
STATUTORY RULES OF NORTHERN IRELAND

2009 No. 273

HEALTH AND SAFETY

**The Explosives (Hazard Information and Packaging
for Supply) Regulations (Northern Ireland) 2009**

Made - - - - 23rd July 2009

To be laid before Parliament

Coming into operation 24th August 2009

The Secretary of State is a Minister designated for the purpose of section 2(2) of the European Communities Act 1972⁽¹⁾ (“the 1972 Act”) in relation to the regulation and control of classification, packaging and labelling of dangerous substances and preparations⁽²⁾, and for measures relating to consumer protection⁽³⁾.

The Secretary of State makes these Regulations in exercise of the powers conferred upon him by section 2(2) of the 1972 Act and Articles 17(1), (2), (3), (4), (6)(b), and 55(2) of, and paragraphs 1 (1), (4), and (5), 2(2), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978⁽⁴⁾ as applied and modified by Article 53 of that Order.

In accordance with Article 46(1)(b) of that Order he has consulted with the Health and Safety Executive for Northern Ireland and such other bodies as appear to him to be appropriate.

The Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for references in these Regulations to:

- (i) the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008⁽⁵⁾ on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC⁽⁶⁾ and 1999/45/EC⁽⁷⁾ and amending Regulation (EC) No 1907/2006⁽⁸⁾ be construed as including references to articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29, 35(2) second and third sub-paragraph and Annexes I to VII of that Regulation as amended from time to time; and
- (ii) the Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals⁽⁹⁾ be construed as including references to Annexes I and V of that Regulation as those Annexes are amended from time to time.

(1) 1972 c. 68
(2) S.I. 1976/897
(3) S.I. 1993/2661
(4) S.I. 1978/1039 (N19)
(5) O.J. No. L 353, 31.12.08, p. 1
(6) O.J. No. L196, 16.8.67, p. 1
(7) O.J. No. L200, 30.7.99, p. 1
(8) O.J. No. L396, 30.12.2006, p. 1
(9) O.J. No. L204, 31.7.08, p. 1

Status: Point in time view as at 01/06/2015.

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Explosives (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details)

PART 1

INTRODUCTION

Citation and commencement

1. These Regulations may be cited as the Explosives (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 and shall come into operation on 24th August 2009.

Commencement Information

11 [Reg. 1](#) in operation at 24.8.2009, see [reg. 1](#)

Interpretation

^{F1}2.

Textual Amendments

F1 [Reg. 2](#) revoked (with effect in accordance with reg. 11(c) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(c)** (with [reg. 2](#))

Application

^{F2}3.

Textual Amendments

F2 [Reg. 3](#) revoked (with effect in accordance with reg. 11(c) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(e)** (with [reg. 2](#))

PART 2

GENERAL REQUIREMENTS

Classification of dangerous substances and dangerous preparations

^{F3}4.

Textual Amendments

F3 [Reg. 4](#) revoked (with effect in accordance with reg. 11(a) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(a)** (with [reg. 2](#))

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Safety data sheets for substances and preparations

^{F4}5.

Textual Amendments

- F4** Reg. 5 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(a)** (with reg. 2)

[^{F5}Advertisements for dangerous preparations

5A.—(1) Subject to paragraph (2), a person who supplies a dangerous preparation shall not advertise that preparation, or arrange for the production of any such advertisement, unless mention is made in the advertisement of the type of hazard indicated on the label.

(2) Paragraph (1) shall apply only in respect of a dangerous preparation where the advertisement enables a person, otherwise than in the course of a business, to conclude a contract to purchase the dangerous preparation before that person has seen the label relating to the dangerous preparation.

(3) In this regulation “supply” has the same meaning as it has in section 46 of the Consumer Protection Act 1987.

(4) This regulation has effect until 31st May 2017.]

Textual Amendments

- F5** Reg. 5A inserted (31.5.2015) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(3), **12(1)** (with reg. 2)

Packaging of dangerous substances, dangerous preparations and certain specified preparations

^{F6}6.

Textual Amendments

- F6** Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(a)** (with reg. 2)

Labelling of dangerous substances and dangerous preparations

^{F6}7.

Textual Amendments

- F6** Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(a)** (with reg. 2)

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Labelling of single receptacles and receptacles in outer packagings

^{F6}8.

Textual Amendments

F6 Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(a)** (with reg. 2)

Particular labelling requirements for certain preparations

^{F6}9.

Textual Amendments

F6 Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(a)** (with reg. 2)

Methods of marking or labelling packages

^{F6}10.

Textual Amendments

F6 Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(a)** (with reg. 2)

Child resistant fastenings, tactile warning devices and other consumer protection measures

^{F6}11.

Textual Amendments

F6 Regs. 6-11 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(a)** (with reg. 2)

Retention of data for dangerous preparations

^{F7}12.

Textual Amendments

F7 Reg. 12 revoked (with effect in accordance with reg. 11(c) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(c)** (with reg. 2)

Transitional provisions for dangerous substances, dangerous preparations and certain specified preparations

^{F8}13.

Textual Amendments

F8 Reg. 13 revoked (with effect in accordance with reg. 11(a) of the amending Rule) by The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 (S.R. 2015/236), regs. 1(2), **11(a)** (with reg. 2)

PART 3

MISCELLANEOUS

Enforcement

14.—^{F9}(1) To the extent that they would not otherwise do so, Articles—

- (a) 18 to 30 (approval of codes of practice; enforcement; indemnification of inspectors; power to obtain information and restrictions on disclosure of information);
- (b) 31 to 39 (provisions as to offences); and
- (c) 43(2) (civil liability),

of the 1978 Order shall apply to these Regulations and the CLP Regulation as if these Regulations and the CLP Regulation were health and safety regulations for the purposes of that Order except that these Articles shall not apply to duties placed by the CLP Regulation on the competent authority or the Member State.

^{F10}(1A) The maximum penalty for an offence under this regulation is—

- (a) on summary conviction, imprisonment for a term not exceeding three months or a fine not exceeding the statutory maximum, or both; and
- (b) on conviction on indictment, imprisonment for a term not exceeding two years, or a fine or both.]

(2) Any function of the Secretary of State for Northern Ireland under any other provision of the 1978 Order under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if these Regulations and the CLP Regulation were health and safety regulations for the purpose of that Order to the extent that they would not otherwise do so.

(3) Notwithstanding anything in the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999⁽¹⁰⁾ and subject to paragraph (4), the enforcing authority for these Regulations and the CLP Regulation shall be the Secretary of State.

(4) Where a substance or preparation is supplied, or a substance, mixture or article falling within the meaning of and the provisions of the CLP Regulation is placed on the market within the meaning of the CLP Regulation in or from premises which are registered under section 75 of the Medicines Act 1968⁽¹¹⁾, the enforcing authority shall be the Department of Health, Social Services and Public Safety.]

⁽¹⁰⁾ S.R. 1999 No. 90, as amended by S.R. 2000 No. 375, S.R. 2003 No. 33, S.R. 2006 No. 205, S.R. 2006 No. 425, S.R. 2007 No. 31 and S.R. 2007 No. 291

⁽¹¹⁾ 1968 c. 67; section 75(8) was amended by S.I. 1968/1699

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Textual Amendments

- F9** Regs. 14-17 revoked (except to the extent they continue to apply for the purposes of enforcing reg. 12 of S.R. 2009/273) (with effect in accordance with reg. 11(b) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(b)** (with reg. 2)
- F10** Reg. 14(1A) inserted (31.5.2015) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(3), **12(2)** (with reg. 2)

Commencement Information

- I2** [Reg. 14](#) in operation at 24.8.2009, see [reg. 1](#)

Defence

15. [^{F9}In any proceedings for an offence for a contravention of any of the provisions of these Regulations and the CLP Regulation it shall be a defence for the person charged to prove that the person took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.]

Textual Amendments

- F9** Regs. 14-17 revoked (except to the extent they continue to apply for the purposes of enforcing reg. 12 of S.R. 2009/273) (with effect in accordance with reg. 11(b) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(b)** (with reg. 2)

Commencement Information

- I3** [Reg. 15](#) in operation at 24.8.2009, see [reg. 1](#)

Application within the territorial sea

16. [^{F9}Within the territorial sea these Regulations and the CLP Regulation shall apply only to and in relation to an activity to which any of paragraphs 2 to 6 of Schedule 6 applies.]

Textual Amendments

- F9** Regs. 14-17 revoked (except to the extent they continue to apply for the purposes of enforcing reg. 12 of S.R. 2009/273) (with effect in accordance with reg. 11(b) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(b)** (with reg. 2)

Commencement Information

- I4** [Reg. 16](#) in operation at 24.8.2009, see [reg. 1](#)

Revocation and Amendment

17.—[^{F9}(1) The Explosive Substances (Hazard Information) Regulations (Northern Ireland) 2000 are revoked(**12**).

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(2) The regulation in Schedule 7 shall be amended to the extent specified in that table.]

Textual Amendments

F9 Regs. 14-17 revoked (except to the extent they continue to apply for the purposes of enforcing reg. 12 of S.R. 2009/273) (with effect in accordance with reg. 11(b) of the amending Rule) by [The Explosives \(Appointment of Authorities and Enforcement\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/236\)](#), regs. 1(2), **11(b)** (with reg. 2)

Commencement Information

I5 [Reg. 17](#) in operation at 24.8.2009, see [reg. 1](#)

Northern Ireland Office
23rd July 2009

Shaun Woodward
One of Her Majesty's Principal Secretaries of
State

Status: Point in time view as at 01/06/2015.

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SCHEDULE 1

Regulations 2(1) and 4(4)

CLASSIFICATION OF DANGEROUS SUBSTANCES AND DANGEROUS PREPARATIONS

Commencement Information

I6 Sch. 1 in operation at 24.8.2009, see **reg. 1**

CATEGORIES OF DANGER

<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
PHYSICO-CHEMICAL PROPERTIES		
Explosive	Solid, liquid, pasty or gelatinous substances and preparations which may react exothermically without atmospheric oxygen thereby quickly evolving gases, and which under defined test conditions detonate, quickly deflagrate or upon heating explode when partially confined.	E
Oxidising	Substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances.	O
Extremely flammable	Liquid substances and preparations having an extremely low flash point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.	F+
Highly flammable	The following substances and preparations, namely— (a) substances and preparations which may become hot and finally	F

Notes

- As further described in the approved classification and labelling guide.
- The categories are specified in the approved classification and labelling guide.
- In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.

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<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
	catch fire in contact with air at ambient temperature without application of energy, (b) solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, (c) liquid substances and preparations having a very low flash point, or (d) substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities.	
Flammable	Liquid substances and preparations having a low flash point.	None
HEALTH EFFECTS		
Very toxic	Substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.	T+
Toxic	Substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.	T
Harmful	Substances and preparations which may cause death or acute or chronic damage to health when inhaled,	Xn
Notes		
1. As further described in the approved classification and labelling guide.		
2. The categories are specified in the approved classification and labelling guide.		
3. In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.		

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<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
	swallowed or absorbed via the skin.	
Corrosive	Substances and preparations which may, on contact with living tissues, destroy them.	C
Irritant	Non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation.	Xi
Sensitising	Substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction by hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced.	
Sensitising by inhalation		Xn
Sensitising by skin contact		Xi
Carcinogenic (See Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.	
Category 1		T
Category 2		T
Category 3		Xn
Mutagenic (See Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.	
Category 1		T
Category 2		T
Notes		
1.	As further described in the approved classification and labelling guide.	
2.	The categories are specified in the approved classification and labelling guide.	
3.	In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.	

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<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
Category 3		Xn
Toxic for reproduction (See Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of non-heritable adverse effects in the progeny and/or of male or female reproductive functions or capacity.	
Category 1		T
Category 2		T
Category 3		Xn
ENVIRONMENTAL EFFECTS		
Dangerous for the environment (See Note 3)	Substances and preparations which, were they to enter into the environment, would present or might present an immediate or delayed danger for one or more components of the environment.	N
Notes		
1. As further described in the approved classification and labelling guide.		
2. The categories are specified in the approved classification and labelling guide.		
3. In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.		

SCHEDULE 2

Regulations 2(1), 8(2) and 10(6)









INDICATIONS OF DANGER AND SYMBOLS FOR DANGEROUS SUBSTANCES AND DANGEROUS PREPARATIONS

Commencement Information
I7 Sch. 2 in operation at 24.8.2009, see **reg. 1**

<i>Column 1</i> <i>Indication of danger</i>	<i>Column 2</i> <i>Symbol-letter</i>	<i>Column 3</i> <i>Symbol</i>
Explosive	E	


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<i>Column 1</i> Indication of danger	<i>Column 2</i> Symbol-letter	<i>Column 3</i> Symbol
Oxidising	O	
Extremely flammable	F+	
Highly flammable	F	
Very toxic	T+	
Toxic	T	
Harmful	Xn	
Corrosive	C	
Irritant	Xi	
Dangerous for the environment	N	

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<i>Column 1</i> <i>Indication of danger</i>	<i>Column 2</i> <i>Symbol-letter</i>	<i>Column 3</i> <i>Symbol</i>
		

SCHEDULE 3

Regulation 4(7)

PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

PART I

GENERAL PROVISIONS

Application

1. The provisions of this Schedule shall apply for the classification of preparations.

Commencement Information

18 Sch. 3 Pt. 1 para. 1 in operation at 24.8.2009, see [reg. 1](#)

Interpretation and application

- 2.—(1) In this Schedule, for the purposes of classification—

“physico-chemical properties” means the properties to be applied for the classifications “explosive”, “oxidising”, “extremely flammable”, “highly flammable” or “flammable”;

“health effects” means the effects to be assessed for the classifications “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant”, “sensitising”, “carcinogenic”, “mutagenic” or “toxic for reproduction”; and

“environmental hazards” means the hazards to be assessed for the classification “dangerous for the environment”.

- (2) In its application to preparations that are gases, this Part shall be modified so that reference to concentrations expressed as percentage by weight are to concentrations expressed as the same percentage by volume.

Commencement Information

19 Sch. 3 Pt. 1 para. 2 in operation at 24.8.2009, see [reg. 1](#)

Classification of preparations by physico-chemical properties

- 3.—(1) The requisite physico-chemical properties for the classification of preparations shall be determined in accordance with the criteria set out in the approved classification and labelling guide.

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(2) Subject to sub-paragraph (3), preparations shall be classified as explosive, oxidising, extremely flammable, highly flammable or flammable when they satisfy the criteria referred to in sub-paragraph (1) for the category of danger.

(3) The determination of explosive, oxidising, extremely flammable, highly flammable or flammable properties is not necessary provided that—

- (a) none of the constituents possess such properties and that, on the basis of information available to the manufacturer, the preparation is unlikely to present dangers of this kind;
- (b) in the event of a change in composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification; and
- (c) in the case of a preparation supplied in the form of an aerosol, that preparation satisfies the provisions of Article 8.1a of Council Directive [75/324/EEC](#)(13).

Commencement Information

110 Sch. 3 Pt. 1 para. 3 in operation at 24.8.2009, see [reg. 1](#)

Classification of preparations by health effects

4.—(1) The health effects of a preparation shall be assessed by one or more of the following methods—

- (a) by the conventional method described in paragraphs 7 to 15 using concentration limits; or
- (b) by the criteria set out in the approved classification and labelling guide in relation to the preparation for an appropriate classification and label.

(2) Any one or more of the health effects of the preparation which are not assessed by the method set out in sub-paragraph (1)(b) shall be assessed in accordance with the conventional method.

(3) Where the health effects have been established by both methods, the results of the method referred to in sub-paragraph (1)(b) shall be used for classifying the preparation except in the case of carcinogenic and mutagenic effects and toxic effects for reproduction, when the conventional method referred to in sub-paragraph (1)(a) shall always be used.

(4) Where it can be demonstrated—

- (a) by epidemiological studies, by scientifically valid case studies as specified in the approved classification and labelling guide or by statistically backed experience (such as the assessment of data from poison information units or concerning occupational diseases) that toxicological effects on man differ from those suggested by the application of the methods set out in paragraph (1), then the preparation shall be classified according to its effects on man;
- (b) that owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation; or
- (c) that owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(5) Subject to sub-paragraph (6), for preparations of a known composition, with the exception of plant protection products, classified in accordance with the method referred to in sub-paragraph (1)

(13) O.J. No. L147, 9.6.1975, p. 40; Article 8 is amended to add paragraph 1a by Commission Directive [2008/47/EC](#), O.J. No. L96, 9.4.2008, p. 15

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(b), a new health effect assessment shall be performed either by the method referred to in sub-paragraph (1)(a) or (1)(b) whenever—

- (a) changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer which exceed the permitted variations set out in the following table—

<i>Initial concentration range of the constituent</i>	<i>Permitted variation in actual concentration of the constituent</i>
≤ 2.5%	± 30%
> 2.5 ≤ 10%	± 20%
> 10 ≤ 25%	± 10%
> 25 ≤ 100%	± 5%

or,

- (b) changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions in Schedule 1, are introduced by the manufacturer.

(6) The revised assessment required by sub-paragraph (5) shall not be required where there is a valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Commencement Information

I11 Sch. 3 Pt. 1 para. 4 in operation at 24.8.2009, see [reg. 1](#)

Use of concentration limits in classification for health effects by the conventional method

5.—(1) In accordance with paragraph 4(1)(a), the health effects shall be assessed by the conventional method described in paragraphs 7 to 15 using concentration limits.

(2) Where the substances concerned are dangerous substances and are listed as dangerous substances in Table 3.2 of part 3 of Annex VI of the CLP Regulation and are assigned concentration limits necessary for the application of the method of assessment described below, these concentration limits shall be used.

(3) Where the substances concerned are dangerous substances and do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation as dangerous substances or appear there without the concentration limits necessary for the application of the method of evaluation described below, the concentration limits shall be assigned in accordance with Part II of this Schedule.

Commencement Information

I12 Sch. 3 Pt. 1 para. 5 in operation at 24.8.2009, see [reg. 1](#)

Lower limits of concentration

6.—(1) For preparations to which this Schedule applies, account shall be taken of dangerous substances which are classified as dangerous on the basis of their health or environmental effects (whether they are present as additives or impurities) when their concentrations are equal to or greater

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than those defined in the following table unless lower limits are given in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in Part II of this Schedule—

<i>Category of danger of the substance</i>	<i>Concentration to take into consideration for</i>	
	<i>gaseous preparations % vol/vol</i>	<i>other preparations % w/w</i>
Very toxic	≥ 0.02	≥ 0.1
Toxic	≥ 0.02	≥ 0.1
Carcinogenic Category 1 or 2	≥ 0.02	≥ 0.1
Mutagenic Category 1 or 2	≥ 0.02	≥ 0.1
Toxic for reproduction Category 1 or 2	≥ 0.02	≥ 0.1
Harmful	≥ 0.2	≥ 1
Corrosive	≥ 0.02	≥ 1
Irritant	≥ 0.2	≥ 1
Sensitising	≥ 0.2	≥ 1
Carcinogenic Category 3	≥ 0.2	≥ 1
Mutagenic Category 3	≥ 0.2	≥ 1
Toxic for reproduction Category 3	≥ 0.2	≥ 1
Dangerous for the environment N		≥ 0.1
Dangerous for the environment ozone	≥ 0.1	≥ 0.1
Dangerous for the environment		≥ 1

(2) Some substances may have more than one health effect and each of these properties shall be characterised by its specific concentration limit.

Commencement Information

I13 Sch. 3 Pt. 1 para. 6 in operation at 24.8.2009, see [reg. 1](#)

Status: Point in time view as at 01/06/2015.

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Classification by the conventional method as very toxic

7.—(1) The following preparations shall be classified as very toxic owing to their acute lethal effects and assigned the symbol “T+”, the indication of danger “very toxic” and the risk phrase R26, R27 or R28—

- (a) preparations containing one or more substances classified as very toxic that produce such effects, in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits; and
- (b) preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA), if the sum of the quotients obtained by dividing the percentage weight of each very toxic substance in the preparation by the very toxic limit specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{T+}}{L_{T+}} \right) \geq 1$$

where—

P_{T+} is the percentage by weight of each very toxic substance in the preparation,

L_{T+} is the very toxic limit specified for each very toxic substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as very toxic owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “T+”, the indication of danger “very toxic” and the risk phrase R39/route of exposure—

Preparations containing one or more dangerous substances which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I14 Sch. 3 Pt. 1 para. 7 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as toxic

8.—(1) The following preparations shall be classified as toxic owing to their acute lethal effects and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R23, R24, or R25—

- (a) preparations containing one or more substances classified as very toxic or toxic that produce such effects in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

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- (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits:
- (b) preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA) if the sum of the quotients obtained by dividing the percentage weight of each very toxic or toxic substance in the preparation by the toxic limit specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{T+}}{L_T} + \frac{P_T}{L_T} \right) \geq 1$$

where—

P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,

P_T is the percentage by weight or by volume of each toxic substance in the preparation,

L_T is the respective toxic limit specified for each very toxic or toxic substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as toxic owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R39/route of exposure—

Preparations containing one or more dangerous substances classified as very toxic or toxic which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(3) The following preparations shall be classified as toxic owing to their long-term effects and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R48/route of exposure—

Preparations containing one or more dangerous substances which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 3 of Part II of this Schedule (Table III or Table IIIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I15 Sch. 3 Pt. 1 para. 8 in operation at 24.8.2009, see [reg. 1](#)

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Classification by the conventional method as harmful

9.—(1) The following preparations shall be classified as harmful owing to their acute lethal effects and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R20, R21 or R22—

- (a) preparations containing one or more substances classified as very toxic, toxic or harmful and that produce such effects in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA) if the sum of the quotients obtained by dividing the percentage weight of each very toxic, toxic or harmful substance in the preparation by the harmful limit specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{T+}}{L_{Xn}} + \frac{P_T}{L_{Xn}} + \frac{P_{Xn}}{L_{Xn}} \right) \geq 1$$

where—

P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,

P_T is the percentage by weight or by volume of each toxic substance in the preparation,

P_{Xn} is the percentage by weight or by volume of each harmful substance in the preparation,

L_{Xn} is the respective harmful limit specified for each very toxic, toxic or harmful substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as harmful owing to their acute effects to the lungs if swallowed and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R65—

Preparations classified as harmful according to the criteria specified in the approved classification and labelling guide.

In applying the conventional method according to sub-paragraph (1), no account shall be taken of the classification of a substance as R65.

(3) The following preparations shall be classified as harmful owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R68/route of exposure—

Preparations containing one or more dangerous substances classified as very toxic, toxic or harmful which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

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(4) The following preparations shall be classified as harmful owing to their long-term effects and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R48/ route of exposure—

Preparations containing one or more dangerous substances classified as toxic or harmful that produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 3 of Part II of this Schedule (Table III or Table IIIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I16 Sch. 3 Pt. 1 para. 9 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as corrosive

10.—(1) The following preparations shall be classified as corrosive and assigned the symbol “C”, the indication of danger “corrosive” and the risk phrase R35—

- (a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as corrosive to which is assigned the risk phrase R35 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each corrosive substance in the preparation by the corrosive limit R35 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C-R35}}{L_{C-R35}} \right) \geq 1$$

where—

P_{C-R35} is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

L_{C-R35} is the corrosive limit R35 specified for each corrosive substance to which is assigned the risk phrase R35 expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as corrosive and assigned the symbol “C”, the indication of danger “corrosive” and risk phrase R34—

- (a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 or R34 in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

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- (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as corrosive to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each corrosive substance in the preparation by the corrosive limit R34 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C,R35}}{L_{C,R34}} + \frac{P_{C,R34}}{L_{C,R34}} \right) \geq 1$$

where—

$P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$L_{C,R34}$ is the respective corrosive limit R34 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 expressed as a percentage by weight or by volume.

Commencement Information

I17 Sch. 3 Pt. 1 para. 10 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as irritant

11.—(1) The following preparations shall be classified as irritants liable to cause serious eye damage and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R41—

- (a) preparations containing one or more substances classified as irritant to which is assigned the risk phrase R41 in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for substance or substances under consideration, or
- (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R41, or classified as corrosive and to which is assigned the risk phrase R35 or R34, in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R41 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C,R35}}{L_{Xi,R41}} + \frac{P_{C,R34}}{L_{Xi,R41}} + \frac{P_{Xi,R41}}{L_{Xi,R41}} \right) \geq 1$$

where—

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P_{C-R35} is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

P_{C-R34} is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

P_{Xi-R41} is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R41 in the preparation,

L_{Xi-R41} is the respective irritant limit R41 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R41, expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as irritant to eyes and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R36—

- (a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 or R34 or as irritant to which is assigned the risk phrase R41 or R36 in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R41 or R36 or as corrosive and to which is assigned the risk phrase R35 or R34, in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R36 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C-R35}}{L_{Xi-R36}} + \frac{P_{C-R34}}{L_{Xi-R36}} + \frac{P_{Xi-R41}}{L_{Xi-R36}} + \frac{P_{Xi-R36}}{L_{Xi-R36}} \right) \geq 1$$

where—

P_{C-R35} is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

P_{C-R34} is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

P_{Xi-R41} is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R41 in the preparation,

P_{Xi-R36} is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R36 in the preparation,

L_{Xi-R41} is the respective irritant limit R36 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R41 or R36, expressed as a percentage by weight or by volume.

(3) The following preparations shall be classified as irritant to skin and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R38—

- (a) preparations containing one or more substances classified as irritant and to which is assigned the risk phrase R38 or as corrosive and to which is assigned the risk phrase R35 or R34 in individual concentrations equal to or exceeding—

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- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R38, or as corrosive and to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each substance in the preparation by the irritant limit R38 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C,R35}}{L_{Xi,R38}} + \frac{P_{C,R34}}{L_{Xi,R38}} + \frac{P_{Xi,R38}}{L_{Xi,R38}} \right) \geq 1$$

where—

$P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi,R38}$ is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R38 in the preparation,

$L_{Xi,R38}$ is the respective irritant limit R38 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R38, expressed as a percentage by weight or by volume.

(4) The following preparations shall be classified as irritant to the respiratory system and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R37—

- (a) preparations containing one or more substances classified as irritant to which is assigned the risk phrase R37 in individual concentrations equal to or exceeding—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for substance or substances under consideration, or
 - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R37 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R37 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{Xi,R37}}{L_{Xi,R37}} \right) \geq 1$$

where—

$P_{Xi,R37}$ is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R37 in the preparation,

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$L_{Xi,R37}$ is the irritant limit R37 specified for each irritant substance to which is assigned the risk phrase R37, expressed as a percentage by weight or by volume.

- (c) gaseous preparations containing more than one substance classified as irritant and to which is assigned the risk phrase R37 or as corrosive and to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage volume of each substance in the preparation by the irritant limit R37 specified for that substance is 1 or more, i.e.—

$$\sum \left(\frac{P_{C,R35}}{L_{Xi,R37}} + \frac{P_{C,R34}}{L_{Xi,R37}} + \frac{P_{Xi,R37}}{L_{Xi,R37}} \right) \geq 1$$

where—

$P_{C,R35}$ is the percentage by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi,R37}$ is the percentage by volume of each irritant substance to which is assigned the risk phrase R37 in the preparation,

$L_{Xi,R37}$ is the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned the risk phrase R35 or R34 or gaseous irritant substance to which is assigned the risk phrase R37, expressed as a percentage by weight or by volume.

Commencement Information

I18 Sch. 3 Pt. 1 para. 11 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as sensitising

12.—(1) The following preparations shall be classified as sensitising by skin contact and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R43—

Preparations containing one or more substances classified as sensitising and to which is assigned the risk phrase R43 that produces such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for substance or substances under consideration, or
- (ii) the concentration specified in paragraph 5 of Part II of this Schedule (Table V or Table VA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) The following preparations shall be classified as sensitising by inhalation and assigned the symbol “Xn”, the indication of danger “harmful” and risk phrase R42—

Preparations containing one or more substances classified as sensitising and to which is assigned the risk phrase R42 that produces such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

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- (ii) the concentration specified in paragraph 5 of Part II of this Schedule (Table V or Table VA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I19 Sch. 3 Pt. 1 para. 12 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as carcinogenic

13.—(1) Preparations shall be classified as carcinogenic category 1 or 2 and assigned the symbol “T” and the risk phrase R45 or R49 if they contain one or more substance producing such effects to which is assigned the risk phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as carcinogenic category 3 and assigned the symbol “Xn” and risk phrase R40 if they contain one or more substances producing such effects to which is assigned the risk phrase R40 which denotes carcinogenic substances in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I20 Sch. 3 Pt. 1 para. 13 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as mutagenic

14.—(1) Preparations shall be classified as mutagenic category 1 or 2 and assigned the symbol “T” and risk phrase R46 if they contain one or more substances producing such effects to which is assigned the risk phrase R46 which denotes mutagenic substances in category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as mutagenic category 3 and assigned the symbol “Xn” and risk phrase R68 if they contain one or more substances producing such effects to which is assigned the risk phrase R68 which denotes mutagenic substances in category 2 in individual concentrations equal to or exceeding—

Status: Point in time view as at 01/06/2015.

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- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

Commencement Information

I21 Sch. 3 Pt. 1 para. 14 in operation at 24.8.2009, see [reg. 1](#)

Classification by the conventional method as toxic for reproduction

15.—(1) Preparations shall be classified as toxic for reproduction category 1 or 2 and assigned the symbol “T” and risk phrase R60 (fertility) if they contain one or more substances producing such effects to which is assigned the risk phrase R60 which denotes substances toxic for reproduction of category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as toxic for reproduction category 3 and assigned the symbol “Xn” and the risk phrase R62 (fertility) if they contain one or more substances producing such effects to which is assigned the risk phrase R62 which denotes substances toxic for reproduction in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(3) Preparations shall be classified as toxic for reproduction category 1 or 2 and assigned the symbol “T” and risk phrase R61 (development) if they contain one or more substances producing such effects to which is assigned the risk phrase R61 which denotes substances toxic for reproduction of category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(4) Preparations shall be classified as toxic for reproduction category 3 and assigned the symbol “Xn” and the risk phrase R63 (development) if they contain one or more substances producing such effects to which is assigned the risk phrase R63 which denotes substances toxic for reproduction in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

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Commencement Information

I22 Sch. 3 Pt. 1 para. 15 in operation at 24.8.2009, see [reg. 1](#)

Classification of preparations for environmental hazards

16.—(1) The environmental hazards of a preparation shall be assessed by one or more of the following methods—

- (a) by the conventional method described in paragraphs 18 and 19 using concentration limits; or
- (b) by the criteria referred to in the approved classification and labelling guide in relation to the preparation for an appropriate classification and label.

(2) Where the environmental hazards have been established by both methods, the results of the method referred to in sub-paragraph (1)(b) shall be used for classifying the preparation.

(3) Subject to sub-paragraph (4), for preparations of a known composition, with the exception of plant protection products, classified in accordance with the method set out in sub-paragraph (1) (b), a new assessment of the environmental hazards shall be performed either by the method set out in sub-paragraph (1)(a) or (1)(b) whenever—

- (a) changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer which exceed the permitted variations set out in the following table—

<i>Initial concentration range of the constituent</i>	<i>Permitted variation in actual concentration of the constituent</i>
$\leq 2.5\%$	$\pm 30\%$
> 2.5	$\pm 20\%$
> 10	$\pm 10\%$
> 25	$\pm 5\%$

- (b) changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions in Schedule 1, are introduced by the manufacturer.

(4) The revised assessment required by paragraph (3) shall not be required where there is a valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Commencement Information

I23 Sch. 3 Pt. 1 para. 16 in operation at 24.8.2009, see [reg. 1](#)

Use of concentration limits in classification for environmental effects

17.—(1) In accordance with paragraph 16(1)(a), the environmental hazards shall be assessed by the conventional method described in paragraphs 18 and 19 using concentration limits.

(2) Where the substances concerned are dangerous substances and are listed as dangerous substances in Table 3.2 of part 3 of Annex VI of the CLP Regulation and are assigned concentration

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limits necessary for the application of the method of assessment described below, these concentration limits shall be used.

(3) Where the substances concerned are dangerous substances and do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation as dangerous substances or appear there without the concentration limits necessary for the application of the method of evaluation described below, the concentration limits shall be assigned in accordance with Part III of this Schedule.

Commencement Information

I24 Sch. 3 Pt. 1 para. 17 in operation at 24.8.2009, see [reg. 1](#)

Conventional method for the evaluation of hazards to the aquatic environment

18.—(1) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrases R50 and R53 (R50-R53)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-R53 in individual concentrations equal to or greater than—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrases R50-R53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{N,R50-53}}{L_{N,R50-53}} \right) \geq 1$$

where—

$P_{N,R5053}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$L_{N,R5053}$ is the limit R50-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53 expressed as a percentage by weight.

(2) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and risk phrases R51 and R53 (R51-R53) unless the preparation is already classified according to sub-paragraph (1)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-R53 or R51-R53 in individual concentrations equal to or greater than—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;

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- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrases R50-R53 or R51-R53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{N,R50-53}}{L_{N,R51-53}} + \frac{P_{N,R51-53}}{L_{N,R51-53}} \right) \geq 1$$

where—

$P_{N,R5053}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{N,R5153}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation,

$L_{N,R5153}$ is the respective limit R51-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53 or R51-53 expressed as a percentage by weight.

- (3) The following preparations shall be classified as dangerous for the environment and assigned the risk phrases R52 and R53 (R52-R53) unless the preparation is already classified according to sub-paragraph (1) or (2)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-R53 or R51-R53 or R52-R53 in individual concentrations equal to or greater than—

(i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

(ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;

- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrases R50-R53 or R51-R53 or R52-R53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{N,R50-53}}{L_{R52-53}} + \frac{P_{N,R51-53}}{L_{R52-53}} + \frac{P_{R52-53}}{L_{R52-53}} \right) \geq 1$$

where—

$P_{N,R5053}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{N,R5153}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation,

P_{R5253} is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R52-53 in the preparation,

L_{R5253} is the respective limit R52-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53, R51-53 or R52-53 expressed as a percentage by weight.

- (4) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrase R50 unless the preparation is already classified according to sub-paragraph (1)—

- (a) preparations containing one or more substances classified as dangerous for the environment and assigned risk phrase R50 individual concentrations equal to or greater than—

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- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in Part III of this Schedule (Table 2) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrase R50 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{N,R50}}{L_{N,R50}} \right) \geq 1$$

where—

$P_{N,R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R50 in the preparation,

$L_{N,R50}$ is the limit R50 for each substance dangerous for the environment to which is assigned risk phrase R50 expressed as a percentage by weight.

- (c) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrase R50 not meeting the criteria under paragraph (a) or (b) and containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-R53 if—

$$\sum \left(\frac{P_{N,R50}}{L_{N,R50}} + \frac{P_{N,R50-53}}{L_{N,R50}} \right) \geq 1$$

where—

$P_{N,R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R50 in the preparation,

$P_{N,R5053}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$L_{N,R50}$ is the respective limit R50 for each substance dangerous for the environment to which is assigned risk phrases R50 or R50-53 expressed as a percentage by weight.

- (5) The following preparations shall be classified as dangerous for the environment and assigned the risk phrase R52 unless the preparation is already classified according to sub-paragraph (1), (2), (3) or (4)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrase R52 in individual concentrations equal to or greater than—
 - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
 - (ii) the concentration specified in Part III of this Schedule (Table 3) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrase R52 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{R52}}{L_{R52}} \right) \geq 1$$

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where—

P_{R52} is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R52 in the preparation,

L_{R52} is the limit R52 for each substance dangerous for the environment to which is assigned risk phrase R52 expressed as a percentage by weight.

(6) The following preparations shall be classified as dangerous for the environment and assigned the risk phrase R53 unless the preparation is already classified according to sub-paragraph (1), (2) or (3)—

- (a) preparations containing one or more substances classified as dangerous for the environment and assigned risk phrase R53 in individual concentrations equal to or greater than—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in Part III of this Schedule (Table 4) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrase R53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left(\frac{P_{R53}}{L_{R53}} \right) \geq 1$$

where—

P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R53 in the preparation,

L_{R53} is the limit R53 for each substance dangerous for the environment to which is assigned risk phrase R53 expressed as a percentage by weight.

- (c) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrase R53 not meeting the criteria under paragraph (b) and containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-R53, R51-R53 or R52-R53 if—

$$\sum \left(\frac{P_{R53}}{L_{R53}} + \frac{P_{N,R50-53}}{L_{R53}} + \frac{P_{N,R51-53}}{L_{R53}} + \frac{P_{R52-53}}{L_{R53}} \right) \geq 1$$

where—

P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R53 in the preparation,

$P_{N,R5053}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{N,R5153}$ is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation,

P_{R5253} is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R52-53 in the preparation,

L_{R53} is the respective limit R53 for each substance dangerous for the environment to which is assigned risk phrases R53, R50-53, R51-53 or R52-53 expressed as a percentage by weight.

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Commencement Information

I25 Sch. 3 Pt. 1 para. 18 in operation at 24.8.2009, see [reg. 1](#)

Conventional method for the evaluation of hazards to the ozone layer

19. Preparations containing one or more substances classified as dangerous for the environment and to which is assigned the symbol “N” and the risk phrase R59 in individual concentrations equal to or greater than—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in Part III of this Schedule (Table 5) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits,

shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrase R59.

Commencement Information

I26 Sch. 3 Pt. 1 para. 19 in operation at 24.8.2009, see [reg. 1](#)

PART II

CONCENTRATION LIMITS TO BE USED IN THE EVALUATION OF HEALTH HAZARDS

Commencement Information

I27 Sch. 3 Pt. 2 in operation at 24.8.2009, see [reg. 1](#)

An assessment shall be made of the health effects that the use of a substance or a preparation might entail. For that purpose the dangerous health effects have been subdivided into:

1. acute lethal effects;
2. non-lethal irreversible effects after a single exposure;
3. severe effects after repeated or prolonged exposure;
4. corrosive effects, irritant effects;
5. sensitising effects;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The systematic assessment of the dangerous health effects is expressed by means of concentration limits, expressed as weight/weight percentage except for gaseous preparations (Tables A) where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

The classification of the substance is expressed either by a symbol and one or more risk phrases or by categories (category 1, category 2 or category 3) also expressed by risk phrases when substances are

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shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

Acute lethal effects

1

Other than gaseous preparations

1.1 The concentration limits fixed in Table I determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table I

Classification of the substance	Classification of the preparation		
	T+	T	Xn
T+ with R26, R27, R28	concentration $\geq 7\%$	$1\% \leq \text{concentration} < 7\%$	$0.1\% \leq \text{concentration} < 1\%$
T with R23, R24, R25		concentration $\geq 25\%$	$3\% \leq \text{concentration} < 25\%$
Xn with R20, R21, R22			concentration $\geq 25\%$

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

Gaseous preparations

1.2 The concentration limits expressed as a volume/volume percentage in Table IA determine the classification of the gaseous preparations in relation to the individual concentrations of the gas(es) present whose classification is also shown.

Table IA

Classification of the substance (gas)	Classification of the preparation		
	T+	T	Xn
T+ with R26, R27, R28	concentration $\geq 1\%$	$0.2\% \leq \text{concentration} < 1\%$	$0.02\% \leq \text{concentration} < 0.2\%$
T with R23, R24, R25		concentration $\geq 5\%$	$0.5\% \leq \text{concentration} < 5\%$

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

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Classification of the substance (gas)	Classification of the preparation		
	T+	T	Xn
Xn with R20, R21, R22			concentration \geq 5%

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

Non-lethal irreversible effects after a single exposure

2

Other than gaseous preparations

2.1 For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation.

Table II

Classification of the substance	Classification of the preparation		
	T+	T	Xn
T+ with R39/ route of exposure	concentration \geq 10% R39 ^(*) obligatory	1% \leq concentration < 10% R39 ^(*) obligatory	0.1% \leq concentration < 1% R68 ^(*) ^(†) obligatory
T with R39/ route of exposure		concentration \geq 10% R39 ^(*) obligatory	1% \leq concentration < 10% R68 ^(*) ^(†) obligatory
Xn with R68/ route of exposure			concentration \geq 10% R68 ^(*) ^(†) obligatory

(*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of the Council Directive 67/548/EEC shall be used.

(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified mutagenic are given in Table VI.

Gaseous preparations

2.2 For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table IIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Status: Point in time view as at 01/06/2015.

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Table IIA

Classification of the substance (gas)	Classification of the preparation		
	T+	T	Xn
T+ with R39/ route of exposure	concentration \geq 1% R39 ^(*) obligatory	0.2% \leq concentration < 1% R39 ^(*) obligatory	0.02% \leq concentration < 0.2% R68 ^(*) ^(†) obligatory
T with R39/ route of exposure		concentration \geq 5% R39 ^(*) obligatory	0.5% \leq concentration < 5% R68 ^(*) ^(†) obligatory
Xn with R68/ route of exposure			concentration \geq 5% R68 ^(*) ^(†) obligatory

(*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified mutagenic are given in Table VI.

Severe effects after repeated or prolonged exposure

3

Other than gaseous preparations

3.1 For substances that produce severe effects after repeated exposure (R48/route of exposure), the individual concentration limits specified in Table III determine, when appropriate, the classification of the preparation.

Table III

Classification of the substance	Classification of the preparation	
	T	Xn
T with R48/ route of exposure	concentration \geq 10% R48 ^(*) obligatory	1% \leq concentration < 10% R48 ^(*) obligatory
Xn with R48/ route of exposure		concentration \geq 10% R48 ^(*) obligatory

(*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

Gaseous preparations

3.2 For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table IIIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

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Table IIIA

Classification of the substance (gas)	Classification of the preparation	
	T	Xn
T with R48/ route of exposure	concentration \geq 5% R48 ^(*) obligatory	0.5% \leq concentration < 5% R48 ^(*) obligatory
Xn with R48/ route of exposure		concentration \geq 5% R48 ^(*) obligatory

(*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

Corrosive and irritant effects including serious damage to eye

4

Other than gaseous preparations

4.1 For substances that produce corrosive effects (R34, R35) or irritant effect (R36, R37, R38, R41), the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37 R38
C with R35	concentration \geq 10% R35 obligatory	5% \leq concentration < 10% R34 obligatory	5% ^(*)	1% \leq concentration < 5% R36/38 obligatory
C with R34		concentration \geq 10% R34 obligatory	10% ^(*)	5% \leq concentration < 10% R36/38 obligatory
Xi with R41			concentration \geq 10% R41 obligatory	5% \leq concentration < 10% R36 obligatory
Xi with R36, R37, R38				concentration \geq 20% R36, R37, R38 are obligatory in the light of the concentration present if they apply to the

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Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37 R38
				substances under consideration

- (*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

Note

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity consider the advice given in the approved classification and labelling guide regarding classification as corrosive and paragraph 4(4) (b) and (c) of Part I of this Schedule.

Gaseous preparations

4.2 For gases that produce such effects (R34, R35 or R36, R37, R38, R41), the individual concentration limits specified in Table IVA, expressed as a volume/volume percentage determine, when appropriate, the classification of the preparation.

Table IVA

Classification of the substance (gas)	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37 R38
C with R35	concentration $\geq 1\%$ R35 obligatory	$0.2\% \leq$ concentration $< 1\%$ R34 obligatory	$0.2\%^{(*)}$	$0.02\% \leq$ concentration $< 0.2\%$ R36/37/38 obligatory
C with R34		concentration $\geq 5\%$ R34 obligatory	$5\%^{(*)}$	$0.5\% \leq$ concentration $< 5\%$ R36/37/38 obligatory
Xi with R41			concentration $\geq 5\%$ R41 obligatory	$0.5\% \leq$ concentration $< 5\%$ R36 obligatory
Xi with R36, R37, R38				concentration $\geq 5\%$ R36, R37, R38 are obligatory as appropriate

- (*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34

Status: Point in time view as at 01/06/2015.

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below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

Note

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in approved classification and labelling guide regarding classification as corrosive and paragraph 4(4) (b) and (c) of Part I of this Schedule.

Sensitising effects

5

Other than gaseous preparations

5.1 Preparations that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V determine, when appropriate, the classification of the preparation.

Table V

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration \geq 1% R42 obligatory	
Sensitising with R43		concentration \geq 1% R43 obligatory

Gaseous preparations

5.2 Gases that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced by inhalation and through contact with the skin.

The individual concentration limits specified in Table VA expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table VA

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration \geq 0.2% R42 obligatory	
Sensitising with R43		concentration \geq 0.2% R43 obligatory

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Carcinogenic/mutagenic/toxic effects for reproduction

6

Other than gaseous preparations

6.1 For substances that produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

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 (unless already assigned R45)
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 (unless already assigned R46)
substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration \geq 0.5% toxic for reproduction (fertility) R60 obligatory	
a	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	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table II.	

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Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
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>)
a	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	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table II.	

Gaseous preparations

6.2 For gases which produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VIA, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

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Table VIA

Classification of the substance (gas)	Classification of the gaseous 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 (unless already assigned R45)
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 (unless already assigned R46)
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 (unless already assigned R60)
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 (unless already assigned R61)
a	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	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA.	

PART III

CONCENTRATION LIMITS TO BE USED FOR THE EVALUATION OF ENVIRONMENT HAZARDS

The aquatic environment

1. The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substances present whose classification is also shown.

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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			$C_n \geq 25\%$

For 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).

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
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$

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<i>LC₅₀ or EC₅₀ value ("L(E)C₅₀") of substance classified either as N, R50 or as N,R50-53 (mg/l)</i>	<i>Classification of the preparation N, R50</i>
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).

Table 3*Aquatic toxicity*

<i>Classification of the substance</i>	<i>Classification of the preparation R52</i>
R52	C _n ≥ 25%

Table 4*Long-term adverse effects*

<i>Classification of the substance</i>	<i>Classification of the preparation R53</i>
R53	C _n ≥ 25%
N, R50-53	C _n ≥ 25%
N, R51-53	C _n ≥ 25%
R52-53	C _n ≥ 25%

Commencement Information

I28 Sch. 3 Pt. 3 para. 1 in operation at 24.8.2009, see [reg. 1](#)

The non-aquatic environment

2. The concentration limits fixed in the following table, expressed as a weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substances present whose classification is also shown.

Table 5*Dangerous for the ozone layer*

<i>Classification of the substance</i>	<i>Classification of the preparation N, R59</i>
N with R59	C _n ≥ 0.1%

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Commencement Information

I29 Sch. 3 Pt. 3 para. 2 in operation at 24.8.2009, see [reg. 1](#)

SCHEDULE 4

Regulations 7 and 9

LABELLING PARTICULARS FOR DANGEROUS SUBSTANCES, DANGEROUS PREPARATIONS AND FOR CERTAIN OTHER PREPARATIONS

PART I

GENERAL PROVISIONS RELATING TO LABELS

Labelling particulars for dangerous substances

1.—(1) In the case of a dangerous substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the particulars to be shown on the label in accordance with regulation 7(2)(c) shall be the particulars specified for that dangerous substance in the relevant entry in that table.

(2) Subject to paragraph 4, in the case of a dangerous substance which is not listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the particulars required to be shown on the label in accordance with regulation 7(2)(c) shall be determined from the classification of the substance in accordance with regulation 4 in conjunction with the approved classification and labelling guide.

Commencement Information

I30 Sch. 4 Pt. 1 para. 1 in operation at 24.8.2009, see [reg. 1](#)

Labelling particulars for dangerous preparations

2.—(1) Subject to paragraphs 3 and 4, the provisions of this paragraph shall have effect in relation to the labelling of dangerous preparations.

(2) Subject to sub-paragraph (3), the particulars relating to the chemical name required to be shown on the label in accordance with regulation 7(3)(c)(i) shall be shown according to the following rules—

- (a) in the case of a dangerous preparation classified as requiring the indication of danger T+, T or Xn, only substances requiring those indications of danger present in the dangerous preparation in concentrations equal to or greater than—
 - (i) the lowest limit (the Xn limit) for the substance laid down in Table 3.2 of part 3 of Annex VI of the CLP Regulation, or
 - (ii) where there is no such limit, the relevant limit laid down in Part II of Schedule 3, have to be taken into consideration;
- (b) in the case of a dangerous preparation classified as requiring the indication of danger C, only substances requiring that indication of danger present in the dangerous preparation in concentrations equal to or greater than—

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- (i) the lowest limit (the Xi limit) for the substance laid down in Table 3.2 of part 3 of Annex VI of the CLP Regulation, or
- (ii) where there is no such limit, the relevant limit laid down in Part II of Schedule 3, have to be taken into consideration;
- (c) if the dangerous preparation is assigned one or more of the following danger categories:
 - carcinogen category 1, 2 or 3,
 - mutagen category 1, 2 or 3,
 - toxic for reproduction category 1, 2 or 3,
 - very toxic, toxic or harmful due to non-lethal effects after a single exposure,
 - toxic or harmful due to severe effects after repeated or prolonged exposure,
 - sensitising,

the name of any substance causing the dangerous preparation to be assigned shall be referred to;

- (d) as a consequence of the provisions set out in paragraphs (a) to (c), the name of any substance which led to the classification of the dangerous preparation in the following danger categories:
 - explosive,
 - oxidising,
 - extremely flammable,
 - highly flammable,
 - flammable,
 - irritant,
 - dangerous for the environment,

need not be referred to on the label unless so required by paragraph (a), (b) or (c).

- (3) The chemical name referred to in sub-paragraph (2) shall be—
 - (a) in the case of a substance listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the name or one of the names under which that substance is listed; or
 - (b) in the case of a substance not so listed, an internationally recognised name.

(4) For the purpose of labelling, no account shall be taken of a substance in the dangerous preparation where the concentration of that substance is less than the concentration referred to in paragraph 6 of Part I of Schedule 3.

(5) Subject to sub-paragraph (4), the particulars to be shown on the label in accordance with regulation 7(3)(c)(ii), (iii) and (iv) shall be determined from the classification of the dangerous preparation made in accordance with regulation 4 in conjunction with the approved classification and labelling guide.

(6) As a general rule, a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding risk phrases – although in some cases more than four chemical names may be necessary.

Commencement Information

I31 Sch. 4 Pt. 1 para. 2 in operation at 24.8.2009, see **reg. 1**

Status: Point in time view as at 01/06/2015.

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Confidentiality of chemical names

3.—(1) Subject to sub-paragraph (2), where the supplier of a dangerous preparation is able to demonstrate to the Secretary of State that the disclosure on the label or safety data sheet of the chemical identity of a substance which is exclusively classified as—

- (a) irritant with the exception of those assigned R41 or irritant in combination with one or more of the other properties mentioned in paragraph 2(2)(d); or
- (b) harmful or harmful in combination with one or more of the properties mentioned in paragraph 2(2)(d) presenting acute lethal effects alone,

will put at risk the confidential nature of his intellectual property, the person shall, in accordance with the provisions of Annex VI of Council Directive [1999/45/EEC\(14\)](#), be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name.

(2) The derogation in sub-paragraph (1) shall not apply in respect of a substance which has been assigned a Community exposure limit.

(3) Where a supplier wishes to take advantage of the derogation contained in sub-paragraph (1), he shall make application to the Secretary of State accordingly, enclosing the information specified in Annex VI of Council Directive [1999/45/EEC](#).

(4) The Secretary of State may require such further information from the supplier as is necessary to determine the validity of an application made under sub-paragraph (3).

Commencement Information

I32 [Sch. 4 Pt. 1 para. 3](#) in operation at 24.8.2009, see [reg. 1](#)

Indications of danger and symbols for dangerous substances and dangerous preparations

4.—(1) Except in the case of a dangerous substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, where a dangerous substance or dangerous preparation is required to have more than one indication of danger in either of the following groups listed in decreasing order of severity, namely—

- (a) explosive, oxidising, extremely flammable and highly flammable; or
- (b) very toxic, toxic, corrosive, harmful and irritant,

only one of the indications of danger with its symbol from each group corresponding to the most severe indication of danger in that group need be shown.

(2) The risk phrases R12 (extremely flammable) and R11 (highly flammable) need not be used if they repeat the indication of danger shown on the label.

Commencement Information

I33 [Sch. 4 Pt. 1 para. 4](#) in operation at 24.8.2009, see [reg. 1](#)

(14) O.J. No. L200, 30.7.1999, p. 1

PART II

PARTICULAR PROVISIONS CONCERNING CERTAIN PREPARATIONS

A

SPECIAL PROVISIONS FOR DANGEROUS PREPARATIONS

Dangerous preparations to be supplied to the general public

1.—(1) The label on the packaging of dangerous preparations intended to be supplied to the general public shall in addition to the relevant safety advice bear the relevant safety phrase S1, S2, S45 or S46 in accordance with the approved classification and labelling guide.

(2) When the dangerous preparations referred to in sub-paragraph (1) are classified as very toxic, toxic or corrosive and where it is physically impossible to give the information on the package itself, packages containing such preparations shall be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

Commencement Information

I34 Sch. 4 Pt. 2 Section A para. 1 in operation at 24.8.2009, see [reg. 1](#)

Dangerous preparations intended for use by spraying

2. The label on the packaging containing dangerous preparations intended to be used for spraying shall bear the safety phrase S23 and safety phrase S38 or S51 assigned in accordance with the approved classification and labelling guide.

Commencement Information

I35 Sch. 4 Pt. 2 Section A para. 2 in operation at 24.8.2009, see [reg. 1](#)

Dangerous preparations containing a substance affected by the risk phrase R33 (danger of cumulative effects)

3. When a dangerous preparation contains at least one substance required to show the risk phrase R33, that phrase shall be shown on the label on the packaging of the dangerous preparation when the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation.

Commencement Information

I36 Sch. 4 Pt. 2 Section A para. 3 in operation at 24.8.2009, see [reg. 1](#)

Dangerous preparations containing a substance affected by the risk phrase R64 (may cause harm to breast-fed babies)

4. When a dangerous preparation contains at least one substance required to show the risk phrase R64, that phrase shall be shown on the label on the packaging of the dangerous preparation when

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the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation.

Commencement Information

I37 Sch. 4 Pt. 2 Section A para. 4 in operation at 24.8.2009, see [reg. 1](#)

B

SPECIAL PROVISIONS APPLYING TO ANY PREPARATION

Preparations not classified as sensitising but containing at least one sensitising substance

1. The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration $\geq 0.1\%$ or in a concentration greater than or equal to that specified under a specific note for the substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation shall bear the inscription—

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

Commencement Information

I38 Sch. 4 Pt. 2 Section B para. 1 in operation at 24.8.2009, see [reg. 1](#)

Preparations containing a substance assigned the risk phrase R67

2. When a preparation contains one or more substances assigned the risk phrase R67, the label on the packaging of the preparation shall bear the following inscription—

“Vapours may cause drowsiness and dizziness.”,

when the total concentration of such substances present in the preparation is $\geq 15\%$, 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.

Commencement Information

I39 Sch. 4 Pt. 2 Section B para. 2 in operation at 24.8.2009, see [reg. 1](#)

C

SPECIAL PROVISIONS APPLYING TO CERTAIN OTHER PREPARATIONS

Preparations not intended for the general public

1. The label on the packaging of a preparation of the type specified in Article 31(3) of REACH shall bear the following inscription—

“Safety data sheet available for professional user on request.”.

Commencement Information

I40 Sch. 4 Pt. 2 Section C para. 1 in operation at 24.8.2009, see [reg. 1](#)

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SCHEDULE 5

Regulation 11

BRITISH AND INTERNATIONAL STANDARDS RELATING TO CHILD RESISTANT FASTENINGS AND TACTILE WARNING DEVICES

Commencement Information

I41 Sch. 5 in operation at 24.8.2009, see **reg. 1**

The British Standards and International Standards referred to in regulation 11 are as follows—

“BS EN 28317” means the British Standard Specification for packagings resistant to opening by children, BS EN 28317: 1993 which was published by the British Standards Institution and came into effect on 15 February 1993;

“ISO 8317” means the International Standard ISO 8317 (1 July 1989 edition) relating to “Child-resistant packagings – Requirements for the testing of reclosable packages” adopted by the International Standards Organisation;

“BS 6652” means the British Standard Specification for packagings resistant to opening by children, BS 6652: 1989 which was published by the British Standards Institution and came into effect on 30 June 1989;

“EN 862” means the CEN standard EN 862 (March 1997 edition) relating to “Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products” adopted by the European Committee for Standardisation;

“EN ISO 11683” means the EN ISO Standard 11683 (1997 Edition) relating to “Packaging — Tactile warnings of danger — Requirements.”;

“BS 7501” means the British Standard on the general criteria for the operation of testing laboratories BS 7501: 1989 which was published by the British Standards Institution and came into effect on 31 October 1989;

“EN 45 000” means the European Standards Series 45 000 which sets out the general criteria which laboratories must adhere to in order to obtain accreditation for the certification of child resistant fastenings.

SCHEDULE 6

Regulation 16

PREMISES AND ACTIVITIES WITHIN THE TERRITORIAL SEA

Interpretation

1.—(1) In this Schedule—

“activity” includes a diving project;

“designated area” means any area designated by order under section 1(7) of the Continental Shelf Act 1964⁽¹⁵⁾ and “within a designated area” includes over and under it;

“diving project” has the meaning assigned to it by regulation 2(1) of the Diving at Work Regulations (Northern Ireland) 2005⁽¹⁶⁾ save that it includes an activity in which a person takes part as a diver wearing an atmospheric pressure suit and without breathing in air or other gas at a pressure greater than atmospheric pressure;

⁽¹⁵⁾ 1964 c. 29; section 1 was amended by the Oil and Gas (Enterprise) Act 1982 (1982 c. 23), Schedule 3, paragraph 1

⁽¹⁶⁾ S.R. 2005 No. 45, as amended by S.R. 2007 No. 247

Status: Point in time view as at 01/06/2015.

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“energy structure” means a fixed or floating structure, other than a vessel, for producing energy from wind or water;

“offshore installation” shall be construed in accordance with paragraph 2(2) and (3);

“supplementary unit” means a fixed or floating structure, other than a vessel, for providing energy, information or substances to an offshore installation;

“stand-by vessel” means a vessel which is ready to give assistance in the event of an emergency on or near an offshore installation;

“vessel” includes a hovercraft and any floating structure which is capable of being staffed.

(2) For the purposes of this Schedule, any structures and devices on top of a well shall be treated as forming part of the well.

(3) Any reference in this Schedule to premises and activities includes a reference to any person, article or substance on those premises or engaged in, or, as the case may be, used or for use in connection with any such activity, but does not include a reference to an aircraft which is airborne.

Commencement Information

I42 Sch. 6 para. 1 in operation at 24.8.2009, see [reg. 1](#)

Offshore installations

2.—(1) This paragraph shall apply to and in relation to—

- (a) any offshore installation and any activity on it;
- (b) any activity in connection with an offshore installation, or any activity which is immediately preparatory thereto, whether carried on from the installation itself, on or from a vessel or in any other manner, other than—
 - (i) transporting, towing or navigating the installation; and
 - (ii) any activity in or from a vessel being used as a stand-by vessel;
- (c) a diving project involving—
 - (i) the survey and preparation of the sea bed for an offshore installation;
 - (ii) the survey and restoration of the sea bed consequent on the removal of an offshore installation.

(2) Subject to sub-paragraph (3), in this paragraph, “offshore installation” means a structure which is, or is to be, or has been, used while standing or stationed in water, or on the foreshore or other land intermittently covered with water—

- (a) for the exploitation, or exploration with a view to exploitation, of mineral resources by means of a well;
- (b) for the storage of gas in or under the shore or bed of any water or the recovery of gas so stored;
- (c) for the conveyance of things by means of a pipe; or
- (d) mainly for the provision of accommodation for persons who work on or from a structure falling within any of the provisions of this sub-paragraph,

together with any supplementary unit which is ordinarily connected to it, and all the connections.

(3) Any reference in sub-paragraph (2) to a structure or unit does not include—

- (a) a structure which is connected with dry land by a permanent structure providing access at all times and for all purposes;

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- (b) a well;
- (c) a structure which has ceased to be used for any of the purposes specified in sub-paragraph (2) and has since been used for a purpose not so specified;
- (d) a mobile structure which has been taken out of use and is not yet being moved with a view to its being used for any of the purposes specified in sub-paragraph (2); and
- (e) any part of a pipeline.

Commencement Information

I43 Sch. 6 para. 2 in operation at 24.8.2009, see [reg. 1](#)

Wells

3.—(1) Subject to sub-paragraph (2), this paragraph applies to and in relation to—

- (a) a well and any activity in connection with it; and
- (b) an activity which is immediately preparatory to any activity in head (a).

(2) Sub-paragraph (1) includes keeping a vessel on station for the purpose of working on a well but otherwise does not include navigation or an activity connected with navigation.

Commencement Information

I44 Sch. 6 para. 3 in operation at 24.8.2009, see [reg. 1](#)

Pipelines

4.—(1) This paragraph applies to and in relation to—

- (a) any pipeline;
- (b) any pipeline works;
- (c) the following activities in connection with pipeline works—
 - (i) the loading, unloading, fuelling or provisioning of a vessel;
 - (ii) the loading, unloading, fuelling, repair and maintenance of an aircraft on a vessel, being in either case a vessel which is engaged in pipeline works.

(2) In this paragraph—

“pipeline” means a pipe or system of pipes for the conveyance of any thing, together with—

- (a) any apparatus for inducing or facilitating the flow of any thing through, or through part of, the pipe or system;
- (b) any apparatus for treating or cooling any thing which is to flow through, or through part of, the pipe or system;
- (c) valves, valve chambers and similar works which are annexed to, or incorporated in the course of, the pipe or system;
- (d) apparatus for supplying energy for the operation of any such apparatus or works as are mentioned in heads (a) to (c);
- (e) apparatus for the transmission of information for the operation of the pipe or system;
- (f) apparatus for the cathodic protection of the pipe or system; and

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(g) a structure used or to be used solely for the support of a part of the pipe or system; but not including a pipeline of which no initial or terminal point is situated in the United Kingdom, within the territorial sea adjacent to the United Kingdom, or within a designated area;

“pipeline works” means—

- (a) assembling or placing a pipeline or length of pipeline including the provision of internal or external protection for it;
- (b) inspecting, testing, maintaining, adjusting, repairing, altering or renewing a pipeline or length of pipeline;
- (c) changing the position of or dismantling or removing a pipeline or length of pipeline;
- (d) opening the bed of the sea for the purposes of the works mentioned in heads (a) to (c), and tunnelling or boring for those purposes;
- (e) any activities incidental to the activities described in heads (a) to (d);
- (f) a diving project in connection with any of the works mentioned in heads (a) to (e) or for the purpose of determining whether a place is suitable as part of the site of a proposed pipeline and the carrying out of surveying operations for settling the route of a proposed pipeline.

Commencement Information

I45 Sch. 6 para. 4 in operation at 24.8.2009, see [reg. 1](#)

Mines

5.—(1) This paragraph applies to and in relation to a mine within the territorial sea or extending beyond it, and any activity in connection with it, while it is being worked.

(2) In this paragraph “mine” has the same meaning as in the Mines Act (Northern Ireland) 1969⁽¹⁷⁾.

Commencement Information

I46 Sch. 6 para. 5 in operation at 24.8.2009, see [reg. 1](#)

Other activities

6.—(1) Subject to paragraph (2), this paragraph applies to and in relation to—

- (a) the construction, reconstruction, alteration, repair, maintenance, cleaning, use, operation, demolition and dismantling of any building, energy structure or other structure, not being in any case a vessel, or any preparation for any such activity;
- (b) the transfer of people or goods between a vessel or aircraft and a structure (including a building) mentioned in head (a);
- (c) the loading, unloading, fuelling or provisioning of a vessel;
- (d) a diving project;

⁽¹⁷⁾ 1969 c. 6 (N.I.)

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- (e) the construction, reconstruction, finishing, refitting, repair, maintenance, cleaning or breaking up of a vessel except when carried out by the master or any officer or member of the crew of that vessel;
 - (f) the maintaining on a station of a vessel which would be an offshore installation were it not a structure to which paragraph 2(3)(d) applies;
 - (g) the operation of a cable for transmitting electricity from an energy structure to shore;
 - (h) the transfer of people or goods between a vessel or aircraft and a structure mentioned in head (f).
- (2) This paragraph shall not apply—
- (a) to a case where paragraph 2, 3, 4 or 5 applies; or
 - (b) to vessels which are registered outside the United Kingdom and are on passage through the territorial sea.

Commencement Information

I47 Sch. 6 para. 6 in operation at 24.8.2009, see [reg. 1](#)

SCHEDULE 7

Regulation 17

PART I
AMENDMENT

Commencement Information

I48 Sch. 7 Pt. 1 in operation at 24.8.2009, see [reg. 1](#)

<i>Regulations to be amended</i>	<i>Regulation</i>	<i>Amendment to be made</i>
The Chemical (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009(18)	Regulation 3(5)	For the Explosive Substances (Hazard Information) Regulations (Northern Ireland) 2000 substitute the Explosives (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009

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EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations revoke and re-enact with amendments the Explosive Substances (Hazard Information) Regulations (Northern Ireland) 2000. They apply to explosives and certain substances which are controlled as if they were explosives.

2. These Regulations, as respects Northern Ireland—

- (a) provide for the enforcement of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (O.J. No. L353, 31.12.08, p.1) (“the CLP Regulation”), in addition to the enforcement of these Regulations;
- (b) implement parts of Directive 2006/121/EC (O.J. No. L396, 30.12.06, p.850) of the European Parliament and the Council of 18 December 2006 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 (O.J. No. L142, 31.5.08, p.1) concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency;
- (c) implement Council Directive 1992/32/EEC (O.J. No. L154, 5.6.92, p.1) amending for the 7th time Council Directive 67/548/EEC (O.J. No. L196, 16.8.67, p.1), in so far as its provisions relate to the classification, packaging and labelling of dangerous substances (“the substances Directive”); and
- (d) implement Council Directive 1999/45 (O.J. No. L200, 30.7.99, p.1) on the classification, packaging and labelling of dangerous preparations (“the preparations Directive”).

3. These Regulations also implement the Directives referred to below which adapt to technical progress and modify the substances Directive and the preparations Directive. These Directives are—

- (a) Commission Directive 91/410/EEC (O.J. No. L228, 17.8.91, p.67) 14th adaptation to technical progress of the substances Directive;
- (b) Commission Directive 93/21/EEC (O.J. No. L110, 4.5.93, p.20), 18th adaptation to technical progress of the substances Directive;
- (c) Commission Directive 2000/32/EC (O.J. No. L136, 8.6.2000, p.1) 26th adaptation to technical progress of the substances Directive;
- (d) Commission Directive 2001/59/EC (O.J. No. L225, 21.8.2001, p.1) 28th adaptation to technical progress of the substances Directive;
- (e) Commission Directive 2004/73/EC (O.J. No. L152, 30.4.04, p.1) 29th adaptation to technical progress of the substances Directive;
- (f) Commission Directive 2001/60/EC (O.J. No. L226, 22.8.2001, p.5) 1st adaptation to technical progress of the preparations Directive; and
- (g) Commission Directive 2006/8/EC (O.J. No. L19, 24.1.2006 p.12) amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to the preparations Directive.

4. The main purpose of the CLP Regulation is to adopt within the European Community the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) published by the UN Social and Economic Council (Second Revised Edition ISBN-13:978-92-1-116957-7). The

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UN GHS is the result of an international agreement made at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992, and the World Summit on Sustainable Development in Johannesburg in 2002. It sets out internationally accepted definitions and criteria to identify the hazards of chemicals and to communicate those hazards via labels and safety data sheets. The GHS is a voluntary international agreement and countries may keep national requirements that are not covered by the GHS provided that they do not contradict it.

5. The CLP Regulation progressively replaces, with transitional arrangements, the current Community classification and labelling system for hazardous chemicals with a new system based on the GHS. It replaces certain provisions of the substances Directive and the preparations Directive relating to the classification, packaging and labelling of substances and preparations through a two-stage process, first for substances and then for mixtures (currently referred to as “preparations”). Whilst many of the classification criteria, hazard symbols and labelling phrases are similar to the existing system, there are also some differences. The CLP Regulation requires dutyholders to classify, label and package hazardous chemicals before placing them on the market in accordance with its provisions.

6. Council Directive [2006/121/EC](#) of Regulation [\(EC\) No 1907/2006](#) (“REACH”) amends the substances Directive in order to adapt it to REACH. The major changes effected by Council Directive [2006/121/EC](#) are to remove the provisions on the notification of new substances and on the provision of safety data sheets from the substances Directive. These provisions are now included in REACH and the changes are implemented by the REACH Enforcement Regulations 2008 ([S.I. 2008/2852](#)). The remaining changes effected by Council Directive [2006/121](#) are to delete references to Annex V of the substances Directive and replace references to it with references to the relevant parts of Commission Regulation [\(EC\) No 440/2008](#) (O.J. No. L142, 31.5.08, p.1) laying down test methods pursuant to REACH and to amend certain other references. These remaining changes are implemented in these Regulations by the approved classification and labelling guide.

7. The terms and expressions used in the Regulations are defined in regulation 2 and the scope of the Regulations is described in regulation 3.

8. Regulations 4 to 10 implement the substances Directive and the preparations Directive. Regulation 11 implements the preparations Directive.

9. Regulation 4 describes the procedures for classifying dangerous substances and dangerous preparations. Regulation 5 refers to the safety data sheet provisions of REACH. Regulation 6 imposes requirements relating to the packaging of dangerous substances and dangerous preparations.

10. Regulation 7 imposes requirements in respect of the particulars that shall be shown on the labels for dangerous substances and dangerous preparations. Special labelling requirements are imposed in regulations 8 and 9. Regulation 10 imposes requirements in respect of the methods of marking and labelling of packages that contain dangerous substances or dangerous preparations.

11. Regulation 11 requires that the packaging of certain substances and preparations be provided with child resistant fastenings or tactile warning devices or both, and sets out the standards to which they shall conform.

12. Regulation 12 requires a person who classifies a dangerous preparation to retain the data used for the classification for at least three years after the preparation was last supplied.

13. Regulation 13 provides for transitional periods for compliance with the CLP Regulation. According to these arrangements, suppliers must classify both substances and mixtures according to regulation 4 until 1st June 2015, and must classify, label and package according to the CLP Regulation from 1st December 2010 for substances and 1st June 2015 for mixtures. However, they may choose to classify, label and package in accordance with the CLP Regulation before 1st December 2010 for substances and 1st June 2015 for mixtures, in which case the requirements in regulations 6 to 11 on labelling and packaging cease to apply. Regulations 6 to 11 in any case cease

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to apply from 1st December 2010 for substances and 1st June 2015 for mixtures. Regulation 13 also describes the transitional arrangements for retention of data for dangerous preparations.

14. Regulation 14 makes provision for the enforcement of the Regulations and the CLP Regulation. Regulation 15 provides for a defence in specific circumstances in the case of contravention of the Regulations. Provision is made in regulation 16 to specify an activity within the territorial sea of the United Kingdom adjacent to Northern Ireland to which the Regulations apply. A revocation is set out in regulation 17.

15. Copies of the publications referred to in the Regulations are obtainable as follows—

- (a) the approved classification and labelling guide is available from the Health and Safety Executive for Northern Ireland, 83 Ladas Drive, Belfast BT6 9FR or on-line (<http://www.hse.gov.uk/chip/classification.pdf>).
- (b) The British and International Standards referred to in regulation 11 and Schedule 5 (relating to child resistant fastenings and tactile warning devices) from the British Standards Institution, 389 Chiswick High Road, London W4 4AL or online (<http://www.bsi-global.com/upload/Standards%20&%20Publications/shop.html>).

16. In Great Britain the corresponding Regulations are the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 ([S.I. 2009/716](#)). The Great Britain Health and Safety Executive (GB HSE) has prepared a regulatory impact assessment in respect of those Regulations and a copy of that assessment, together with a Northern Ireland supplement prepared by the Health and Safety Executive for Northern Ireland, is held at the offices of that Executive at 83 Ladas Drive, Belfast BT6 9FR from where copies may be obtained. A copy of the transposition note in relation to the implementation of the Directives set out in paragraphs 2 and 3 is also available at that office.

17. A person who contravenes the Regulations is guilty of an offence under Article 31 of the Health and Safety at Work (Northern Ireland) Order 1978 and is liable—

- (a) on summary conviction to imprisonment for a term not exceeding six months, or a fine not exceeding £20,000, or both; or
- (b) on conviction on indictment to imprisonment for a term not exceeding two years or a fine or both.

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