

DRAFT

STATUTORY INSTRUMENTS
S.I. No. of 2006

European Communities (Classification, Packaging and Labelling of Dangerous Preparations) (Amendment) Regulations 2006

Public Consultation Draft

I,, Minister for Enterprise, Trade and Employment in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999¹ as amended by Commission Directive 2006/8/ EC of 23 January 2006² hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) (Amendment) Regulations 2006 and come into operation on 1 March 2007.

(2) The Principal Regulations and these Regulations may be cited together as the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004 and 2006.

2. (1) In these Regulations –

“Principal Regulations” means the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004 (S.I. No. 62 of 2004).

(2) A word or expression that is used in these Regulations and is also used in Council Directive 1999/45/EC of 31 May 1999 and Directive 2006/8/EC of the European Parliament and of the Council of 23 January 2006, has, unless the contrary intention appears, the same meaning in these Regulations as in the Directive concerned.

3. (1) Schedule 3 to the Principal Regulations is amended –

(a) in Part B under the heading Point 6.1 Non-gaseous preparations, Table VI, by substituting the provisions set out in Schedule A, and

(b) in Part B under the heading Point 6.2 Gaseous preparations, Table VIA, by substituting the provision set out in Schedule B.

4. (1) Schedule 4 to the Principal Regulations is amended –

(a) by deleting in Part A, section (b)(1), paragraph 1.2 -

“1.2 Preparations should be classified as dangerous for the environment and assigned the risk phrase R59 if they contain one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

¹ O.J. No. L200, 30.7.1999, p.1

² O.J. No. L19, 24.1.2006, p.12

- (b) the concentration specified in Part B of this Schedule (Table 5) where the substance or substances do not appear in Annex I or appear in it without concentration limits;”,
- (b) by substituting Tables 1a and 1b set out in Schedule C for Table 1, Part B set out in the said Schedule 4,
- (c) by substituting Table 2 set out in Schedule D for Table 2, Part B in the said Schedule 4,
- (d) by substituting Table 5 set out in Schedule E for Table 5 of point II, Part B of the said Schedule 4.
5. (1) Schedule 7 to the Principal Regulations is replaced with the provisions set out in Schedule F.

Schedule A

Regulation 3(1)(a)

“Point 6.1 (of Schedule 3) - Non-gaseous preparations

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 \geq 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 \geq 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 \geq 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 \geq 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.		

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Schedule B

Regulation 3(1)(b)

“Point 6.2 (of Schedule 3) - Gaseous preparations

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 \geq 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 \geq 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 \geq 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 \geq 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.		

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“ PART B (of Schedule 4) – Concentration limits to be used for the evaluation of environmental hazards

1. For the aquatic environment

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
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25 \%$	$2.5 \% \leq C_n < 25 \%$	$0.25 \% \leq C_n < 2.5\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5 \%$	$0.25 \% \leq C_n < 2.5 \%$	$0.025 \% \leq C_n < 0.25 \%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25 \%$	$0.025 \% \leq C_n < 0.25 \%$	$0.0025 \% \leq C_n < 0.025 \%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025 \%$	$0.0025 \% \leq C_n < 0.025 \%$	$0.00025 \% \leq C_n < 0.0025 \%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025 \%$	$0.00025 \% \leq C_n < 0.0025 \%$	$0.000025 \% \leq C_n < 0.00025 \%$
For preparations containing substances with a lower LC ₅₀ or EC ₅₀ value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).			

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Schedule D

Regulation 4(1)(c)

“ PART B (of Schedule 4) – Concentration limits to be used for the evaluation of environmental hazards

1. For the aquatic environment

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
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25 \%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5 \%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25 \%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025 \%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025 \%$
For preparations containing substances with a lower LC ₅₀ or EC ₅₀ value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).	

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Schedule E

Regulation 4(1)(d)

“ PART B (of Schedule 4) – Concentration limits to be used for the evaluation of environmental hazards

II. For the non-aquatic environment

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	$C_n \geq 0.1 \%$

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“SCHEDULE 7

**SPECIAL PROVISIONS CONCERNING THE LABELLING
OF CERTAIN PREPARATIONS**

A. For preparations classified as dangerous as defined under Regulation 3(2)

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 as defined under Regulation 3(3)

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 Regulation 3(2) 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”.

Given under my Official Seal

2006

Minister for Enterprise, Trade and Employment

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EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations amend Schedules 3, 4 and 7 to the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, 2004 (S.I. No. 62 of 2004).

The Regulations transpose Commission Directive 2006/8/EC of 23 January 2006 which amends Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

The aim of these Regulations is to protect human health and the environment from the harmful effects of dangerous preparations. The Regulations requires each manufacturer, importer or distributor of a dangerous preparation to classify and label it according to its inherent hazards and to provide safety data sheets.

The Regulations introduce a number of amendments to the Principal Regulations (S.I. No 62 of 2004) as follows:

- (i) The classification of preparations containing Carcinogens, Mutagens and Reprotoxins (CMRs) is amended so that, where previously a preparation would have to be classified and labelled with both Category 1 or 2 and Category 3 R-phrases, they will now only be classified and labelled with the highest relevant category. This is to prevent conflicting messages on labels for users.
- (ii) The classification of preparations containing substances classified as very toxic to the aquatic environment is amended, to resolve differences in the way that substances with specific concentration limits in Annex I to Directive 67/548/EC are classified compared to self-classified substances.
- (iii) Changes are introduced to classifications for preparations containing substances dangerous to the ozone layer in that the symbol “N” is now required for substances classified as “R59 (Dangerous for the ozone layer)”.
- (iv) The terminology in Schedule 7 to the Principal Regulations regarding “Special Provisions Concerning the Labelling of Certain Preparations” is replaced to make it more consistent and accurate.

Schedules A and B to these Regulations amend Schedule 3 to the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004 (S.I. No. 62 of 2004); Schedules C, D and E to these Regulations amend Schedule 4 to the 2004 Regulations and Schedule F to these Regulations sets out a replacement Schedule 7 to the 2004 Regulations.

These Regulations come into operation on 1 March 2007.