

COMMISSION

COMMISSION RECOMMENDATION

of 1 July 1998

on childcare articles and toys intended to be placed in the mouth by children of less than three years of age, made of soft PVC containing certain phthalates

(notified under document number SEC(1998) 738)

(98/485/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 155, second indent, thereof,

Whereas, pursuant to the Treaty establishing the European Community, the Community must contribute to the attainment of a high level of consumer health protection;

Whereas, pursuant to Article 3 of Council Directive 92/59/EEC of 29 June 1992 on general product safety⁽¹⁾, only safe products may be placed on the market; whereas the Directive emphasises in particular the need to ensure a high level of protection for the health and safety of children;

Whereas the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), after being consulted by the Commission, delivered an opinion on 24 April 1998, supplemented by clarifications on 16 June 1998, on the effects on the health of children of the use of certain phthalate-containing soft PVC toys and childcare articles; whereas in this opinion it expressed its concern about the exposure of children to some of these phthalates;

Whereas the SCTEE has in particular recommend that certain limit values for the migration of the phthalates DINP, DEHP, DBP, DIDP, DNOP and BBP released by soft PVC toys and childcare articles intended to be placed in the mouth by children of less than three years of age should not be exceeded;

Whereas it is important that Member States take the measures required to ensure a high level of child health

protection in regard to these products, pending the implementation of permanent Community measures;

Whereas the said migration limit values are liable to be exceeded in certain cases; whereas it is therefore important that the Member States proceed, in the context of appropriate checks, to monitor the level of exposure of children to phthalates which may be caused by the migration of these substances when using the products in question;

Whereas it is important that Member States should exchange information on the test and measurement methods used in these checks and on the results obtained and that they should collaborate among themselves and with the Commission in order to achieve as consistent as possible an approach throughout the Community, pending the adoption of a standardised method;

Whereas it is appropriate in the context of this collaboration, to examine, *inter alia*, the results of the ongoing study in the Netherlands concluded by the Rijksinstituut voor Volksgezondheid en Milieu (RIVM), which may make it possible to define a common reference method;

Whereas, whenever a Member State restricts the placing on the market of products covered by this recommendation, it must inform the Commission in line with the procedure prescribed in Article 7 of Directive 92/59/EEC on general product safety, in the case of childcare articles, Article 7 of Council Directive 88/378/EEC⁽²⁾ of 3 May 1988 on the safety of toys, in the case of toys, or in accordance with the Article 8 procedure of Directive 92/59/EEC, if it considers that there is a serious and immediate risk and, where appropriate, proceed to notify the Commission in compliance with Council Directive

⁽¹⁾ OJ L 228, 11. 8. 1992, p. 24.

⁽²⁾ OJ L 187, 16. 7. 1988, p. 1.

83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations ⁽¹⁾,

HEREBY RECOMMENDS:

Article 1

1. Member States shall adopt the measures required to ensure a high level of child health protection in regard to phthalate-containing soft PVC childcare articles and toys intended to be placed in the mouth of less than three years of age, and notably the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP). Particular attention should be paid to the substances DINP and DEHP.

2. In vetting the products in question, Member States shall monitor the levels of migration of these substances in the context of appropriate checks, taking into account the opinion on phthalates in toys delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on 24 April 1998 and notably the migration limit values for phthalates released by these products recommended by this Committee and reproduced in the Annex.

3. Member States shall regularly inform the Commission of the test methods and measurement methods used to determine the levels of migration in question, the results of the checks, and the conclusions they have

reached; Member States are invited to furnish initial information before the end of August 1998.

4. Member States shall participate in the exchange of information with other Member States and in work to ensure a consistent approach to test and measurement methods and to identifying a common method, which will be organised by the Commission.

Article 2

For the purpose of this recommendation,

- (1) *toy*: means any product designed or clearly intended for use in play by children,
- (2) *childcare article*: means any product designed to facilitate sleep, relaxation, the feeding of children, or sucking on the part of children.

Article 3

This recommendation is addressed to the Member States.

Done at Brussels, 1 July 1998.

For the Commission

Emma BONINO

Member of the Commission

⁽¹⁾ OJ L 109, 26. 4. 1983, p. 8.

ANNEX

Substance	Maximum tolerable extractable quantity ⁽¹⁾ (mg)
DINP	1,2
DNOP	3,0
DEHP	0,4
DIDP	2,0
BBP	6,8
DBP	0,8

⁽¹⁾ These quantities relate to a sample with a surface of 10 cm², over a test period of six hours, for a child weighing 8 kg.