

Commission Regulation (EC) No 465/2008 of 28 May 2008 imposing, pursuant to Council Regulation (EEC) No 793/93, testing and information requirements on importers and manufacturers of certain substances that may be persistent, bioaccumulating and toxic and are listed in the European Inventory of Existing Commercial Chemical Substances (Text with EEA relevance)

COMMISSION REGULATION (EC) No 465/2008

of 28 May 2008

imposing, pursuant to Council Regulation (EEC) No 793/93, testing and information requirements on importers and manufacturers of certain substances that may be persistent, bioaccumulating and toxic and are listed in the European Inventory of Existing Commercial Chemical Substances

(Text with EEA relevance)

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) Manufacturers and importers of certain substances in the European Inventory of Existing Commercial Chemical Substances⁽²⁾ may be required to supply further information which they possess and/or to subject the existing substance to testing where there are valid reasons to believing that the substance presents a serious risk to humans or the environment. Substances that are persistent, bioaccumulating and toxic may present such a risk.
- (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.
- (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 substances that may be persistent, bioaccumulating and toxic, listed in the European Inventory of Existing Commercial Chemical Substances and set out in the Annex to this Regulation shall provide the Commission with the information specified in the Annex within the time limits laid

down therein and perform, with regard to each such substance, the tests indicated in the Annex in accordance with the protocols specified therein.

They shall also 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 day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 28 May 2008.

For the Commission

Stavros DIMAS

Member of the Commission

Status: This is the original version (as it was originally adopted).

ANNEX

| No | Einecs No | CAS No | Substance name | Testing/ information requirements | Time limit from the date of entry into force of this Regulation |
|----|-----------|------------|---|---|---|
| 1 | 204-279-1 | 118-82-1 | 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol | Bioconcentration study on fish (OECD 305 or dietary study) | 18 months |
| 2 | 239-622-4 | 15571-58-1 | 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate | Bioconcentration study on fish (OECD 305 or dietary study) | 18 months |
| 3 | 222-583-2 | 3542-36-7 | Dichlorodioctyltin tetrachloride | Bioconcentration study on fish (to be conducted on substance No 2 (CAS 15571-58-1)) | 18 months |
| 4 | 256-798-8 | 50849-47-3 | 5-Nonylsalicylaldehyde oxime | Bioconcentration study on fish (OECD 305 or dietary study) | 18 months |
| 5 | 281-018-8 | 83846-43-9 | Benzoic acid, 2-hydroxy-, mono-C ^{>} 13-alkyl derivs, calcium salts (2:1) | Enhanced ready biodegradation | 18 months |
| 6 | 250-702-8 | 31565-23-8 | Di(tert-dodecyl) pentasulphide | Further investigation of potential uptake in fish Bioconcentration study on fish (dietary study) | 18 months |
| 7 | 284-578-1 | 84929-98-6 | Magnesium, bis(2-hydroxybenzoate) | Enhanced ready biodegradation | 18 months |

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| | | | O1,O2)-, ar,ar '-di-C>13- alkyl derivs | (to be conducted with substance No 5 (CAS 83846-43-9)) | |
| 8 | 209-136-7 | 556-67-2 | Octamethylcycl | Environmental monitoring programme (together with substance No 15 (CAS 541-02-6)) | 18 months |
| 9 | 262-975-0 | 61788-44-1 | Phenol, styrenated | 21-day Daphnia reproduction test (OECD Guideline 211) conducted on Tristyrenatedphenol (CAS 18254-13-2) Bioconcentration study on fish (dietary study) | 18 months |
| 10 | 262-967-7 | 61788-32-7 | Terphenyl, hydrogenated | Soil degradation test (OECD 307) for selected hydrogenated terphenyls Bioconcentration study on fish for quaterphenyls Depending on the results — study on T criterion (to read across to terphenyls (CAS 26140-60-3)) | 18 months |
| 11 | 222-733-7 | 3590-84-9 | Tetraoctyltin | Bioconcentration study on fish (to be conducted | 18 months |

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| | | | | on substance No 2 (CAS 15571-58-1)) | |
| 12 | 246-619-1 | 25103-58-6 | tert.-Dodecanethiol | Enhanced biodegradation test Bioconcentration study on fish | 18 months |
| 13 | 248-227-6 | 27107-89-7 | 2-Ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]ethoxy]-4-thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate | Bioconcentration study on fish (to be conducted on substance No 2 (CAS 15571-58-1)) | 18 months |
| 14 | 250-709-6 | 31570-04-4 | Tris(2,4-di-tert-butylphenyl)phosphite | Bioconcentration study on fish (dietary study) | 18 months |
| 15 | 208-764-9 | 541-02-6 | Decamethylcyclopentasiloxane Screening: PBT & vPvB | Open air monitoring programme (together with substance No 8 (CAS 556-67-2)) | 18 months |
| 16 | 254-052-6 | 38640-62-9 | DIPN | Ready biodegradation study on marketed material (OECD 301B) | 18 months |

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- (1) [OJ L 84, 5.4.1993, p. 1](#). Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (2) [OJ C 146 A, 15.6.1990, p. 1](#).