

COMMISSION RECOMMENDATION

of 7 November 2001

on the results of the risk evaluation and the risk reduction strategies for the substances: acrylaldehyde; dimethyl sulphate; nonylphenol phenol, 4-nonyl-, branched; tert-butyl methyl ether

(notified under document number C(2001) 3380)

(Text with EEA relevance)

(2001/838/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) Article 10 of the Regulation (EEC) No 793/93 established the procedure to be followed for the risk evaluation of the substances on the priority lists at the level of the Member States designated as rapporteur.
- (2) Commission Regulation (EC) No 1488/94 ⁽²⁾ outlines the principles for the assessment of risks to man and the environment of existing substances in accordance with Regulation (EEC) No 793/93.
- (3) The Member State rapporteur after evaluating the risk of a given priority substance to man and the environment should suggest where appropriate a strategy for limiting the risk, including control measures and/or surveillance programmes.
- (4) Article 11 of Regulation (EEC) No 793/93 foresees that the results of the risk evaluation and the recommended strategy for limiting risks in respect to substances on the priority lists should be adopted at Community level in accordance with the procedure laid down in Article 15 and shall be published by the Commission.
- (5) Article 1 of Regulation (EEC) No 793/93 provides that that Regulation should apply without prejudice to Community legislation on the protection of consumers and on safety and protection of health of workers at work, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽³⁾.

- (6) A first priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 1179/94 ⁽⁴⁾; this priority list provides, among other substances, for the evaluation of the following:
 - acrylaldehyde.
- (7) A second priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 2268/95 ⁽⁵⁾. This second priority list provides, among other substances, for the evaluation of the following:
 - dimethyl sulphate,
 - nonylphenol,
 - phenol, 4-nonyl-, branched.
- (8) A third priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 143/97 ⁽⁶⁾. This third priority list provides, among other substances, for the evaluation of the following:
 - tert-butyl methyl ether.
- (9) The rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for the above five substances ⁽⁷⁾ and, where appropriate, have suggested strategies for limiting the risks.
- (10) The results of the risk evaluation of the five substances and the recommended risk reduction strategies for the five substances should be adopted at the Community level.

⁽⁴⁾ OJ L 131, 26.5.1994, p. 3.⁽⁵⁾ OJ L 231, 28.9.1995, p. 18.⁽⁶⁾ OJ L 25, 28.1.1997, p. 13.⁽⁷⁾ The comprehensive risk assessment reports as forwarded to the Commission by the Member States rapporteur are publicly available. Short summaries are also available. Both can be found on the internet site of the European Chemicals Bureau, Institute for Health and Consumer Protection of the Joint Research Centre in Ispra, Italy (<http://ecb.ei.jrc.it/existing-chemicals/>).⁽¹⁾ OJ L 84, 5.4.1993, p. 1.⁽²⁾ OJ L 161, 29.6.1994, p. 3.⁽³⁾ OJ L 183, 29.6.1989, p. 1.

(11) In accordance with Article 11(3) of Regulation (EEC) No 793/93, the Commission will consider the results of the risk evaluation and the recommended strategy for limiting the risks, when proposing Community measures in the framework of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations ⁽⁸⁾ and in the framework of Directive 89/391/EEC as well as in the framework of other relevant existing Community instruments.

- nonylphenol
CAS No 25154-52-3
EINECS No 246-672-0
- phenol, 4-nonyl-, branched
CAS No 84852-15-3
EINECS No 284-325-5
- *tert*-butyl methyl ether
CAS No 1634-04-4
EINECS No 216-653-1

(12) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted and has issued an opinion with respect to the risk assessment reports referred to in this recommendation.

should take into account the results of the risk evaluation as summarized in Section I (human health/environment) of Parts 1, 2, 3, 4 and 5 of the Annex to this recommendation and include them, where appropriate, in the safety data sheets ⁽⁹⁾. These results were formulated in the light of the opinions delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) ⁽¹⁰⁾.

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

HEREBY RECOMMENDS:

1. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substances:

2. The risk reduction strategies described in Section II (strategy for limiting risks) of Parts 1, 2, 3, 4, 5 of the Annex to this recommendation should be implemented.

- acrylaldehyde
CAS No 107-02-8
EINECS No 203-453-4
- dimethyl sulphate
CAS No 77-78-1
EINECS No 201-058-1

Done at Brussels, 7 November 2001.

For the Commission
Margot WALLSTRÖM
Member of the Commission

⁽⁸⁾ OJ L 262, 27.9.1976, p. 201.

⁽⁹⁾ In accordance with the provisions of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 1.8.1967, p. 1), Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (OJ L 76, 22.3.1991, p. 35), Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (14th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC, OJ L 131, 5.5.1998, p. 11 and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

⁽¹⁰⁾ The risk assessment reports were peer-reviewed by the CSTEE and its opinions were expressed at the 13th plenary meeting (Brussels, 4 February 2000), 15th plenary meeting (Brussels, 19 June 2000), 22nd plenary meeting (Brussels, 6 and 7 March 2001) and 23rd plenary meeting (Brussels, 24 April 2001). The CSTEE opinions can be found on the internet site:
(http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html).

ANNEX

PART 1

CAS No 107-02-8	Einecs No 203-453-4
Molecular formula:	C ₃ H ₄ O
Einecs Name:	Acrylaldehyde
Rapporteur:	The Netherlands
Classification (¹):	F; R11 T+; R26 T; R24/25 C: R34 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 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 only used as an intermediate for the manufacturing of a number of different substances (e.g. animal feed additives, biocides, pesticides, leather tanning agents, fragrances). Outside the European Community the substance is also used as an effective broad-spectrum biocide, tissue fixative, in etherification of food starch and production of colloidal metals. 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.

The risk assessment has identified other sources of exposure of the substance to man and the environment in particular releases of the substance from industrial combustion processes, automobile exhaust gases and tobacco smoke, 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 risk assessment forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

I. RISK ASSESSMENT

A. HUMAN HEALTH

The conclusions of the assessment of the risks to

WORKERS

are

1. that there is a need for specific measures to limit the risks. This conclusion is reached because of concerns for eye, nose and respiratory tract irritation as a consequence of single and repeated inhalation exposure arising from the production and processing of the substance;

and:

2. that, in addition to the conclusion given above, the risk assessment shows that there are uncertainties with regard to the possible genotoxic and carcinogenic effects of the substance locally at the exposure site after long-term exposure by inhalation to non-cytotoxic concentrations. However, at this moment no validated genotoxicity test exists to investigate this, and the relatively low exposure levels do not justify the request for a carcinogenicity study by inhalation.

The conclusion of the assessment of the risks to

⁽¹⁾ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress or the 28th time Council Directive 67/548 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).

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 is reached, because the risk assessment shows that the substance is not used in products available for consumers.

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 related to the environment 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.

II. 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.

Within this framework it is recommended to develop at Community level occupational exposure limit values for the substance to subirritating levels. Until such time as occupational exposure limit values for the substance have been adopted at Community level, exposure in the workplace should be reduced as low as technically feasible because of possible local carcinogenic effects.

PART 2

CAS No 77-78-1

Einecs No 201-058-1

Molecular formula: $C_2H_6O_4S$
Einecs Name: Dimethyl sulphate
IUPAC Name: Dimethyl sulfate
Rapporteur: The Netherlands
Classification ⁽²⁾: Carc. Cat.2; R45
Muta. Cat.2; R40
T+; R26
T; R25
C; R34
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 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 intermediate and methylating agent in production of many organic chemicals (dyes, perfumes, pharmaceuticals). Other uses reported are as a sulphating agent in the manufacturing of various products (e.g. dyes, fabric softeners). 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.

The risk assessment has identified other sources of exposure of this substance to man and the environment. In particular releases of the substance from combustion of sulphur containing fossil fuels and formation in the atmosphere as a reaction product of sulphur dioxide and organic compounds, which does 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 risk assessment forwarded to the Commission by the Member State Rapporteur does however provide information which could be used to assess these risks.

This substance has not been tested for all aspects of reproductive toxicity and consequently the risk assessment does not evaluate in full the risks to any population of this endpoint. This test has not been required, as the substance has been identified as a non-threshold carcinogen.

I. RISK ASSESSMENT

A. HUMAN HEALTH

The conclusions of the assessment of the risks for

WORKERS

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

- concerns for risks for respiratory tract irritation, mutagenicity and carcinogenicity as a consequence of inhalation exposure arising from production, processing and use of the substance,
- concerns for the pregnant population for adverse health effects as a consequence of repeated inhalation exposure arising from the use of the substance as an intermediate.

⁽²⁾ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 136, 8.6.2000, p. 1).

The conclusion of the assessment of the risks for

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that the risk assessment shows that risks cannot be excluded at any exposure, as the substance is identified as a non-threshold carcinogen. However the risks covered by this risk assessment are not of a magnitude, that immediate action is deemed necessary. Risk reduction measures already being applied are considered sufficient to impose pressure in reducing and controlling exposure to the substance.

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 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.

II. 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.

Within this framework it is recommended:

- to develop at Community level occupational exposure limit values for the substance.

PART 3

CAS No 25154-52-3

Einecs No 246-672-0

Molecular formula: $C_{15}H_{24}O$

Einecs Name: Nonylphenol

Rapporteur: United Kingdom

Classification ⁽³⁾: Xn; R22, C; R34
N: R50-53

⁽³⁾ The classification of the substance is established by Commission Directive 2001/59/EC of 26 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/CEE 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).

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 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 intermediate in the production of nonylphenol ethoxylates (e.g. in detergents and paints) and in the production of resins, plastics and stabilisers in the polymer industry. Other uses include the manufacture of phenolic oximes for use outside the EU in the metal extraction industry and in some speciality paints.

I. 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 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 for human health.

This conclusion is reached while evaluation of the available data submitted in accordance with the relevant provisions of Regulation (EEC) No 793/93 is underway ⁽⁴⁾.

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 related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM are:

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

- concerns for effects on the aquatic spheres including sediment.

The information and/or test requirements are:

- further toxicity testing on sediment organisms.

However, the implementation of the strategy for limiting risks for the environment in Section II Part 3 of the Annex will eliminate the need for further information requirements.

and

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

- concerns for effects on local and regional aquatic environmental spheres including sediment as a consequence of exposure arising from nonylphenol production ⁽⁵⁾, production of phenolic oximes, phenol/formaldehyde resins ⁽⁶⁾, epoxy resins ⁽⁷⁾ and other plastic stabilisers, nonylphenol ethoxylate production, formulation and use,

⁽⁴⁾ The need for further information and/or testing applies to one scenario only. The full conclusions of the human health risk assessment will be published in a subsequent Commission recommendation.

⁽⁵⁾ For these uses risks to the aquatic environment only occur because of the contribution of background concentrations to local levels. The same applies to the use of nonylphenol ethoxylates in agricultural pesticide formulations, small scale photographic processes and domestic and industrial emulsion paints.

⁽⁶⁾ For these uses risks to the aquatic environment only occur because of the contribution of background concentrations to local levels. The same applies to the use of nonylphenol ethoxylates in agricultural pesticide formulations, small scale photographic processes and domestic and industrial emulsion paints.

⁽⁷⁾ For these uses risks to the aquatic environment only occur because of the contribution of background concentrations to local levels. The same applies to the use of nonylphenol ethoxylates in agricultural pesticide formulations, small scale photographic processes and domestic and industrial emulsion paints.

- concerns for effects for terrestrial spheres as a consequence of exposure arising from the production, formulation and uses of nonylphenol ethoxylates in veterinary medicines, captive use by the chemical industry, electrical engineering, industrial and institutional cleaning, in leather processing, metal extraction, in the photographic, pulp and paper, polymer and textile industry, in paint manufacture and in civil and mechanical engineering,
- concerns for effects on secondary poisoning to fish and earthworm predators as a consequence of exposure arising from nonylphenol ethoxylate production and formulation, and the use of nonylphenol ethoxylates in industrial and institutional cleaning, the electrical engineering industry, the paints, lacquers and varnish industry, civil engineering, leather processing, metal extraction, the pulp, paper and board industry, and in textile processing.

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.

II. STRATEGY FOR LIMITING RISKS

For the ENVIRONMENT:

Marketing and use restrictions should be considered at Community level to protect the environment from the use of nonylphenol/nonylphenol ethoxylates (NP/NPEs) in particular in:

- industrial, institutional and domestic cleaning,
- textiles processing,
- leather processing,
- agriculture (biocidal products, in particular use in teat dips),
- metal working,
- pulp and paper industry,
- cosmetics including shampoos and other personal care products.

Further work is necessary to establish those uses for which derogations can be justified.

In addition to the above, and recognising development of new Community procedures, additional measures for nonylphenol and nonylphenol ethoxylates should be considered including pollution prevention measures⁽⁸⁾ at Community level, as appropriate, for the following sectors:

- production of nonylphenol and nonylphenol ethoxylates;
- use of nonylphenol ethoxylates in the synthesis of other chemicals (captive use);

⁽⁸⁾ Work currently underway at Community level in the framework of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26) in developing BAT Reference Documents (BREFs) that cover various chemical processes may be particularly significant in this respect. Further information on the matter can be obtained consulting the European IPPC Bureau website: <http://eippcb.jrc.es>.

- use of nonylphenol ethoxylates in emulsion polymerisation in particular use in acrylic esters used for specialist coatings, adhesives and fibre bonding;
- production of phenol/formaldehyde resins using nonylphenol;
- production of other plastic stabilisers using nonylphenol.

The results achieved through marketing and use restrictions and pollution control measures should be monitored and if necessary additional measures should be considered. In particular, consideration should be given to other Community instruments ⁽⁹⁾ to ensure control of environmental concentrations of nonylphenol and nonylphenol ethoxylates via the objectives as set-out in those instruments. These measures should be applied to the above sectors and those listed below:

- formulation (in sectors where nonylphenol/nonylphenol ethoxylates use will continue);
- civil and mechanical engineering including the manufacture of wall construction materials, road surface materials and also in the cleaning of metals;
- additives in lubricating oil and in the blending of fuel additive packages;
- electronics/electrical engineering in particular use in fluxes in the manufacture of painted circuit boards, in dyes to identify cracks in printed circuit boards and as a component of chemical baths used in the etching of circuit boards;
- the photographic industry (small and large scale) in particular use in products intended for home use by amateur photographers, for photo developers who develop film for amateur photographers, some professional products and also use in x-ray film;
- production of phenolic oximes/epoxy resins;
- the preparation of paint resin and also as a paint mixture stabiliser.

The need for further marketing and use restrictions should be considered at Community level if the measures taken in these sectors are shown to be inadequate.

For possible use in biocides as an active substance, within the legislative framework currently in force at Community level for biocidal products, it is recommended that due consideration be taken of the results of the risk assessment.

For use in pesticides as an active substance, within the legislative framework currently in force at Community level for plant protection products ⁽¹⁰⁾, national authorities when granting authorisation decisions and in particular in cases where significant environmental impact is already experienced at local level should take into due consideration the results of the risk assessment. In such cases encouragement should be given to the development and use of alternatives to nonylphenol and nonylphenol ethoxylates.

For the use as an adjuvant/co-formulant ⁽¹¹⁾ in pesticide and biocidal products national authorities when granting authorisation decisions and in particular in cases where significant environmental impact is already experienced at local level should take into due consideration the results of the risk assessment. Encouragement should be given to the development and use of alternatives to nonylphenol and nonylphenol ethoxylates and the adoption of other measures aimed at modifying consumer behaviour.

Furthermore, information should be disseminated to all interested parties in the Community to ensure protection of the environment.

⁽⁹⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1) introduces provisions for pollution reduction measures at Community level. Based on the list of priority substances in Annex X of the Directive, the Commission will propose quality standards and emission controls, including emission limit values two years after adoption of the list. For certain 'priority hazardous substances' amongst the priority substances, the emission controls shall aim at the cessation or phase-out of discharges, emissions and losses within 20 years. Nonylphenols are included as a 'priority hazardous substance' in the first list of priority substances which has been proposed by the Commission in February 2000 (COM (2000) 47 final (OJ C 177 E, 27.6.2000, p. 74) as amended by COM (2001) 17 final of 16 January 2001). The first list of priority substances including nonylphenols was adopted on 11 June 2001 by the Council thus allowing the measures under Directive 2000/60/EC to be used as an additional instrument to reduce risks to or via the aquatic environment.

⁽¹⁰⁾ In the framework of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991) it is foreseen that nonylphenol and nonylphenol ethoxylates as active substances in pesticides will be withdrawn from the market as from July 2003.

⁽¹¹⁾ For the time being this use is not subject to Community evaluation in the framework of 91/414/EEC.

For the possible uses of nonylphenol and nonylphenol ethoxylates in veterinary medicinal products, within the legislative framework currently in force at Community level for veterinary medicinal products, it is recommended to holders of marketing authorisations for products containing the substances that they should substitute them with less harmful alternatives.

For the use of sludge containing nonylphenol and nonylphenol ethoxylates, within the legislative framework currently in force at Community level for sludge management, it is recommended that consideration be given to the development of provisions on concentration limit values for nonylphenol and nonylphenol ethoxylates when sludge is spread on land.

The measures identified to protect the environment will also reduce human exposure.

PART 4

CAS No 84852-15-3

Einecs No 284-325-5

Molecular formula: $C_{15}H_{24}O$
Einecs Name: Phenol, 4-nonyl-, branched
IUPAC Name: 4-nonylphenol, branched
Rapporteur: United Kingdom
Classification ⁽¹²⁾: Xn; R22, C; R34
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 intermediate in the production of nonylphenol ethoxylates e.g. in detergents and paints and in the production of resins, plastics and stabilisers in the polymer industry. Other uses include the manufacture of phenolic oximes for use outside the EU in the metal extraction industry and in some specialty paints.

I. RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

WORKERS, CONSUMERS, HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for further information and/or testing. This conclusion is reached because there is a need for better information to adequately characterise the risks for human health.

This conclusion is reached while evaluation of the available data submitted in accordance with the relevant provisions of Regulation (EEC) No 793/93 is underway ⁽¹³⁾.

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:

⁽¹²⁾ 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 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).

⁽¹³⁾ The need for further information and/or testing applies to one scenario only. The full conclusions of the human health risk assessment will be published in a subsequent Commission recommendation.

- 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 conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM are:

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

- concerns for effects on the aquatic spheres including sediment.

The information and/or test requirements are:

- further toxicity testing on sediment organisms.

However, the implementation of the strategy for limiting risks for the environment in Section II Part 4 of the Annex will eliminate the need for further information requirements;

and

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

- concerns for effects on local and regional aquatic environmental spheres including sediment as a consequence of exposure arising from nonylphenol production⁽¹⁴⁾, production of phenolic oximes⁽¹⁵⁾, phenol/formaldehyde resins, epoxy resins⁽¹⁶⁾ and other plastic stabilisers, nonylphenol ethoxylate production, formulation and use,
- concerns for effects for terrestrial spheres as a consequence of exposure arising from the production, formulation and uses of nonylphenol ethoxylates in veterinary medicines, captive use by the chemical industry, electrical engineering, industrial and institutional cleaning, in leather processing, metal extraction, in the photographic, pulp and paper, polymer and textile industry, in paint manufacture and in civil and mechanical engineering,
- concerns for effects on secondary poisoning to fish and earthworm predators as a consequence of exposure arising from nonylphenol ethoxylate production and formulation, and the use of nonylphenol ethoxylates in industrial and institutional cleaning, the electrical engineering industry, the paints, lacquers and varnish industry, civil engineering, leather processing, metal extraction, the pulp, paper and board industry, and in textile processing.

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.

II. STRATEGY FOR LIMITING RISKS

for the ENVIRONMENT:

Marketing and use restrictions should be considered at Community level to protect the environment from the use of nonylphenol/nonylphenol ethoxylates (NP/NPEs) in particular in:

- industrial, institutional and domestic cleaning,
- textiles processing,

⁽¹⁴⁾ For these uses risks to the aquatic environment only occur because of the contribution of background concentrations to local levels. The same applies to the use of nonylphenol ethoxylates in agricultural pesticide formulations, small scale photographic processes and domestic and industrial emulsion paints.

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- leather processing,
- agriculture (biocidal products, in particular use in teat dips),
- metal working,
- pulp and paper industry,
- cosmetics including shampoos and other personal care products.

Further work is necessary to establish those uses for which derogations can be justified.

In addition to the above, and recognising development of new Community procedures, additional measures for nonylphenol and nonylphenol ethoxylates should be considered including pollution prevention measures⁽¹⁷⁾ at Community level, as appropriate, for the following sectors:

- production of nonylphenol and nonylphenol ethoxylates;
- use of nonylphenol ethoxylates in the synthesis of other chemicals (captive use);
- use of nonylphenol ethoxylates in emulsion polymerisation in particular use in acrylic esters used for specialist coatings, adhesives and fibre bonding;
- production of phenol/formaldehyde resins using nonylphenol;
- production of other plastic stabilisers using nonylphenol.

The results achieved through marketing and use restrictions and pollution control measures should be monitored and if necessary additional measures should be considered. In particular, consideration should be given to other Community instruments⁽¹⁸⁾ to ensure control of environmental concentrations of nonylphenol and nonylphenol ethoxylates via the objectives as set-out in those instruments. These measures should be applied to the above sectors and those listed below:

- formulation (in sectors where nonylphenol/nonylphenol ethoxylates use will continue);
- civil and mechanical engineering including the manufacture of wall construction materials, road surface materials and also in the cleaning of metals;
- additives in lubricating oil and in the blending of fuel additive packages;
- electronics/electrical engineering in particular use in fluxes in the manufacture of painted circuit boards, in dyes to identify cracks in printed circuit boards and as a component of chemical baths used in the etching of circuit boards;
- the photographic industry (small and large scale) in particular use in products intended for home use by amateur photographers, for photo developers who develop film for amateur photographers, some professional products and also use in X-ray film;
- production of phenolic oximes/epoxy resins;
- the preparation of paint resin and also as a paint mixture stabiliser.

The need for further marketing and use restrictions should be considered at Community level if the measures taken in these sectors are shown to be inadequate.

⁽¹⁷⁾ Work currently underway at Community level in the framework of Directive 96/61/EC in developing BAT Reference Documents (BREFs) that cover various chemical processes may be particularly significant in this respect. Further information on the matter can be obtained consulting the European IPPC Bureau website: <http://eippcb.jrc.es>

⁽¹⁸⁾ Directive 2000/60/EC introduces provisions for pollution reduction measures at Community level. Based on the list of priority substances in Annex X of the Directive, the Commission will propose quality standards and emission controls, including emission limit values two years after adoption of the list. For certain 'priority hazardous substances' amongst the priority substances, the emission controls shall aim at the cessation or phase-out of discharges, emissions and losses within 20 years. Nonylphenols are included as a 'priority hazardous substance' in the first list of priority substances which has been proposed by the Commission in February 2000 (COM (2000) 47 final, OJ C 177 E, 27.6.2000, p. 74; as amended by COM (2001) 17 final of 16 January 2001). The first list of priority substances including nonylphenols was adopted on 11 June 2001 by the Council thus allowing the measures under Directive 2000/60/EC to be used as an additional instrument to reduce risks to or via the aquatic environment.

For possible uses in biocides as an active substance, within the legislative framework currently in force at Community level for biocidal products, it is recommended that due consideration be taken of the results of the risk assessment.

For use in pesticides as an active substance, within the legislative framework currently in force at Community level for plant protection products ⁽¹⁹⁾, national authorities when granting authorisation decisions and in particular in cases where significant environmental impact is already experienced at local level should take into due consideration the results of the risk assessment. In such cases encouragement should be given to the development and use of alternatives to nonylphenol and nonylphenol ethoxylates.

For the use as an adjuvant/co-formulant ⁽²⁰⁾ in pesticide and biocidal products national authorities when granting authorisation decisions and in particular in cases where significant environmental impact is already experienced at local level should take into due consideration the results of the risk assessment. Encouragement should be given to the development and use of alternatives to nonylphenol and nonylphenol ethoxylates and the adoption of other measures aimed at modifying consumer behaviour.

Furthermore, information should be disseminated to all interested parties in the Community to ensure protection of the environment.

For the possible use of nonylphenol and nonylphenol ethoxylates in veterinary medicinal products, within the legislative framework currently in force at Community level for veterinary medicinal products, it is recommended to holders of marketing authorisations for products containing the substances that they should substitute them with less harmful alternatives.

For the use of sludge containing nonylphenol and nonylphenol ethoxylates, within the legislative framework currently in force at Community level for sludge management, it is recommended that consideration be given to the development of provisions on concentration limit values for nonylphenol and nonylphenol ethoxylates when sludge is spread on land.

The measures identified to protect the environment will also reduce human exposure.

PART 5

CAS No 1634-04-4

Einecs No 216-653-1

Molecular formula: $C_5H_{12}O$

Einecs Name: *tert*-butyl methyl ether

Rapporteur: Finland

Classification: not yet classified

The risk assessment is based on current practices related to the life-cycle of this substance produced in or imported into the European Community as described in the Comprehensive Risk Assessment forwarded to the Commission by the Member State Rapporteur.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a fuel-additive in petrol. Other uses are in chemical and pharmaceutical industry and laboratories.

I. 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 repeated dose local skin effects as a consequence of exposure arising from maintenance operations and automotive repair.

⁽¹⁹⁾ In the framework of Directive 91/414/EEC it is foreseen that nonylphenol and nonylphenol ethoxylates as active substances in pesticides will be withdrawn from the market as from July 2003.

⁽²⁰⁾ For the time being this use is not subject to Community evaluation in the framework of Directive 91/414/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 a need for specific measures to limit the risks. This conclusion is reached because of:

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

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

AQUATIC ECOSYSTEM are:

1. 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 eco-system regarding the emission of the substance to surface water.

The information and/or test requirements are:

- a tiered testing strategy for the investigation of the avoidance behaviour of fish and possibly wildlife related to water contaminated with the substance;

and

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

- concerns for the aquatic eco-system as a consequence of exposure arising from releases to surface water from terminal site storage tank bottom waters.

The conclusion of the assessment of the risks to

GROUNDWATER

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

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

The conclusion of the assessment of the risks to

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

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

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

The conclusion of the assessment of the risks to

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.

II. 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.

Furthermore, and without prejudice to Community legislation in force in the area ⁽²¹⁾, it is recommended to investigate how to improve the design of fuel filter position in cars and fuel pumps so to facilitate maintenance and repair work while aiming at minimum skin exposure to petrol. It is therefore suggested to pursue discussions with relevant organisations of industry branches in this respect.

For HUMANS EXPOSED VIA THE ENVIRONMENT:

It is considered that measures, presented below, aiming at protection of groundwater will contribute to preventing the contamination of drinking water.

For the ENVIRONMENT:

The prevention of all anthropogenic inputs, including MTBE, to groundwater is a key objective of current Community legislation ⁽²²⁾. It is recommended therefore that monitoring programmes be undertaken, where appropriate, in order to permit the early detection of groundwater contaminated by MTBE.

It is further recommended that the best available techniques be widely applied for the construction and operation of petrol underground storage and distribution facilities at service stations. In this regard Member States should consider mandatory requirements especially for all service stations in groundwater recharge areas. Furthermore, it is recommended that harmonised technical standards for the construction and operation of the storage tanks be developed at a European level by the European Committee for Standardisation (CEN). Potential past release sites, located on critical areas, should be investigated and, where necessary, remediated.

Furthermore, exchange of information on these programmes and their results should be promoted.

It is also recommended that MTBE containing bottom waters of above-ground storage tanks be controlled by plant permits ⁽²³⁾ or national rules.

To facilitate the permitting (as well as any fixing of national rules) these issues are included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT) ⁽²⁴⁾.

It is recommended that Member States carefully monitor the implementation of BAT in this respect and report any important developments in BAT to the Commission in the framework of the exchange of information on BAT.

⁽²¹⁾ Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles (OJ L 76, 6.4.1970, p. 1).

⁽²²⁾ Directive 2000/60/EC.

⁽²³⁾ Plant permits issued under Directive 96/61/EC.

⁽²⁴⁾ Work currently underway at Community level in the framework of Directive 96/61/EC in developing BAT Reference Documents (BREFs) that cover MTBE production and handling, including design and management of storage modes.