

SCHEDULE 3

PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

PART II

CONCENTRATION LIMITS TO BE USED IN APPLYING THE CONVENTIONAL METHOD OF ASSESSING HEALTH EFFECTS IN ACCORDANCE WITH PART I OF THIS SCHEDULE WHERE NO SUCH LIMITS ARE GIVEN IN THE APPROVED SUPPLY LIST

An assessment must 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 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

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1.1 Other than gaseous preparations

The concentration limits fixed in Table 1 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%

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<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>X_n</i>
X _n with R20, R21, R22			concentration ≥25%

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

- (i) the label shall include one or more of the above mentioned R phrases according to the classification used,
- (ii) 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 1A determine the classification of the gaseous preparations in relation to the individual concentration of the gas(es) present whose classification is also shown.

Table IA

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>X_n</i>
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—

- (i) the label shall include one or more of the above mentioned R phrases according to the classification used,
- (ii) 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

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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.

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Table II

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T</i>	<i>X_n</i>	
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
X _n 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 Part V of the approved supply list shall be used.			
†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified as carcinogenic or 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.

Table IIA

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T</i>	<i>X_n</i>	
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
X _n 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 Part V of the approved supply list shall be used.			
†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified as carcinogenic or mutagenic are given in Table VI.			

Severe effects after repeated or prolonged exposure

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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	X _n
T with R48/route of exposure	concentration $\geq 10\%$ R48 ^(*) obligatory	$1\% \leq \text{concentration} < 10\%$ R48 ^(*) obligatory
X _n 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 Part V of the approved supply list 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.

Table IIIA

Classification of the substance (gas)	Classification of the preparation	
	T	X _n
T with R48/route of exposure	concentration $\geq 5\%$ R48 ^(*) obligatory	$0.5\% \leq \text{concentration} < 5\%$ R48 ^(*) obligatory
X _n 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 Part V of the approved supply list shall be used.

Corrosive and irritant effects including serious damage to eye

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Other than gaseous preparations

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

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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 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.

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Table IVA

Classification of the substance (gas)	Classification of the 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 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.

Sensitising effects

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Other than gaseous preparations

5.1 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 determine, when appropriate, the classification of the preparation.

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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 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 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

Carcinogenic/mutagenic/toxic effects for reproduction**6***Other than gaseous preparations*

6.1 For substances which produce such effects and for which specific concentration limits do not yet appear in the approved supply list, 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:	X _{subn} ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X _n R68
Toxic for reproduction fertility categories 1 and 2:	T; R60

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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

Table VI

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
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
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
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq 0.5\%$ toxic for reproduction (fertility) R60 obligatory	
Substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq 5\%$ toxic for reproduction (fertility) R62 obligatory
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

(*) 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 the approved supply list, 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:	X _n ; R40
Mutagenic categories 1 and 2:	T; R46

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Mutagenic category 3: X_n; 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

Table VIA

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Carcinogenic substances of category 1 or 2 with R45 or R49	concentration $\geq 0.0\%$ carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		concentration $\geq 1\%$ carcinogenic R40 obligatory
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
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
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

(*) R68 here refers to substances classified as carcinogenic or mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA