COMMISSION RECOMMENDATION

of 4 July 2002

on the results of the risk evaluation and the risk reduction strategies for the substances: o-anisidine, 1,4-dioxane

(notified under document number C(2002) 2486)

(Text with EEA relevance)

(2002/575/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 Regulation (EEC) No 793/93 establishes the procedure to be followed for the risk evaluation of the substances on the priority lists at the level of the Member State 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 rapporteur Member State 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 shall 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 98/24/EC ([3]) on the protection of the safety and health of workers from the risks related to chemical agents at work, Council Directive 90/394/EEC ([4]) on the protection of workers from risks related to exposure to carcinogens at work and Council Directive 92/85/EEC ([5]) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

(6) A second priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 2268/95 ([6]). This second priority list provides, among other substances, for the evaluation of the following:

— o-anisidine,

— 1,4-dioxane.

(7) The rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for the above two substances ([7]) and, where appropriate, have suggested strategies for limiting the risks.

(8) The results of the risk evaluation of the two substances and the recommended risk reduction strategies for the two substances should be adopted at the Community level.

(9) 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 Council Directive 98/24/EC as well as in the framework of other relevant existing Community instruments.

(10) 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.

(11) 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,

([1]) OJ L 84, 5.4.1993, p. 1.
([2]) OJ L 161, 29.6.1994, p. 3.
([3]) OJ L 131, 5.5.1998, p. 11.
([4]) OJ L 196, 26.7.1990, p. 1.
([5]) OJ L 348, 28.11.1992, p. 1.
([6]) OJ L 231, 28.9.1995, p. 18.
([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/).
([8]) OJ L 262, 27.9.1976, p. 201.

HEREBY RECOMMENDS:

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

   — o-anisidine

   CAS No 90-04-0

   Einecs No 201-963-1

   — 1,4-dioxane

   CAS No 123-91-1

   Einecs No 204-661-8

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

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

Done at Brussels, 4 July 2002.

For the Commission

Margot WALLSTRÖM

Member of the Commission

[1] 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 (fourteenth 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).

[2] The risk assessment reports were peer-reviewed by the CSTEE and its opinions can be found on the internet site: (http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html).

ANNEX

PART ONE

CAS-No. 90-04-0	Einecs-No. 201-963-1

Molecular Formula:	C_7H_9NO
Einecs Name:	o-anisidine
IUPAC Name:	1-amino-2-methoxy-benzene
Rapporteur:	Austria
Classification ([1]):	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25

([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).

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.

The risk assessment has, based on the available information, determined that in the European Community the substance is used as an intermediate in the production of dyes and pigments. 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 has not been tested for reproductive toxicity. Consequently, the risk assessment does not evaluate the risks to any population for these endpoints. These tests have not been required, as the substance has been identified as a non-threshold carcinogen.

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 general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of exposure arising from the installation of gas compensation pipes in the processing of the substance.

Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

Consumers

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

— concerns for general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of dermal exposure arising from textiles coloured with dyes based on the substance,

— concerns for young children for general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of oral exposure by sucking textiles coloured with dyes based on the substance.

Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

Humans exposed via the environment

is that there is a need for specific measures to limit the risks. This conclusion is reached because risks can not be excluded, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

Human health (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

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, and in particular the Directive 90/394/EEC on the protection of workers from the risks related to the exposure to carcinogens at work, are generally considered to give an adequate framework to limit the risks of the substance to the extent needed, and shall apply. Within this legislative framework the concerned companies are reminded of their obligations to ensure that workplace exposure arising from the installation of gas compensation pipes is reduced to as low as technically possible, and that alternative processes and/or substitutes are not dangerous or are less dangerous to workers' health and safety.

For consumers

The draft for the 19th amendment of Directive 76/769/EEC relating to restrictions on the marketing and use of azocolourants is considered to effectively minimise the risk arising from the release of o-anisidine from dyed textiles and clothes. Therefore, implementation of this amendment should be speeded up as far as possible. The effectiveness of the measure would have to be ensured by adequate monitoring programmes.

PART TWO

CAS-No. 123-91-1	Einecs-No. 204-661-8

Molecular Formula:	$C_4H_8O_2$
Einecs Name:	1,4-Dioxane
Rapporteur:	The Netherlands
Classification [2]:	F; R11-19 Carc. Cat. 3; R40 Xi; R36/37 R66

[2] 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).

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 as 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 processing solvent in production of pharmaceuticals, pesticides, magnetic tapes, adhesives and other products. 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 to the substance, relevant for man and the environment, in particular, the substance is created as a by-product in a number of industrial processes like ethoxylation reactions, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures is not part of this risk assessment. The comprehensive Risk Assessment Report, as forwarded to the Commission by the Member State Rapporteur, does however provide information about these risks.

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 defatting with subsequent adverse skin effects as a consequence of exposure arising from production, formulation and use of the substance or the product containing the substance,

— concerns for general systemic toxicity and carcinogenicity as a consequence of dermal exposure arising from the use of the substance in cleaning agents,

— concerns for general systemic toxicity and carcinogenicity as a consequence of inhalation exposure arising from formulation of the substance.

The conclusion of the assessment of the risks to

Consumers and humans exposed via the environment

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

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

The conclusion of the assessment of the risks to

Human health (physico-chemical properties)

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

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

B. ENVIRONMENT

The conclusion of the assessment of the risks to the

Atmosphere, aquatic ecosystem and terrestrial ecosystem

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

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

The conclusion of the assessment of the risks to

Micro-organisms in the sewage treatment plant

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

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

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 and shall apply.

Within this framework it is recommended:

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