

COMMISSION REGULATION (EC) No 1217/2002**of 5 July 2002****requiring importers or manufacturers of certain EINECS substances to supply certain information and perform certain tests pursuant to Council Regulation (EEC) No 793/93**

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 12(2) thereof,

Whereas:

- (1) A number of Member States have apprised the Commission of valid reasons for believing that certain substances in the European Inventory of Existing Commercial Chemical Substances (EINECS) ⁽²⁾ may, due to the degree of exposure entailed in their production or use, pose a serious risk to humans or the environment.
- (2) The manufacturers and importers concerned should therefore be required to provide the Commission with the information in their possession concerning those substances.
- (3) The manufacturers and importers concerned should also be required to test the substances in question, to draw up a report on those tests and to forward those reports, together with the results of the tests, to the Commission, subject to the possibility provided for by Article 12(3) of Regulation (EEC) No 793/93 that, where a substance is produced or imported as such or in a preparation by several manufacturers or importers, further testing may

be performed by one or more manufacturers or importers acting on behalf of the others.

- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 15 of Regulation (EEC) No 793/93,

HAS ADOPTED THIS REGULATION:

Article 1

Manufacturers and importers of one or more of the EINECS substances listed in the Annex to this Regulation shall:

- (a) provide the Commission with the information specified in the Annex within the time-limits laid down therein;
- (b) perform, in relation to each such substance, the tests indicated in the Annex in accordance with the protocols specified therein;
- (c) provide the Commission with a report on each test, including the results thereof, within the time-limits laid down in the Annex.

*Article 2*This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 July 2002.

For the Commission
Margot WALLSTRÖM
Member of the Commission

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJ C 146 A, 15.6.1990, p.1.

ANNEX

The testing/information requirements referred to in this Annex should be addressed to:

European Commission
Directorate-General for Environment
Directorate C — Unit C.3 — Chemicals
B-1049 Brussels

	Einecs No	CAS No	Substance name	Reason(s) for concern	Testing/Information Requirements	Months from the date of entry into force of this Regulation)
1	203-988-3	112-59-4	Diethylene glycol mono-hexyl ether	Human exposure during production and use. Dispersive use in coatings, printing inks and cleaning applications Unavailability of studies on developmental and fertility effects of the substance causes concern because of clear reprotoxicity observed in rodent and non-rodent studies with some ethylene glycol ether derivatives	Fertility Study (EC B.34 ⁽¹⁾ / OECD TG 415 ⁽²⁾ or OECD TG 416 ⁽³⁾)	18
2	263-090-2	61789-80-8	Quaternary Ammonium compounds, bis(hydrogenated tallow alkyl) dimethyl, chlorides	Significant increase in consumption volumes of the substance which would pose a potential risk for the environment	Yearly reports from industry of the total production and use volumes of the substance (period 2000-2002)	6 (volumes year 2000) 18 (volumes year 2001) 24 (volumes year 2002)
3	203-481-7	107-31-3	Methyl formate	High Production Volume Chemical Acute inhalation exposure of experimental animals to the substance has resulted in eye and respiratory tract irritation Uncertainty and impossibility of establishing a scientifically based OEL (SCOEL) due to lack of data Lack of data on prolonged exposure for the establishment of safe exposure level	Subchronic Inhalation Toxicity Study: 90-day repeated inhalation dose study (EC B.29 ⁽³⁾ /OECD TG 413 ⁽⁴⁾)	18
4	200-864-0	75-35-4	1,1-dichloroethene	High Production Volume Chemical Nervous system dysfunctioning upon long term exposure well below present Occupational Exposure Limits (OELs)	Subchronic Inhalation Toxicity Study: 90-day repeated inhalation dose study (recovery period of 4-6 weeks) with special neurological parameters (EC B.29 ⁽³⁾ /OECD TG 413 ⁽⁶⁾ and OECD TG 424 ⁽⁵⁾). General pathology may be waived if this information is available in other studies.	18

	Einecs No	CAS No	Substance name	Reason(s) for concern	Testing/Information Requirements	Months from the date of entry into force of this Regulation)
					Special neurological parameters: — Functional observational battery and motor activity assessment; — Assessment of behavioural performance (e.g. visual discrimination performance); — Assessment of cognitive function (e.g. delayed alternation, Morris water maze). All relevant information and full study reports necessary for evaluation of the hazard potential of the substance	
5	211-309-7	637-92-3	2-ethoxy-2-methylpropane	Data poor substance Growing potential for wide dispersive use of the substance due to its potential use as a substitute for MTBE Adverse effects may occur upon prolonged exposure	Information on annual production and import volumes Acute Toxicity for <i>Daphnia</i> (EC C.2 ⁽³⁾/OECD TG 202 ⁽⁶⁾) Growth Inhibition Test for Algae (EC C.3 ⁽³⁾/OECD TG 201 ⁽⁷⁾) Developmental Toxicity Study (OECD TG 414 ⁽⁸⁾) All relevant information and full study reports necessary for evaluation of the hazard potential of the substance	18
					Fertility Study (OECD TG 416 ⁽⁵⁾)	24

⁽¹⁾ In accordance with Annex V 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, 16.8.1967, p.1).

⁽²⁾ OECD's *Guidelines for the Testing of Chemicals - Section 4 - Health Effects* TG No 415: 'One-Generation Reproduction Toxicity Study' (Original Guideline, adopted 26 May 1983).

⁽³⁾ OECD's *Guidelines for the Testing of Chemicals - Section 4 - Health Effects* TG No 416: 'Two-Generation Reproduction Toxicity Study' (Updated Guideline, adopted 22 January 2001).

⁽⁴⁾ OECD's *Guidelines for the Testing of Chemicals - Section 4 - Health Effects* TG No 413: 'Subchronic Inhalation Toxicity: 90-day Study' (Original Guideline, adopted 12 May 1981).

⁽⁵⁾ OECD's *Guidelines for the Testing of Chemicals - Section 4 - Health Effects* TG No 424: 'Neurotoxicity Study in Rodents' (Original Guideline, adopted 21 July 1997).

⁽⁶⁾ OECD's *Guidelines for the Testing of Chemicals - Section 2 - Effects on Biotic Systems* TG No 202: 'Daphnia sp. Acute Immobilisation Test and Reproduction Test' (Updated Guideline, adopted 4 April 1984).

⁽⁷⁾ OECD's *Guidelines for the Testing of Chemicals - Section 2 - Effects on Biotic Systems* TG No 201: 'Alga, Growth Inhibition Test' (Updated Guideline, adopted 7 June 1984).

⁽⁸⁾ OECD's *Guidelines for the Testing of Chemicals - Section 4 - Health Effects* TG No 414: 'Prenatal Developmental Toxicity Study' (Updated Guideline, adopted 22 January 2001).