

**COMMISSION REGULATION (EC) No 2592/2001  
of 28 December 2001**

**imposing further information and testing requirements on the manufacturers or importers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risk of existing substances**

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 risks of existing substances <sup>(1)</sup>, and in particular Article 10(2) thereof,

Whereas:

- (1) The Member States designated as rapporteur pursuant to Regulation (EEC) No 793/93 for certain priority substances undergoing risk evaluation activities have evaluated the information submitted by the manufacturers or importers in respect of those substances. After consultation of the manufacturers or importers concerned, they have determined whether, for the purposes of the risk evaluation, it is necessary to require those manufacturers or importers to submit further information and/or to carry out further testing.
- (2) The manufacturers and importers have checked whether the information needed to evaluate the substances in question is not available from former manufacturers or importers of those substances, in accordance with Article 10(5) of Regulation (EEC) No 793/93. The manufacturers and importers have also checked, in consultation with the Member States designated as rapporteur, whether tests on animals cannot be replaced or limited by using other methods.
- (3) The Commission has been informed by the Member States designated as rapporteur of the need to request further information and testing from the manufacturers or importers of those substances.
- (4) The Member States designated as rapporteur have submitted to the Commission the protocols on the requested further testing.

- (5) Article 12(3) of Regulation (EEC) No 793/93 provides that in the case of a substance produced or imported as such or in a preparation by several manufacturers or importers, the further testing may be performed by one manufacturer/importer acting on behalf of the other manufacturers or importers concerned. In that case, the other manufacturers or importers are to make reference to the tests carried out and make a fair and equitable contribution to the cost.
- (6) The provisions of 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*

The manufacturer(s) and importer(s) of the substances listed in the Annex to this Regulation, who have submitted information in accordance with the requirements of Articles 3, 4, 7 and 9 of Regulation (EEC) No 793/93, shall provide the information and perform the tests indicated in the Annex to this Regulation and shall deliver the relevant results to the Member States designated as rapporteur.

The tests shall be performed according to the protocols specified by the Member States designated as rapporteur.

The results shall be delivered within the time limits laid down in the Annex.

*Article 2*

This Regulation shall enter into force on the 20th day following 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, 28 December 2001.

*For the Commission*  
Margot WALLSTRÖM  
*Member of the Commission*

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<sup>(1)</sup> OJ L 84, 5.4.1993, p. 1.

## ANNEX

	Einecs No	CAS No	Substance name	Rapporteur	Testing information requirements	Months from the date of entry into force of this Regulation
1	200-539-3	62-53-3	Aniline <sup>(1)</sup>	D	Data about formation of aniline from caoutchouc chemicals	9
					Data about the releases into the waste water and waste water treatment which are representative for the European caoutchouc industry	9
					Data about releases into the atmosphere and the applied exhaust air purification techniques in caoutchouc industry	9
					Plant fumigation toxicity test	6
					Long-term toxicity tests on <i>Lumbriculus variegatus</i> and <i>Chironomus riparius</i> with preincubated sediment	6
					Bioaccumulation test with <i>Lumbriculus variegatus</i> with preincubated sediment	6
					Terrestrial effect tests with princubated soil Terrestrial bioaccumulation tests with preincubated soil	depends on the results of the actual testing of 3,4-dichloroaniline (terrestrial effects) and the results of the sediments tests of aniline
2	201-557-4	84-74-2	Dibutyl phthalate <sup>(1)</sup>	NL	Plant toxicity test	12
3	202-627-7	98-01-1	2-Furaldehyde <sup>(2)</sup>	NL	<i>In vivo</i> gene mutation test	12
4	202-974-4	101-77-9	4,4'-Methylenedianiline <sup>(1)</sup>	D	Long-term toxicity test on <i>Lumbriculus variegatus</i>	6
5	204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate <sup>(2)</sup>	S	Multigeneration fish study in freshwater	18
6	204-825-9	127-18-4	Tetrachloroethylene <sup>(1)</sup>	UK	Environmental monitoring program for tetrachloroethylene and trichloroacetic acid in the EU <sup>14</sup> C isotope fingerprinting analysis on the trichloroacetic acid found in soil from at least one site with high levels Test for the possible natural formation of thichloroacetic acid in soil from at least one site under natural conditions, and determination of the potential flux from this source	18

	Einecs No	CAS No	Substance name	Rapporteur	Testing information requirements	Months from the date of entry into force of this Regulation
7	214-604-9	1163-19-5	Bis(pentabromophenyl) ether <sup>(1)</sup>	F/UK	Developmental toxicity study	3
					Testing of debromination: — anaerobic degradation, — photodegradation	3 6
					28-day sediment toxicity study in <i>Lumbriculus variegatus</i>	6
					Plant growth test	6
					Earthworm reproductive toxicity test	6
					Activated sludge respiratory inhibition study	6
8	231-152-8	7440-43-9	Cadmium <sup>(3)</sup>	B	Determination of the dissolution/transformation of the substance in water	3
9	231-765-0	7722-84-1	Hydrogen peroxide <sup>(2)</sup>	FIN	90-day repeated dose inhalation study	24
10	247-148-4	25637-99-4	Hexabromocyclododecane <sup>(2)</sup>	S	90-day repeated dose toxicity study	6
11	251-087-9	32536-52-0	Diphenyl ether, octabromo derivative <sup>(1)</sup>	F/UK	90-day inhalation study with examination of reproductive organs and immunotoxicity parameters	3
					Testing of debromination: — anaerobic degradation, — photodegradation or equivalent information	6 18
					28-day sediment toxicity study in <i>Lumbriculus variegatus</i>	6
					Plant growth test	6
					Earthworm reproductive toxicity test	6
					Activated sludge respiratory inhibition study	6

	Einecs No	CAS No	Substance name	Rapporteur	Testing information requirements	Months from the date of entry into force of this Regulation
12	287-477-0	85535-85-9	Alkanes, C14-17, chloro <sup>(3)</sup>	UK	28-day sediment toxicity study in <i>Lumbriculus variegatus</i>	6
					28-day toxicity test on a <i>Chironomus</i> midge species	6
					Long-term plant growth test	6
					Earthworm reproductive toxicity test	6

<sup>(1)</sup> Substance listed in the Annex to Commission Regulation (EC) No 1179/94 (OJ L 131, 26.5.1994, p. 3).

<sup>(2)</sup> Substance listed in the Annex to Commission Regulation (EC) No 2268/95 (OJ L 231, 28.9.1995, p. 18).

<sup>(3)</sup> Substance listed in the Annex to Commission Regulation (EC) No 143/97 (OJ L 25, 28.1.1997, p. 13).