

COMMISSION RECOMMENDATION

of 4 July 2002

on the results of the risk evaluation for the substances: ethyl acetoacetate, 4-Chloro-o-cresol, Dimethyldioctadecylammonium chloride

(notified under document number C(2002) 2490)

(Text with EEA relevance)

(2002/576/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 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 provides 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 first priority list identifying substances requiring attention has been adopted by Commission Regulation (EC) No 1179/94 ⁽⁶⁾. This priority list provides, among other substances, for the evaluation of the following:
 - ethyl acetoacetate,
 - 4-Chloro-o-cresol,
 - Dimethyldioctadecylammonium chloride.
- (7) The rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for the above three substances ⁽⁷⁾.
- (8) The results of the risk evaluation of the three substances concerned should be adopted at the Community level.
- (9) 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 ⁽⁸⁾.
- (10) 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:

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

- ethyl acetoacetate
CAS No 141-97-9
Einecs No 205-516-1,

⁽⁶⁾ OJ L 131, 26.5.1994, p. 3.

⁽⁷⁾ The comprehensive risk assessment reports as forwarded to the Commission by the rapporteur Member States 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.jrc.it/existing-chemicals/>).

⁽⁸⁾ The risk assessment reports were peer-reviewed by the CSTEE. The CSTEE opinions can be found on the internet site: http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html.

⁽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.

— 4-Chloro-o-cresol
CAS No 1570-64-5
Einecs No 216-381-3,

— Dimethyldioctadecylammonium chloride
CAS No 107-64-2
Einecs No 203-508-2,

should take into account the results of the risk evaluation as summarised in Parts 1, 2 and 3 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).

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).

ANNEX

PART ONE

CAS-No. 141-97-9

Einecs-No. 205-516-1

Molecular Formula: $C_6H_{10}O_3$

Einecs Name: ethyl acetoacetate

Rapporteur: Germany

Classification (!): Not classified

(!) Based on the information available, no classification of the substance is justified, following the criteria set out in Annex VI 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).

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 mainly used as an intermediate in the production of pharmaceuticals, plant protection products, stabilisers, additives, catalysts and other products. Other uses are in a wide range of household and cosmetic products, as a food additive, in the manufacture of colour films, as a paper impregnation agent and as a solvent in paints and lacquers. 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.

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

Workers, consumers and humans exposed via the environment

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

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

The conclusion of the assessment of the risks to

Human health (physico-chemical properties)

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 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.

PART TWO

CAS-No. 1570-64-5

Einecs-No. 216-381-3

Molecular Formula:	C ₇ H ₇ ClO
Einecs Name:	4-Chloro-o-cresol
IUPAC Name:	4-Chloro-2-Methyl Phenol
Rapporteur:	Denmark
Classification ⁽²⁾ :	T; R23 C; R35 N; R50

⁽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 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 starting material for the manufacture of herbicides. 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 does not cover the possible risks caused by the presence of the substance as an impurity in certain herbicides nor does it cover the possible risks arising from the formation of the substance during environmental degradation of the herbicides.

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

Workers, consumers and humans exposed via the environment

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

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

The conclusion of the assessment of the risks to

Human health (physico-chemical properties)

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 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 THREE

CAS-No. 107-64-2

Einecs-No. 203-508-2

Molecular Formula:	$C_{38}H_{80}N.Cl$
Einecs Name:	Dimethyldioctadecylammonium chloride
Rapporteur:	Germany
Classification ⁽³⁾ :	Xi; R41 N; R50-53

⁽³⁾ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adopting 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).

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 not used as such, but is the main component of the technical product Quarternary Ammonium compound, bis(hydrogenated tallow alkyl) dimethyl, chlorides (CAS-No 61789-80-8). This substance, in turn, is mainly used as a fabric softener and in the synthesis of organic clays. Other uses are as a conditioning agent in cosmetics (shampoos, hair conditioners, emulsifier in lotions) and in car washing agents. 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.

RISK ASSESSMENT

A. HUMAN HEALTH

The conclusion of the assessment of the risks to

Workers, consumers and humans exposed via the environment

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

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

The conclusion of the assessment of the risks to

Human health (physico-chemical properties)

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 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.