

COMMISSION DIRECTIVE 2006/8/EC

of 23 January 2006

amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 ⁽¹⁾, and in particular the first paragraph of Article 20 thereof,

Whereas:

(1) Preparations composed of more than one substance being classified in Annex I to 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 ⁽²⁾ as carcinogenic, mutagenic and/or toxic for reproduction must currently be labelled with risk phrases (R-phrases) to indicate both category 1 or 2 and category 3 classification. However, providing both R-phrases sends a conflicting message. Preparations should therefore only be classified and labelled with the higher category.

(2) For substances very toxic to the aquatic environment (classified as N) and assigned the R-phrases R50 or R50/53, specific concentration limits (SCLs) are currently applied to substances listed in Annex I to Directive 67/548/EEC in order to avoid an underestimation of the hazard. This measure creates distortions between preparations containing substances listed in Annex I to Directive 67/548/EEC, to which SCLs are applied, and those preparations containing substances not yet included in Annex I, but classified and labelled provisionally in accordance with Article 6 of Directive 67/548/EEC and to which no SCLs are applicable. It is therefore necessary to ensure that SCLs are applied in the same way to all preparations containing substances very toxic to the aquatic environment.

(3) On 6 August 2001, the Commission adopted Directive 2001/59/EC ⁽³⁾ adapting to technical progress Directive 67/548/EEC. Directive 2001/59/EC revised the criteria in

Annex VI to Directive 67/548/EEC for the classification and labelling of ozone depleting substances. The revised Annex III now only provides for the assignment of the symbol N in addition to R-phrase R59.

(4) The terminology used to describe the packaging and the labelling requirements in Annex V to Directive 1999/45/EC has raised concerns due to the lack of consistency. It is therefore appropriate to modify the wording in Annex V to Directive 1999/45/EC to make it more accurate.

(5) Annexes II, III and V to Directive 1999/45/EC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives on the removal of technical barriers to trade in dangerous substances and preparations established under Article 20 of Directive 1999/45/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III and V to Directive 1999/45/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 March 2007 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

⁽¹⁾ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Council Directive 2004/66/EC (OJ L 168, 1.5.2004, p. 35).

⁽²⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

⁽³⁾ OJ L 225, 21.8.2001, p. 1.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 January 2006.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 1999/45/EC is amended as follows:

1. Annex II is amended as follows:

(a) table VI is replaced by the following table:

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration $\geq 0,1$ % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (<i>unless already assigned R45 (*)</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration $\geq 0,1$ % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (<i>unless already assigned R46</i>)
Substances "toxic for reproduction" of category 1 or 2 with R60 (fertility)	Concentration $\geq 0,5$ % toxic for reproduction (fertility) R60 obligatory	
Substances "toxic for reproduction" of category 3 with R62 (fertility)		Concentration ≥ 5 % toxic for reproduction (fertility) R62 obligatory (<i>unless already assigned R60</i>)
Substances "toxic for reproduction" of category 1 or 2 with R61 (development)	Concentration $\geq 0,5$ % toxic for reproduction (development) R61 obligatory	
Substances "toxic for reproduction" of category 3 with R63 (development)		Concentration ≥ 5 % toxic for reproduction (development) R63 obligatory (<i>unless already assigned R61</i>)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

(b) table VI A is replaced by the following table:

Table VI A

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration $\geq 0,1$ % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (<i>unless already assigned R45 (*)</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration $\geq 0,1$ % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (<i>unless already assigned R46</i>)
Substances "toxic for reproduction" of category 1 or 2 with R60 (fertility)	Concentration $\geq 0,2$ % toxic for reproduction (fertility) R60 obligatory	
Substances "toxic for reproduction" of category 3 with R62 (fertility)		Concentration ≥ 1 % toxic for reproduction (fertility) R62 obligatory (<i>unless already assigned R60</i>)
Substances "toxic for reproduction" of category 1 or 2 with R61 (development)	Concentration $\geq 0,2$ % toxic for reproduction (development) R61 obligatory	
Substances "toxic for reproduction" of category 3 with R63 (development)		Concentration ≥ 1 % toxic for reproduction (development) R63 obligatory (<i>unless already assigned R61</i>)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

2. Annex III is amended as follows:

(a) in Part A, point 2 of section (b)(1) (I), is deleted;

(b) in Part B, table 1 is replaced by the following tables:

Table 1a

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	see Table 1b	see Table 1b	see Table 1b
N, R51-53		$C_n \geq 25$ %	$2,5 \% \leq C_n < 25$ %
R52-53			$C_n \geq 25$ %

Preparations containing a substance classified with N, R50-53, the concentration limits and the resulting classification given in table 1b are applicable.

Table 1b

Acute aquatic toxicity and long-term adverse effects of substances very toxic to the aquatic environment

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified as N, R50-53 (mg/l)	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
0,1 < L(E)C ₅₀ ≤ 1	C _n ≥ 25 %	2,5 % ≤ C _n < 25 %	0,25 % ≤ C _n < 2,5 %
0,01 < L(E)C ₅₀ ≤ 0,1	C _n ≥ 2,5 %	0,25 % ≤ C _n < 2,5 %	0,025 % ≤ C _n < 0,25 %
0,001 < L(E)C ₅₀ ≤ 0,01	C _n ≥ 0,25 %	0,025 % ≤ C _n < 0,25 %	0,0025 % ≤ C _n < 0,025 %
0,0001 < L(E)C ₅₀ ≤ 0,001	C _n ≥ 0,025 %	0,0025 % ≤ C _n < 0,025 %	0,00025 % ≤ C _n < 0,0025 %
0,00001 < L(E)C ₅₀ ≤ 0,0001	C _n ≥ 0,0025 %	0,00025 % ≤ C _n < 0,0025 %	0,000025 % ≤ C _n < 0,00025 %

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).'

(c) in part B, table 2 is replaced by the following table:

Table 2

Acute aquatic toxicity

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified either as N, R50 or as N, R50-53 (mg/l)	Classification of the preparation N, R50
0,1 < L(E)C ₅₀ ≤ 1	C _n ≥ 25 %
0,01 < L(E)C ₅₀ ≤ 0,1	C _n ≥ 2,5 %
0,001 < L(E)C ₅₀ ≤ 0,01	C _n ≥ 0,25 %
0,0001 < L(E)C ₅₀ ≤ 0,001	C _n ≥ 0,025 %
0,00001 < L(E)C ₅₀ ≤ 0,0001	C _n ≥ 0,0025 %

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).'

(d) in part B, table 5 of point II, is replaced by the following table:

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	C _n ≥ 0,1 %

3. Annex V is replaced by the following:

‘ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous within the meaning of Articles 5, 6 and 7

1. *Preparations sold to the general public*

1.1. The label on the packaging containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

1.2. When such preparations are classified as very toxic (T+), toxic (T) or corrosive (C) and where it is physically impossible to give such information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

2. *Preparations intended for use by spraying*

The label on the packaging containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

3. *Preparations containing a substance assigned phrase R33: Danger of cumulative effects*

When a preparation contains at least one substance assigned the phrase R33, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

4. *Preparations containing a substance assigned phrase R64: May cause harm to breastfed babies*

When a preparation contains at least one substance assigned phrase R64, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

B. For preparations irrespective of their classification within the meaning of Articles 5, 6 and 7

1. *Preparations containing lead*

1.1. *Paint and varnishes*

The label on the packaging of paints and varnishes containing lead in quantities exceeding 0,15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

“Contains lead. Should not be used on surfaces liable to be chewed or sucked by children”.

In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows:

“Warning! Contains lead”.

2. *Preparations containing cyanoacrylates*

2.1. *Adhesives*

The label on the immediate packaging of adhesives based on cyanoacrylate must bear the following inscriptions:

“Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children”.

Appropriate advice on safety must accompany the package.

3. *Preparations containing isocyanates*

The label on the packaging of preparations containing isocyanates (as monomers, oligomers, prepolymers, etc., or as mixtures thereof) must bear the following inscriptions:

“Contains isocyanates.

See information supplied by the manufacturer”.

4. *Preparations containing epoxy constituents with an average molecular weight ≤ 700*

The label on the packaging of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

“Contains epoxy constituents.

See information supplied by the manufacturer”.

5. *Preparations sold to the general public which contain active chlorine*

The label on the packaging of preparations containing more than 1 % of active chlorine must bear the following particular inscriptions:

“Warning! Do not use together with other products. May release dangerous gases (chlorine)”.

6. *Preparations containing cadmium (alloys) and intended to be used for brazing or soldering*

The label on the packaging of the above mentioned preparations must bear the following inscription printed in clearly legible and indelible characters:

“Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions”.

7. *Preparations available as aerosols*

Without prejudice to the provisions of this Directive, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC as last amended by Directive 94/1/EC.

8. *Preparations containing substances not yet tested completely*

Where a preparation contains at least one substance which, in accordance with Article 13.3 of Directive 67/548/EEC, bears the inscription "Caution — substance not yet tested completely", the label on the packaging of the preparation must bear the inscription "Warning — this preparation contains a substance not yet tested completely" if this substance is present in a concentration ≥ 1 %.

9. *Preparations not classified as sensitising but containing at least one sensitising substance*

The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription:

"Contains (name of sensitising substance). May produce an allergic reaction".

10. *Liquid preparations containing halogenated hydrocarbons*

For liquid preparations which show no flashpoint or a flashpoint higher than 55 °C and contain a halogenated hydrocarbon and more than 5 % flammable or highly flammable substances, the label on the packaging must bear the following inscription as appropriate:

"Can become highly flammable in use" or "Can become flammable in use".

11. *Preparations containing a substance assigned phrase R67: vapours may cause drowsiness and dizziness*

When a preparation contains one or more substances assigned the phrase R67, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the total concentration of these substances present in the preparation is equal to or higher than 15 %, unless:

— the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26,

— or the preparation is in a package not exceeding 125 ml.

12. *Cements and cement preparations*

The label on the packaging of cements and cement preparations containing more than 0,0002 % soluble chromium (VI) of the total dry weight of the cement must bear the inscription:

"Contains chromium (VI). May produce an allergic reaction"

unless the preparation is already classified and labelled as a sensitiser with phrase R43.

C. For preparations not classified within the meaning of Articles 5, 6 and 7 but containing at least one dangerous substance

1. *Preparations not intended for the general public*

The label on the packaging of preparations referred to in Article 14.2.1(b) must bear the following inscription:

"Safety data sheet available for professional user on request".
