

## SCHEDULE 3

### CLASSIFICATION PROVISIONS FOR PREPARATIONS DANGEROUS FOR SUPPLY

#### 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. sensitizing 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**

##### **1**

#### *Other than gaseous preparations*

**1.1** 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.

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TABLE I

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T</i>	<i>Xn</i>	
T+ with R26, R27, R28	concentration > 7%	1% < concentration < 7%	0.1% < concentration < 1%
T with R23, R24, R25		concentration > 25%	3% < concentration < 25%
Xn R20, R21, R22			concentration > 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 1A 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 1A

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T</i>	<i>Xn</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%
Xn 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 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, R40/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>Xn</i>	
T+ with R39/route of exposure	concentration > 10% R39 <sup>(*)</sup> obligatory	1% < concentration < 10% R39 <sup>(*)</sup> obligatory	0.1% < concentration < 1% R40 <sup>(*)</sup> (†) obligatory
T with R39/route of exposure		concentration > 10% R39 <sup>(*)</sup> obligatory	1% < concentration < 10% R40 <sup>(*)</sup> (†) obligatory
Xn with R40/route of exposure			concentration > 10% R40 <sup>(*)</sup> (†) obligatory
(*) In order to indicate the route of administration/exposure the combined R phrases listed in paragraphs 44, 45 and 46 of the approved classification and labelling guide shall be used.			
(†) R40 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R40 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, R40/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>Xn</i>	
T+ with R39/route of exposure	concentration > 1% R39 <sup>(*)</sup> obligatory	0.2% < concentration < 1% R39 <sup>(*)</sup> obligatory	0.02% < concentration < 0.2% R40 <sup>(*)</sup> (†) obligatory
T with R39/route of exposure		concentration > 5% R39 <sup>(*)</sup> obligatory	0.5% < concentration < 5% R40 <sup>(*)</sup> (†) obligatory
Xn with R40/route of exposure			concentration > 5% R40 <sup>(*)</sup> (†) obligatory
(*) In order to indicate the route of administration/exposure the combined R phrases listed in paragraphs 44, 45 and 46 of the approved classification and labelling guide shall be used.			
(†) R40 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R40 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**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
<i>T</i>	<i>Xn</i>	
T + with R48/route of exposure	concentration > 10% R48 <sup>(*)</sup> obligatory	1% < concentration < 10% R48 <sup>(*)</sup> obligatory
Xn with R48/route of exposure		concentration > 10% R48 <sup>(*)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in paragraphs 44, 45 and 46 of the approved classification and labelling guide 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 below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**TABLE IIIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>	
<i>T</i>	<i>Xn</i>	
T + with R48/route of exposure	concentration > 5% R48 <sup>(*)</sup> obligatory	0.5% < concentration < 5% R48 <sup>(*)</sup> obligatory
Xn with R48/route of exposure		concentration > 5% R48 <sup>(*)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in paragraphs 44, 45 and 46 of the approved classification and labelling guide 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 effects (R36, R37, R38, R41), the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

#### *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 below, expressed as a volume/volume percentage determine, when appropriate, the classification of the preparation.

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TABLE IV

<i>Classification of the substance</i>	<i>Classification of the preparation</i>			
	<i>C with R35</i>	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37, R38</i>
C with R35	concentration > 10% R35 obligatory	5% < concentration < 10% R34 obligatory	(*)	1% < concentration < 5% R36/38 obligatory
C with R34		concentration > 10% R34 obligatory	(*)	5% < concentration < 10% R36/38 obligatory
Xi with R41			concentration > 10% R41 obligatory	5% < concentration < 10%
Xi 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 (paragraph 57) when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk phrase R41 does not need to be included. 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).

Therefore when the formulae of paragraphs 11(b) and 13(b) of Part I of this Schedule are applied the following concentration limits must be used, unless different values are fixed in the approved supply list.

- (a) when formula 11(b) is applied the limit values for LXiR41 are:
- 10% for the substances XiR41,
  - 10% for the substances C R34,
  - 5% for the substances C R35;
- (b) when the formula 13(b) is applied the limit values for LXiR36 are:
- 20% for the substances Xi R36,
  - 5% for the substances Xi R41,
  - 5% for the substances C R34,
  - 1% for the substances C R35.

TABLE IVA

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>			
	<i>C with R35</i>	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37, R38</i>
C with R35	concentration > 1% R35 obligatory	0.2% < concentration	(*)	0.02% < concentration

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Classification of the substance (gas)	Classification of the preparation		
	C with R34	Xi with R41	Xi with R36, R37, R38
C with R35		< 1% R34 obligatory	< 0.2% R37 obligatory
C with R34		concentration > 5% R34 obligatory	(*) 0.5% < concentration < 5% R37 obligatory
Xi with R41			concentration > 5% R41 obligatory
Xi with R36, R37, R38			concentration < 5% R41 obligatory
			concentration < 5% R36, R37, R38 obligatory as appropriate

(\*) According to the approved classification and labelling guide (paragraph 57) when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk phrase R41 does not need to be included. 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).

Therefore when the formulae of paragraphs 11(b) and 13(b) of Part I of this Schedule are applied the following concentration limits must be used, unless different values are fixed in the approved supply list.

- (a) when formula 11(b) is applied the limit values for LXiR41 are:
- 10% for the substances XiR41,
  - 10% for the substances C R34,
  - 5% for the substances C R35;
- (b) when the formula 13(b) is applied the limit values for LXiR36 are:
- 20% for the substances Xi R36,
  - 5% for the substances Xi R41,
  - 5% for the substances C R34,
  - 1% for the substances C R35.

## Sensitizing effects

### 5

#### Other than gaseous preparations

**5.1** Substances that produce such effects are classified as sensitizing 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 symbol Xn and phrase R42/43 if this effect can be produced by inhalation and 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>Sensitizing with R42</i>	<i>Sensitizing with R43</i>
Sensitizing with R42	concentration > 1% R42 obligatory
Sensitizing with R43	concentration >1% R43 obligatory
Sensitizing with R42/43	concentration > 1% R42/43 obligatory

*Gaseous preparations*

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

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xn and phrase R 42/43 if this effect can be produced by inhalation and through contact with the skin.

The individual concentration limits specified in Table VA below, 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 preparation</i>
<i>Sensitizing with R42</i>	<i>Sensitizing with R43</i>
Sensitizing with R42	concentration > 0.2% R42 obligatory
Sensitizing with R42/43	concentration > 0.2% R42/43 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.

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**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	> 0.1% carcinogenic R45, R49 obligatory as appropriate
Carcinogenic substances of category 3 with R40 <sup>(*)</sup>	> 1% carcinogenic R40 <sup>(*)</sup> obligatory
Mutagenic substances of category 1 or 2 with R46	> 0.1% mutagenic R46 obligatory
Mutagenic substances of category 3 with R40 <sup>(*)</sup>	> 1% mutagenic R40 <sup>(*)</sup> obligatory
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	> 0.5% toxic for reproduction (fertility) R60 obligatory
Substances “toxic for reproduction” of category 3 with R62 (fertility)	> 5% toxic for reproduction (fertility) R62 obligatory
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	> 0.5% toxic for reproduction (development) R61 obligatory
Substances “toxic for reproduction” of category 3 with R63 (development)	> 5% toxic for reproduction (development) R63 obligatory

(\*) R40 here refers to substances classified as carcinogenic or mutagenic. Concentration limits for substances required to be labelled R40 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.

**TABLE VIA**

<i>Classification of the substance (gas)</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	> 0.1% carcinogenic R45, R49 obligatory as appropriate
Carcinogenic substances of category 3 with R40 <sup>(*)</sup>	> 1% carcinogenic R40 <sup>(*)</sup> obligatory
Mutagenic substances of category 1 or 2 with R46	> 0.1% mutagenic R46 obligatory

(\*) R40 here refers to substances classified as carcinogenic or mutagenic. Concentration limits for substances required to be labelled R40 but classified as harmful are given in Table IIA.

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<i>Classification of the substance (gas) Categories 1 and 2</i>	<i>Classification of the preparation Category 3</i>
Mutagenic substances of category 3 with R40 <sup>(*)</sup>	> 1% mutagenic R40 <sup>(*)</sup> obligatory
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	> 0.2% toxic for reproduction (fertility) R60 obligatory
Substances “toxic for reproduction” of category 3 with R62 (fertility)	> 1% toxic for reproduction (fertility) R62 obligatory
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	> 0.2% toxic for reproduction (development) R61 obligatory
Substances “toxic for reproduction” of category 3 with R63 (development)	> 1% toxic for reproduction (development) R63 obligatory
(*) R40 here refers to substances classified as carcinogenic or mutagenic. Concentration limits for substances required to be labelled R40 but classified as harmful are given in Table IIA.	