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Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in ►M8 Part 3 of Annex VI to Regulation (EC) No 1272/2008 ◄ for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in ►M8 Part 3 of Annex VI to Regulation (EC) No 1272/2008 ◄ or appear in it without concentration limits;

9.4. those of category 3 which are assigned the symbol 'X_n' and the phrase R63 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in ►M8 Part 3 of Annex VI to Regulation (EC) No 1272/2008 ◄ for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in ►M8 Part 3 of Annex VI to Regulation (EC) No 1272/2008 ◄ or appear in it without concentration limits.

PART B

Concentration limits to be used in evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables I A to VI A) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentration limits are used in the absence of specific concentration limits for the substance under consideration in ►M8 Part 3 of Annex VI to Regulation (EC) No 1272/2008 ◄.

1. *Acute lethal effects*

1.1. Non-gaseous preparations

The concentration limits fixed in Table I, expressed as a weight/weight percentage, 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	X_n
T^+ with R26, R27, R28	concentration ≥ 7 %	1 % ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R23, R24, R25		concentration ≥ 25 %	3 % ≤ concentration < 25 %
X_n with R20, R21, R22			concentration ≥ 25 %

The R phrases denoting risk are to be assigned to the preparation in accordance with the following criteria:

— the label shall include one or more of the abovementioned R phrases according to the classification used,

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— 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.

1.2. Gaseous preparations

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

Table I A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration ≥ 1 %	0,2 % ≤ concentration < 1 %	0,02 % ≤ concentration < 0,2 %
T with R23, R24, R25		concentration ≥ 5 %	0,5 % ≤ concentration < 5 %
X_n with R20, R21, R22			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 abovementioned 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.

2. *Non-lethal irreversible effects after a single exposure*

2.1. Non-gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, ►**M1** R68 ◄/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table II

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 10 % R39 (*) obligatory	1 % ≤ concentration < 10 % R39 (*) obligatory	0,1 % ≤ concentration < 1 % ►**M1** R68 ◄ (*) obligatory
T with R39/route of exposure		concentration ≥ 10 % R39 (*) obligatory	1 % ≤ concentration < 10 % ►**M1** R68 ◄ (*) obligatory
X_n with ►**M1** R68 ◄/route of exposure			concentration ≥ 10 % ►**M1** R68 ◄ (*) obligatory

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Classification of the substance	Classification of the preparation		
	T^+	T	X_n

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

2.2. Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, ►**M1** R68 ◄/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table II A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 1 % R39 (*) obligatory	0,2 % ≤ concentration < 1 % R39 (*) obligatory	0,02 % ≤ concentration < 0,2 % ►**M1** R68 ◄ (*) obligatory
T with R39/route of exposure		concentration ≥ 5 % R39 (*) obligatory	0,5 % ≤ concentration < 5 % ►**M1** R68 ◄ (*) obligatory
X_n with ►**M1** R68 ◄/route of exposure			concentration ≥ 5 % ►**M1** R68 ◄ (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3. *Severe effects after repeated or prolonged exposure*

3.1. Non-gaseous preparations

For substances that produce severe effects after repeated or prolonged exposure (R 48/route of exposure), the individual concentration limits specified in Table III, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table III

Classification of the substance	Classification of the preparation	
	T	X_n
T with R48/route of exposure	concentration ≥ 10 % R48 (*) obligatory	1 % ≤ concentration < 10 % R48 (*) obligatory
X_n with R48/route of exposure		concentration ≥ 10 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

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3.2. Gaseous preparations

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

Table III A

Classification of the substance (gas)	Classification of the gaseous preparation	
	T	X_n
T with R48/route of exposure	concentration ≥ 5 % R48 (*) obligatory	0,5 % ≤ concentration < 5 % R48 (*) obligatory
X_n with R48/route of exposure		concentration ≥ 5 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

4. *Corrosive and irritant effects including serious damage to the eye*

4.1. Non-gaseous preparations

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

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration ≥ 10 % R35 obligatory	5 % ≤ concentration < 10 % R34 obligatory	5 % (*)	1 % ≤ concentration < 5 % R36/38 obligatory
C with R34		concentration ≥ 10 % R34 obligatory	10 % (*)	5 % ≤ concentration < 10 % R36/38 obligatory
X_i with R41			concentration ≥ 10 % R41 obligatory	5 % ≤ concentration < 10 % R36 obligatory
X_i with R36, R37, R38				concentration ≥ 20 % R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification

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of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

►M1 *NB:* 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 paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive. ◄

4.2. Gaseous preparations

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

Table IV A

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration ≥ 1 % R35 obligatory	0,2 % ≤ concentration < 1 % R34 obligatory	0,2 % (*)	0,02 % ≤ concentration < 0,2 % R36/37/38 obligatory
C with R34		concentration ≥ 5 % R34 obligatory	5 % (*)	0,5 % ≤ concentration < 5 % R36/37/38 obligatory
X_i with R41			concentration ≥ 5 % R41 obligatory	0,5 % ≤ concentration < 5 % R36 obligatory
X_i with R36, R37, R38				concentration ≥ 5 % R36, R37, R38 obligatory as appropriate

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. 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 with R41 or irritant with R36.

►M1 *NB:* 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 paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive. ◄

5. *Sensitising effects*

5.1. Non-gaseous preparations

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

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

— the symbol X_i and phrase R43 if this effect can be produced through contact with the skin.

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

Table V

Classification of the substance	Classification of the preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration ≥ 1 % R42 obligatory	
Sensitising with R43		concentration ≥ 1 % R43 obligatory

5.2. Gaseous preparations

Gaseous preparations that produce such effects are classified as sensitising and assigned:

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

— the symbol X_i and phrase R43 if this effect can be produced through contact with the skin.

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

Table V A

Classification of the substance (gas)	Classification of the gaseous preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration ≥ 0,2 % R42 obligatory	
Sensitising with R43		concentration ≥ 0,2 % R43 obligatory

6. *Carcinogenic/mutagenic/toxic effects for reproduction*

6.1. Non-gaseous preparations

For substances which produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight 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:	X_n; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n; ►**M1** 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:	X_n; R62
Toxic for reproduction development category 3:	X_n; R63

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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 ≥ 0,1 % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (*unless already assigned R45* (*))
Mutagenic substances of category 1 or 2 with R46	Concentration ≥ 0,1 % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (*unless already assigned R46*)
Substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	Concentration ≥ 0,5 % toxic for reproduction (fertility) R60 obligatory	
Substances 'toxic for reproduction' of category 3 with R62 (fertility)		Concentration ≥ 5 % toxic for reproduction (fertility) R62 obligatory (*unless already assigned R60*)
Substances 'toxic for reproduction' of category 1 or 2 with R61 (development)	Concentration ≥ 0,5 % toxic for reproduction (development) R61 obligatory	
Substances 'toxic for reproduction' of category 3 with R63 (development)		Concentration ≥ 5 % toxic for reproduction (development) R63 obligatory (*unless already assigned R61*)

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

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6.2. Gaseous preparations

For gases which produce such effects, the concentration limits laid down in Table VI A, 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:	X_n; R40
Mutagenic categories 1 and 2:	T; R46

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Mutagenic category 3:	X_n; ►M1 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:	X_n; R62
Toxic for reproduction development category 3:	X_n; R63

▼M4

Table VI A

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

(*) 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.