

## SCHEDULE 4

### 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:—

- acute lethal effects;
- non-lethal irreversible effects after a single exposure;
- severe effects after repeated or prolonged exposure;
- corrosive effects;
- irritant effects;
- sensitizing effects;
- carcinogenic effects;
- mutagenic effects; and
- teratogenic effects.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits in conjunction with the classification of the substance, i.e. the symbol and risk phrases which are assigned to each substance under consideration.

In relation to solid and liquid preparations references in this Part to percentage concentrations shall be treated as references to those concentrations on a weight/weight basis.

#### ACUTE LETHAL EFFECTS

##### *Solid and liquid preparations*

##### *Solid and liquid preparations*

1.—(1) —The concentration limits fixed in Table 1 determine the classification of solid and liquid preparations 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>		
	T	Xn	
T+ with R26, R27, R28	conc. $\geq$ 7%	1% $\leq$ conc. < 7%	0.1% $\leq$ conc. < 1%
T with R23, R24, R25		conc. $\geq$ 25%	3% $\leq$ conc. < 25%
Xn with R20, R21, R22			conc. $\geq$ 25%

The risk 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 risk phrases according to the classification used,
- in general, the risk phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

(2) **Gaseous Preparations**—The concentration limits expressed as a volume/volume percentage in Table 1A below determine the classification of gaseous preparations in relation to the individual concentration of the gases present whose classification is also shown.

**TABLE IA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>		
	T	Xn	
T+ with R26	conc. $\geq$ 1%	0.2% $\leq$ conc. < 1%	0.02% $\leq$ conc. < 0.2%
T with R23		conc. $\geq$ 5%	0.5% $\leq$ conc. < 5%
Xn with R20			conc. $\geq$ 5%

## NON-LETHAL IRREVERSIBLE EFFECTS AFTER A SINGLE EXPOSURE

### *Solid and liquid preparations*

### *Solid and liquid preparations*

2.—(1) —For substances that produce non-lethal irreversible effects after a single exposure (R39, R40), the individual concentration limits specified in Table II determine, when appropriate, the classification of solid and liquid preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE II**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	T	Xn	
T+ with R39	conc. $\geq$ 10% R39 <sup>(*)</sup> obligatory	1% $\leq$ conc. < 10% R39 <sup>(*)</sup> obligatory	0.1% $\leq$ conc. < 1% R40 <sup>(*)</sup> obligatory
T with R39		conc. $\geq$ 10% R39 <sup>(*)</sup> obligatory	1% $\leq$ conc. < 10% R40 <sup>(*)</sup> obligatory

(\*) In accordance with the approved classification and labelling guide and depending on the classification, the risk phrases R20 to R28 are also to be assigned to indicate route of administration or means of exposure.

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<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
T+	T	Xn
Xn with R40		conc. $\geq$ 10% R40 <sup>(*)</sup> obligatory

(\*) In accordance with the approved classification and labelling guide and depending on the classification, the risk phrases R20 to R28 are also to be assigned to indicate route of administration or means of exposure.

### ***Gaseous Preparations***

(2) —For gases that produce non-lethal irreversible effects after a single exposure (R39, R40), the individual concentration limits specified in Table IIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of gaseous preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE IIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>		
T+	T	Xn	
T+ with R39	conc. $\geq$ 1% R39 <sup>(*)</sup> obligatory	0.2% $\leq$ conc. $<$ 1% R39 <sup>(*)</sup> obligatory	0.02% $\leq$ conc. $<$ 0.2% R40 <sup>(*)</sup> obligatory
T with R39		conc. $\geq$ 5% R39 <sup>(*)</sup> obligatory	0.5% $\leq$ conc. $<$ 5% R40 <sup>(*)</sup> obligatory
Xn with R40			conc. $\geq$ 5% R40 <sup>(*)</sup> obligatory

(\*) In accordance with the approved classification and labelling guide and depending on the classification, the risk phrases R20, R23 or R26 are also to be assigned to indicate route of administration or means of exposure.

## **SEVERE EFFECTS AFTER REPEATED OR PROLONGED EXPOSURE**

### ***Solid and liquid preparations***

### ***Solid and liquid preparations***

3.—(1) —For substances that produce severe effects after repeated or prolonged exposure (R48), the individual concentration limits specified in Table III determine, when appropriate, the classification of solid and liquid preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE III**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
T	Xn	
T with R48	conc. $\geq$ 10% R48 <sup>(*)</sup> obligatory	1% $\leq$ conc. $<$ 10% R48 <sup>(*)</sup> obligatory
Xn with R48		conc. $\geq$ 10% R48 <sup>(*)</sup> obligatory

(\*) In accordance with the approved classification and labelling guide and depending on the classification, the risk phrases R20 to R28 are also to be assigned to indicate route of administration or means of exposure.

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### ***Gaseous Preparations***

(2) —For gases that produce severe effects after repeated or prolonged exposure (R48), the individual concentration limits specified in Table IIIA below, expressed as a volume/volume percentage, determine, when appropriate, the classification of gaseous preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE IIIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
T	Xn	
T with R48	conc. $\geq$ 5% R48 <sup>(*)</sup> obligatory	0.5% $\leq$ conc. < 5% R48 <sup>(*)</sup> obligatory
Xn with R48	conc. $\geq$ 5% R48 <sup>(*)</sup> obligatory	

(\*) In accordance with the approved classification and labelling guide and depending on the classification, the risk phrases R20, R23 or R26 are also to be assigned to indicate route of administration or means of exposure.

## **CORROSIVE AND IRRITANT EFFECTS**

### ***Solid and liquid preparations***

### ***Solid and liquid 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 solid and liquid preparations.

**TABLE IV**

<i>Classification of the substance and/or relevant standard risk phrase</i>	<i>Classification of the preparation and standard risk phrase</i>			
	<i>at least C with R35</i>	<i>at least C with R34</i>	<i>at least Xi with R41</i>	<i>at least Xi with R36, R37, R38</i>
at least C with R35	conc. $\geq$ 10% R35 obligatory	5% $\leq$ conc. < 10% R34 obligatory		1% $\leq$ conc. < 5% R36, R38 obligatory
at least C with R34		conc. $\geq$ 10% R34 obligatory		5% $\leq$ conc. < 10% R36, R38 obligatory
at least Xi with R41			conc. $\geq$ 10% R41 obligatory	5% $\leq$ conc. < 10% R36 obligatory
at least Xi with R36, R37, R38				conc. $\geq$ 20% R36, R37 and R38 are obligatory in light of the concentration present if they apply to the substances under consideration

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**Gaseous Preparations**

(2) —For gases that produce corrosive effects (R34, R35) or irritant effects (R37, R41), the individual concentration limits specified in Table IVA below, expressed as a volume/volume percentage determine, when appropriate, the classification of gaseous preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE IVA**

<i>Classification of the substance (gas) and/or relevant standard risk phrase</i>	<i>Classification of the gaseous preparation and standard risk phrase</i>			
	<i>at least C with R35</i>	<i>at least C with R34</i>	<i>at least Xi with R41</i>	<i>at least Xi with R36, R37 or R38</i>
at least C with R35	conc. ≥ 1% R35 obligatory	0.2% ≤ conc. < 1% R34 obligatory		0.02% ≤ conc. < 0.2% R37 obligatory
at least C with R34		conc. ≥ 5% R34 obligatory		0.5% ≤ conc. < 5% R37 obligatory
at least Xi with R41			conc. ≥ 5% R41 obligatory	0.5% ≤ conc. < 5% R36 obligatory
at least Xi with R36, R37, R38				conc. ≥ 5% percent; R37, R36, R38 obligatory as appropriate

**SENSITIZING EFFECTS**

- 5.—(1) Solid and liquid preparations**—Substances that produce such effects are classified:
- at least as harmful (Xn) and assigned R42 if this effect can be produced by inhalation,
  - at least as irritant (Xi) and assigned R43 if this effect can be produced through contact with the skin,
  - at least as harmful (Xn) and assigned R42/43 if this effect can be produced in both these ways.

The individual concentration limits specified in Table V determine, when appropriate, the classification of solid and liquid preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE V**

<i>Classification of the substance</i>	<i>Classification of the preparation and standard risk phrase</i>
<i>At least Xn and R42</i>	<i>At least Xi and R43</i>
At least Xn and R42	conc. ≥ 1% R42 obligatory
At least Xi and R43	conc. ≥ 1% R43 obligatory
At least Xn and R42/43	conc. ≥ 1% R42/43 obligatory

(2) **Gaseous Preparations**—Gases that produce such effects are classified:

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- at least as harmful (Xn) and assigned R42 or R42/43 as appropriate. The individual concentration limits specified in Table VA below, expressed as a volume/volume percentage determine, when appropriate, the classification of gaseous preparations and shall determine which particular risk phrases are to be assigned to them.

**TABLE VA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation and standard risk phrase</i>
<i>At least Xn with R42</i>	
At least Xn with R42	conc. $\geq$ 0.2% R42 obligatory
At least Xn with R42/43	conc. $\geq$ 0.2% R42/43 obligatory

**CARCINOGENIC/MUTAGENIC/TERATOGENIC EFFECTS**

***Solid and liquid preparations***

***Solid and liquid preparations***

6.—(1) —For substances that produce such effects and for which specific concentration limits do not yet appear in the approved supply list, the concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparations and the risk phrases to be assigned to them.

**TABLE VI**

<i>Substance Symbol-letter and risk phrase</i>	<i>Symbol-letter and risk phrase for the preparation</i>
<i>At least T</i>	<i>At least Xn</i>
At least T with R45 or R49 denoting carcinogenic substances of Category 1 or 2	conc. $\geq$ 0.1% R45 or R49 obligatory
At least Xn with R40 denoting carcinogenic substances of Category 3	conc. $\geq$ 1% R40 obligatory
At least T with R46 denoting mutagenic substances of Category 1	conc. $\geq$ 0.1% R46 obligatory
At least Xn with R46 denoting mutagenic substances of Category 2	conc. $\geq$ 0.1% R46 obligatory
At least Xn with R40 denoting mutagenic substances of Category 3	conc. $\geq$ 1% R40 obligatory
At least T with R47 denoting teratogenic substances of Category 1	conc. $\geq$ 0.5% R47 obligatory

<i>Substance Symbol-letter and risk phrase</i> <i>At least T</i>	<i>Symbol-letter and risk phrase for the preparation</i> <i>At least Xn</i>
At least Xn with R47 denoting teratogenic substances of Category 2	conc. $\geq$ 5% R47 obligatory

***Gaseous Preparations***

(2) —For gases that produce such effects and for which specific concentration limits do not yet appear in the approved supply list the concentration limits laid down in Table VIA, expressed as a volume/volume percentage shall determine, where appropriate, the classification of gaseous preparations and the risk phrases to be assigned to them.

**TABLE VIA**

<i>Substance Symbol-letter and risk phrase</i> <i>At least T</i>	<i>Symbol-letter and risk phrase for the gaseous preparation</i> <i>At least Xn</i>
At least T with R45 or R49 denoting carcinogenic substances of Category 1 or 2	conc. $\geq$ 0.1% R45 or R49 obligatory
At least Xn with R40 denoting carcinogenic substances of Category 3	conc. $\geq$ 1% R40 obligatory
At least T with R46 denoting mutagenic substances of Category 1	conc. $\geq$ 0.1% R46 obligatory
At least Xn with R46 denoting mutagenic substances of Category 2	conc. $\geq$ 0.1% R46 obligatory
At least Xn with R40 denoting mutagenic substances of Category 3	conc. $\geq$ 1% R40 obligatory
At least T with R47 denoting teratogenic substances of Category 1	conc. $\geq$ 0.2% R47 obligatory
At least Xn with R47 denoting teratogenic substances of Category 2	conc. $\geq$ 1% R47 obligatory