einecs No 203-400-5

Structural formula:



EINECS name:	1,4-Dichlorobenzene
IUPAC name:	1,4-Dichlorobenzene
Rapporteur:	France
Classification ([1])	Carc. Cat. 3; R40
	Xi; R36;
	R 50/53

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 comprehensive Risk Assessment Reports as 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 as an intermediate in the chemical industry, in the formulation of moth repellents, air fresheners and toilet blocks. Other uses are as a processing aid in the production of grinding wheels and as a carrier for textile dyes.

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 general systemic toxicity, carcinogenicity and reproductive toxicity as a consequence of inhalation and dermal exposure arising from manufacture and use (intermediate, formulation of products containing the substance and production of grinding wheels),

— concerns for ocular and nasal irritation as a consequence of exposure to vapours arising during use of formulation of products containing the substance and production of grinding wheels.

The conclusion of the assessment of the risks for

CONSUMERS

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

— concerns for carcinogenicity as a consequence of inhalation exposure arising from use of moth repellents, air fresheners and toilet blocks.

([1]) 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, corrected by OJ L 216, 16.6.2004, 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 for

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, TERRESTRIAL ECOSYSTEM MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT and NON ECOSYSTEM-SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN

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 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.

For CONSUMERS

It is recommended:

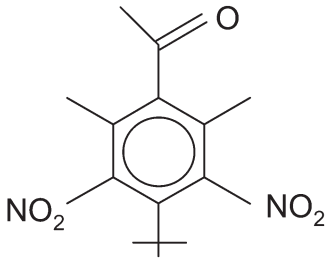
— to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC ([3]) for the use of 1,4-dichlorobenzene in air fresheners, moth repellents and toilet blocks.

([3]) OJ L 262, 27.9.1976, p. 201.

PART 9

CAS No 81-14-1	Einecs No 201-328-9

Structural formula:



EINECS name:	4'-tert-butyl-2',6'-dimethyl-3',5'-dinitroacetophenone
IUPAC name:	3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone
Rapporteur:	The Netherlands
Classification ([1]):	At the June 2002 meeting for environment and at the January 2003 CMR meeting it was agreed as Carc. Cat. 3; R40 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.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an ingredient in fragrance compositions for cosmetic products.

Other uses are detergents, fabric softeners, household cleaning products and other fragranced products.

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 and no need for risk reduction measures beyond those, which are being applied already. 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 arising from

COMBINED EXPOSURE

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

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

([1]) The classification of the substance is established by Commission Directive [to be published in the 31st ATP)] adapting to technical progress for the 31st 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, as last amended by Directive 2004/73/EC.

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:

— given the physico-chemical data, musk ketone is considered not to form a risk with respect to flammability, and explosive and oxidizing properties.

B. **ENVIRONMENT**

The conclusion of the assessment of the risks to the

ATMOSPHERE, the AQUATIC ECOSYSTEM and the TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing and no need for risk reduction measures beyond those, which are being applied already. 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

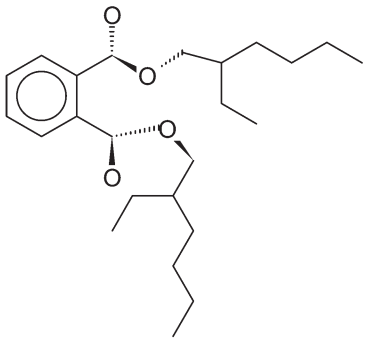
is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

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

PART 10

CAS No 117-81-7	Einecs No 204-211-0

Structural formula:



EINECS name:	Di-(2-ethylhexyl) phthalate (DEHP)
IUPAC name:	Bis(2-ethylhexyl)phthalate
Rapporteur:	Sweden
Classification ([1]):	Repr. Cat. 2; R60-61

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 (97 %) as a plasticizer (improving the polymer material's flexibility and workability) in polymer products, mainly PVC.

Flexible PVC is used in many different articles e.g. toys, building material such as flooring, cables, profiles and roofs, as well as medical products like blood bags, dialysis equipment etc. DEHP is used also in other polymer products, e.g. other vinyl resins and cellulose ester plastics.

Other uses (3 %) are for non-polymer applications such as adhesives and sealant, lacquers and paints, printing inks for paper and plastics, printing inks for textiles, rubber and ceramics for electronic purposes. Another use is as a dielectric fluid in capacitors.

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 testicular effects, fertility, toxicity to kidneys on repeated exposure, and developmental toxicity as a consequence of inhalation and dermal exposure during production, processing and industrial end-use of preparations or materials containing DEHP.

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 children with regard to testicular effects, fertility and toxicity to kidneys on repeated exposure, as a consequence of oral exposure arising from the use of toys and child-care articles;

([1]) The classification of the substance is established by 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. 1.).

([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/

— concerns for children undergoing long-term blood transfusion and neonates undergoing transfusions with regard to testicular toxicity and fertility, as a consequence of exposure from materials in medical equipment containing DEHP;

— concerns for adults undergoing long-term haemodialysis with regard to testicular effects, fertility, toxicity to kidneys on repeated exposure, and developmental toxicity, as a consequence of exposure from materials in medical equipment containing DEHP.

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; risk reduction measures which are already being applied shall be taken into account. This conclusion is reached because of:

— concerns for children with regard to testicular effects, fertility, and toxicity to kidneys on repeated exposure, as a consequence of exposure via food grown locally near sites processing polymers with DEHP, or sites producing sealants and/or adhesives, paints and lacquers or printing inks with DEHP. The scenarios that give concern are generic scenarios based on default emission data. There is no concern for the limited number of sites that have reported measured emission data.

— concerns for children with regard to testicular toxicity, as a consequence of exposure via food grown locally near sites recycling paper or municipal sewage treatment plants. The scenarios that give concern are generic scenarios based on default emission data.

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

is 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 because of:

— concern for birds consuming mussels exposed to DEHP near sites processing polymers with DEHP or sites producing sealants and/or adhesives with DEHP. The scenarios that give concern are generic scenarios based on default emission data. There is no concern for the limited number of sites that have reported measured emission data.

There is a need for further information and/or testing. This conclusion is reached because of:

— concern for sediment-dwelling organisms as a consequence of exposure to DEHP near sites processing polymers with DEHP or sites producing lacquers, paints, printing inks, sealants and/or adhesives with DEHP. The scenarios that give concern are generic scenarios based on default emission data. There is no concern for the limited number of sites that have reported measured emission data.

Further refinement of the assessment may remove some concern. However implementation of risk management measures to address the risks identified for other environmental spheres will eliminate the need for further information on sediment-dwelling organisms.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is 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 because of:

— concern for mammals consuming earthworms exposed to DEHP near sites processing polymers with DEHP or sites producing lacquers, paints, printing inks, sealants and/or adhesives with DEHP. The scenarios that give concern are generic scenarios based on default emission data. There is no concern for the limited number of sites that have reported measured emission data.

There is a need for further information and/or testing. This conclusion is reached because of:

— concern for soil organisms exposed to DEHP near sites processing polymers with DEHP or sites producing printing inks, sealants and/or adhesives with DEHP. The scenarios that give concern are generic scenarios based on default emission data. There is no concern for the limited number of sites that have reported measured emission data.

Further refinement of the assessment may remove some concern. However implementation of risk management measures to address the risks identified for other environmental spheres will eliminate the need for further information on soil organisms.

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 THE RISKS

A. HUMAN HEALTH

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:

— to establish at community level Occupational Exposure Limit values for DEHP according to Council Directive 98/24/EC ([3]).

For CONSUMERS

It is recommended:

— to restrict the use of DEHP in packaging materials for foods (plastic materials in contact with food (Directive 2002/72/EC ([4])).

— to consider restricting the use of DEHP in medical devices giving rise to possible exposure of neonates and identified groups of concern following the procedure laid down in Council Directive 93/42/EEC ([5]) concerning medical devices, assuming the availability of safe alternatives.

([3]) OJ L 131, 5.5.1998, p. 11.
([4]) OJ L 220, 15.8.2002, p. 18.
([5]) OJ L 169, 12.7.1993, p. 1.

As regards consumer use of DEHP, the existing legislative measures for consumer protection, in particular the provisions under Council Directive 76/769/EEC ([6]) (marketing and use Directive) as regards CMR substances and Directive 2005/84/EC of the European Parliament and of the Council ([7]) on phthalates in toys and child care articles are considered sufficient to address risks identified to consumers.

HUMANS indirectly EXPOSED VIA THE ENVIRONMENT

Within the framework of existing legislative measures under Council Directive 76/769/EEC (marketing and use Directive) it is recommended:

— to consider at Community level restrictions for the use of DEHP in industrial installations for processing polymers with DEHP (extrusion, calendaring, spread coating) and for producing sealants and/or adhesives, paints and lacquers or printing inks with DEHP, exempting installations with no emission of DEHP to the environment as well as installations where DEHP 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;

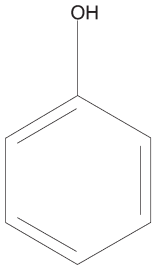
— to consider, within a reasonable time period, the need for Community level restrictions due to emissions to water from products containing DEHP, taking into account any additional information.

([6]) OJ L 262, 27.9.1976, p. 201.
([7]) OJ L 344, 27.12.2005, p. 40.

PART 11

CAS No 108-95-2	Einecs No 203-632-7

Structural formula:



EINECS name:	Phenol
IUPAC name:	Phenol
Rapporteur:	Germany
Classification ([1]):	T; R23/24/25
	C; R34
	Xn; R48/20/21/22
	Muta Cat. 3; R68

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 as an intermediate in the production of bisphenol A, phenol resins, alkylphenols, caprolactam, salicylic acid, nitrophenols, diphenyl ethers, halogen phenols and other chemicals.

Other uses are as a component in cosmetics and medical preparations as well as in non-agricultural biocides, adhesives and impregnating agents.

The risk assessment has identified other sources of exposure to the substance to human and the environment, in particular, releases of phenol as a product of human metabolism and livestock farming, from processing of coal and pulp manufacture and from landfills, 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 Reports as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these 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. The conclusion is reached because of:

— concerns for acute toxic effects (systemic) as a consequence of inhalation exposure, arising from the formulation of phenolic resins;

— concerns for acute toxic effects (systemic) as a consequence of dermal exposure, arising from the use of phenolic resins in spraying techniques;

([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, corrected by OJ L 216, 16.6.2004, 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/

— concerns for corrosivity following skin contact and contact to the eyes arising from all dermal exposure scenarios (production and further processing, formulation and use of phenolic resins);

— concerns for systemic effects as a consequence of repeated inhalation exposure arising from all scenarios (production and further processing, formulation and use of phenolic resins);

— concerns for systemic effects as a consequence of repeated dermal exposure arising from the formulation of phenolic resins and use of phenolic resins in spraying techniques.

The conclusion of the assessment of the risks to

CONSUMERS

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

— concerns for skin irritation as a consequence of exposure arising from the use of phenol containing disinfectants;

— concerns for systemic effects as a consequence of repeated inhalation exposure arising from phenol in floor waxes;

— concerns for systemic effects as a consequence of repeated dermal exposure arising from phenol in disinfectants.

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. The conclusion is reached because of:

— concerns for systemic effects as a consequence of repeated oral exposure arising from local indirect exposure via plant shoots.

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

— concerns for effects on micro-organisms in industrial waste water treatment plants at eight production and processing or mere processing sites

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.

ENVIRONMENT AND HUMANS EXPOSED VIA THE ENVIRONMENT

The risk assessment has identified other sources of phenol emissions (from non isolated phenol, e.g. from cooking, gasification and liquefaction of coal, refineries and pulp manufacture, as a product of human or livestock metabolism or from landfills), than those from the produced or imported chemical. The need to consider if additional risk management is needed can best be considered under Directive 2000/60/EC of the European Parliament and of the Council [3] (Water Framework Directive) and forthcoming EU legislation with regard to soil protection using the information in the comprehensive risk assessment report.

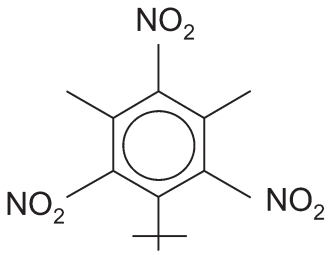
The existing legislative measures for the protection of the environment are considered sufficient to address potential risks from landfills without landfill leachate collecting systems (Council Directive 1999/31/EC [4]).

[3] OJ L 327, 22.12.2000, p. 1.
[4] OJ L 182, 16.7.1999, p. 1.

PART 12

CAS No 81-15-2	Einecs No 201-329-4

Structural formula:



EINECS name:	5-tert-butyl-2,4,6-trinitro-m-xylene
IUPAC name:	1-tert-butyl-3,5-dimethyl-2,4,6-trinitrobenzene
Rapporteur:	The Netherlands
Classification ([1]):	Carc. Cat. 3; R40 E; R2 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 as an ingredient in fragrance compositions for cosmetic products.

Other uses are detergents, fabric softeners, household cleaning products and other fragranced products.

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 and no need for risk reduction measures beyond those, which are being applied already. 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 arising from

COMBINED EXPOSURE

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

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

([1]) 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, corrected by OJ L 216, 16.6.2004, p. 3).

([2]) The comprehensive Risk Assessment Report 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:

— given the physico-chemical data, 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) is considered not to form a risk with respect to oxidizing properties.

— It is noted that musk xylene is flammable and explosive by shock and heat, and should be labelled with respect to these aspects. Therefore, measures to avoid flammability and explosion are indicated. If the appropriate conditions of handling and storage are adhered to, there are no concerns for risks to human health arising from the physicochemical properties of musk xylene.

B. **ENVIRONMENT**

The conclusion of the assessment of the risks to the

ENVIRONMENT

is that there is need for further information and/or testing. This conclusion is reached because the substance is considered a PBT candidate chemical. A further PBT-testing strategy is proposed.

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

RECOMMENDATIONS

COMMISSION

COMMISSION RECOMMENDATION

of 6 December 2007

on risk reduction measures for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene

(notified under document number C(2007) 5901)

(Text with EEA relevance)

(2008/98/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 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulations (EC) No 1179/94 [2], (EC) No 2268/95 [3] and (EC) No 143/97 [4] respectively concerning the first, second and third list of priority substances as foreseen under Regulation (EEC) No 793/93:

— Piperazine,

— Cyclohexane,

— Methylenediphenyl diisocyanate,

— But-2-yne-1,4-diol,

— Methyloxirane,

— Aniline,

— 2-Ethylhexylacrylate,

— 1,4-Dichlorobenzene,

— 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone,

— Di-(2-ethylhexyl)phthalate (DEHP),

— Phenol,

— 5-tert-butyl-2,4,6-trinitro-m-xylene.

(2) 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 [5] and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

[1] OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parlament and of the Council (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 131, 26.5.1994, p. 3.
[3] OJ L 231, 28.9.1995, p. 18.
[4] OJ L 25, 28.1.1997, p. 13.
[5] OJ L 161, 29.6.1994, p. 3.

(3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) or the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued opinions with respect to the risk evaluations carried out by the rapporteurs. The opinions have been published on the website of the Scientific Committees.

(4) The results of the risk evaluation and further results of the strategies for limiting the risks are set out in the corresponding Commission Communication of 7 February 2008 [1] on the risk evaluation and the risk reduction strategies for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances.

(6) The risk reduction measures recommended for workers should be considered within the framework of the legislation for workers protection, which is considered to provide an adequate framework to limit the risks of the relevant substances to the extent needed.

(7) The risk reduction measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93,

HEREBY RECOMMENDS:

SECTION 1

PIPERAZINE

(CAS No 110-85-0; Einecs No 203-808-3)

Risk reduction measures for the environment (1, 2, 3)

1. The competent authorities in the Member States concerned lay down conditions, emission limit values or equivalent parameters or technical measures regarding piperazine in the permits issued under Council Directive 96/61/EC [2] (Integrated Pollution Prevention and Control) in order to operate according to the best available techniques taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.

2. Member States should carefully monitor the implementation of BAT regarding piperazine and report any important developments to the Commission in the framework of the exchange of information on BAT. To facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) piperazine should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

3. Local emissions to the environment shall, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

SECTION 2

METHYLENEDIPHENYL DIISOCYANATE

(CAS No 26447-40-5; Einecs No 247-714-0)

Risk reduction measures for workers (4)

4. Employers using MDI for uses identified as a concern in the risk assessment should take note of any sector specific guidance developed at national level based on the practical non-binding guidance, to be published by and available from the Commission as foreseen under Article 12(2) of Council Directive 98/24/EC [3] (Chemical Agents Directive).

SECTION 3

BUT-2-YNE-1,4-DIOL

(CAS No 110-65-6; Einecs No 203-788-6)

Risk reduction measures for workers

5. Employers using But-2-yne-1,4-diol for uses identified as a concern in the risk assessment and especially the use of flakes, should take note of any sector specific guidance developed at national level based on the practical non-binding guidance, to be published by and available from the Commission as foreseen under Article 12(2) of Directive 98/24/EC (Chemical Agents Directive).

[1] OJ C 34, 7.2.2008, p. 1.

[2] OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council (OJ L 33, 4.2.2006, p. 1).

[3] OJ L 131, 5.5.1998, p. 11. Directive as amended by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

SECTION 4

ANILINE

(CAS No 62-53-3; Einecs No 200-539-3)

Risk reduction measures for workers (6), Consumers (7) and the environment (8, 9, 10, 11)

6. That employers using Aniline for use in to develop activities with foreseeable exposure (e.g. servicing or maintenance work on closed systems) should take note of any sector specific guidance developed at national level based on the practical non-binding guidance, to be published by and available from the Commission as foreseen under Article 12(2) of Directive 98/24/EC (Chemical Agents Directive).

7. Member States should carry out an active and effective market surveillance of the situation in their territories concerning the presence of Aniline containing consumer products and to notify the Commission through the Rapid Alert System of Directive 2001/95/EC [1] (General Product Safety). If proved necessary these products should be removed from the market as being unsafe under the general safety obligation provisions of the Directive.

8. For the river basins where emissions of Aniline may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Council and Parliament Directive 2000/60/EC [2] (Water Framework Directive).

9. Competent authorities in the Member States concerned lay down conditions, emission limit values or equivalent parameters or technical measures regarding Aniline in the permits issued under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) in order to operate according to the best available techniques taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.

10. Member States should carefully monitor the implementation of BAT regarding Aniline and report any important developments to the Commission in the framework of the exchange of information on BAT. To facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) Aniline should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

11. Local emissions to the aquatic environment and via air emissions of Aniline should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected. The measures identified to protect the environment will also reduce exposure of humans via the environment.

SECTION 5

DI-(2-ETHYLHEXYL)PHTHALATE (DEHP)

(CAS No 117-81-7; Einecs No 204-211-0)

Risk reduction measures for the environment

12. For the river basins where emissions of DEHP may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Council and Parliament Directive 2000/60/EC (Water Framework Directive).

SECTION 6

PHENOL

(CAS No 108-95-2; Einecs No 203-632-7)

Risk reduction measures for Consumers and the environment

13. Member States should carry out an active and effective market surveillance of the situation in their territories concerning the presence of consumer products containing phenol and, if necessary, should notify the Commission through the Rapid Alert System of Directive 2001/95/EC (General Products Safety Directive). If proven necessary, these products should be removed from the market as being unsafe under the general safety obligation provisions of the Directive.

14. Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 96/61/EC, emission limit values or equivalent parameters or technical measures regarding phenol in order to operate by 31 October 2007 according to the BAT taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions. Competent authorities in the Member States concerned should pay special regard to potential risks from phenol production and/or processing sites, in respect of industrial wastewater treatment plants situated at such sites, and in respect of humans exposed via the environment (plant shoots contaminated by air emissions from such sites).

[1] OJ L 11, 15.1.2002, p. 4.
[2] OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

15. Member States should carefully monitor the implementation of BAT regarding phenol and report any important developments to the Commission in the framework of the exchange of information on BAT. To facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) phenol should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

16. Local emissions to the environment and to industrial wastewater treatment plants should, where necessary, be controlled by national rules to ensure that no risk for the microorganisms in the industrial wastewater treatment plants and to humans exposed via the environment is expected.

SECTION 7

ADDRESSEES

17. This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the substances and to the Member States.

Done at Brussels, 6 December 2007.

For the Commission

Stavros DIMAS

Member of the Commission