

## SCHEDULE 3

Regulations 5(5) and 9(3)(d)

### CLASSIFICATION PROVISIONS FOR PREPARATIONS DANGEROUS FOR SUPPLY

## PART I

### GENERAL PROVISIONS

#### **Application**

1. The provisions of this Schedule shall apply for the classification of preparations (other than pesticides).

#### **Interpretation**

2. In this Schedule, for the purposes of classification—

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

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

#### **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.

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

(3) By way of derogation from sub-paragraph (2), the determination of explosive, oxidizing, extremely flammable, highly flammable or flammable properties is not necessary provided that 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.

#### **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 the following paragraphs 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) above 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 set out in sub-paragraph (1)(b) above 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 set out in sub-paragraph (1)(a) shall always be used.

(4) Where it can be demonstrated that—

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- (a) the health effects on man differ from those suggested by a toxicological determination or a conventional assessment, then the preparation shall be classified according to its effects on man;
  - (b) owing to effects such as potentiation a conventional assessment would underestimate the health effects, these effects shall be taken into account in classifying the preparation; or
  - (c) owing to effects such as antagonism a conventional assessment would overestimate the health effects, these effects shall be taken into account in classifying the preparation.
- (5) For preparations of a known composition classified in accordance with the method set out in sub-paragraph (1)(b) above, a new health effect assessment either by the method set out in sub-paragraph (1)(a) or (1)(b) above shall be performed whenever—
- (a) changes of composition of the initial concentration of a weight/weight percentage of one or more of the 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%	± 15%
> 2.5 < 10%	± 10%
> 10 < 25%	± 6%
> 25 < 50%	± 5%
> 50 < 100%	± 2.5%

- (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.

**Classification by the conventional method**

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

(2) Where the substances concerned are dangerous for supply and are listed as dangerous for supply in the approved supply list 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 for supply and do not appear in the approved supply list as dangerous for supply 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.

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

(5) Where a preparation contains at least one substance which, in accordance with regulation 6(7) of the Notification of New Substances Regulations 1993(1) bears the warning “Caution — Substance not yet fully tested”, the label of the preparation must bear the words “Caution — This preparation contains a substance not yet fully tested” if the substance is present in a concentration equal to or in excess of 1% by weight.

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(1) [S.I. 1993/3050](#).

(6) A substance referred to in sub-paragraph (5) above must, whatever its concentration level, be treated on the same basis as the other substances present in the preparation when applying the method of evaluation by calculation, if its labelling gives at least an indication of the health effect.

**Classification by the conventional method as very toxic**

6. The following preparations shall be regarded as very toxic—
- (a) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic in concentrations exceeding—
    - (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits;
  - (b) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic in individual concentrations not exceeding the limits specified in the approved list 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—

PT+ the percentage by weight of each very toxic substance in the preparation,

LT+ the very toxic limit specified for each very toxic substance expressed as a percentage.

- (c) owing to their non-lethal irreversible effects after a single exposure, preparations containing one or more substances dangerous for supply which produce such effects in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits.

**Classification by the conventional method as toxic**

7. The following preparations shall be regarded as toxic—
- (a) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic or toxic in concentrations exceeding—
    - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
  - (b) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic or toxic in individual concentrations not exceeding the limits specified in the approved supply list or in paragraph 1 of Part II of this Schedule

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(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—

PT+ the percentage by weight of each very toxic substance in the preparation,

PT the percentage by weight of each toxic substance in the preparation,

LT the toxic limit specified for each very toxic or toxic substance expressed as a percentage;

- (c) owing to their non-lethal irreversible effects after a single exposure, preparations containing one or more substances dangerous for supply which produce such effects in individual concentrations exceeding—
- (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (d) owing to their long term effects after repeated or prolonged exposure, preparations containing one or more substances dangerous for supply which produce such effects in individual concentrations exceeding—
- (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits.

### **Classification by the conventional method as harmful**

8. The following preparations shall be regarded as harmful—

- (a) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or harmful in concentrations exceeding—
- (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (b) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic, toxic or harmful in individual concentrations not exceeding the limits specified in the approved supply list 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.—

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

where—

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- PT+ the percentage by weight of each very toxic substance in the preparation,  
PT the percentage by weight of each toxic substance in the preparation,  
PXn the percentage by weight of each harmful substance in the preparation,  
LXn the harmful limit specified for each very toxic, toxic or harmful substance expressed as a percentage;
- (c) owing to their non-lethal irreversible effects after a single exposure, preparations containing one or more substances dangerous for supply which produce such effects in individual concentrations exceeding—
    - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
  - (d) owing to their long-term effects after repeated or prolonged exposure, preparations containing one or more substances dangerous for supply that produce such effects in individual concentrations exceeding—
    - (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits;
  - (e) owing to their sensitizing effects by inhalation, preparations containing at least one substance dangerous for supply to which is assigned the risk phrase R42 (may cause sensitization by inhalation) that produces such effects in individual concentrations exceeding—
    - (i) either the concentration specified in the approved supply list for the substance or substances under consideration, or
    - (ii) the concentration specified in paragraph 5 of Part II of this Schedule (Table V or Table VA in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits.

#### **Classification by the conventional method as corrosive**

9.—(1) In this Schedule a preparation shall be regarded as “very corrosive” if it has been classified as corrosive with the risk phrase R35 (causes severe burns).

- (2) The following preparations shall be regarded as very corrosive—
- (a) preparations containing one or more substances classified or regarded as very corrosive in concentrations exceeding—
    - (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits;
  - (b) preparations containing more than one substance classified or regarded as very corrosive in individual concentrations not exceeding the limits specified either in the approved supply list or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the

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quotients obtained by dividing the percentage weight of each very corrosive substance in the preparation by the corrosive (R35) limit specified for that substance is 1 or more, i.e.—

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

where—

PC.R35 the percentage by weight of each very corrosive substance in the preparation,  
LC.R35 the corrosive (R35) limit specified for each very corrosive substance expressed as a percentage by weight.

10. The following preparations shall also be regarded as corrosive—

- (a) preparations containing one or more substances classified or regarded as corrosive to which is assigned the risk phrase R35 or R34 (causes burns) in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (b) preparations containing more than one substance classified or regarded as corrosive to which is assigned the risk phrase R35 or R34 in individual concentrations not exceeding the limits specified either in the approved supply list 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 (R34) limit 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—

PC.R35 the percentage by weight of each corrosive substance to which is assigned the risk phrase R35 in the preparation,  
PC.R34 the percentage by weight of each corrosive substance to which is assigned the risk phrase R34 in the preparation,  
LC.R34 the corrosive (R34) limit specified for each corrosive substance to which is assigned the risk phrase R35 or R34 expressed as a percentage by weight.

#### **Classification by the conventional method as irritant**

11. The following preparations shall be regarded as liable to cause serious eye damage—

- (a) preparations containing one or more substances classified or regarded as irritant to which is assigned the risk phrase R41 (risk of serious damage to eyes) in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (b) preparations containing more than one substance classified or regarded as corrosive, to which is assigned the risk phrase R35 or R34, or irritant, to which is assigned the risk

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phrase R41, in individual concentrations not exceeding the limits specified either in the approved supply list or in paragraph 4 of Part II of this Schedule (Table IV or IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant (R41) limit specified for that substance is 1 or more, i.e.—

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

where—

PC.R35 the percentage by weight of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

PC.R34 the percentage by weight of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

PXi.R41 the percentage by weight of each irritant substance to which is assigned the risk phrase R41 in the preparation,

LXi.R41 the irritant (R41) limit specified for each irritant substance expressed as a percentage by weight to which is assigned the risk phrase R 41 in the preparation.

**12.** The following preparations shall be regarded as skin irritants—

- (a) preparations containing one or more substances classified or regarded as corrosive, to which is assigned the risk phrase R35 or R34, or irritant, to which is assigned the risk phrase R38 (irritating to skin) in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits;
- (b) preparations containing more than one substance classified or regarded as corrosive, to which is assigned the risk phrase R35 or R34, or irritant, to which is assigned the risk phrase R38, in individual concentrations not exceeding the limits specified either in the approved supply list 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 (R38) limit specified for that substance is 1 or more, i.e.—

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

where—

PC.R35 the percentage by weight of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

PC.R34 the percentage by weight of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

PXi.R38 the percentage by weight of each irritant substance to which is assigned the risk phrase R38 in the preparation,

LXi.R38 the irritant (R38) limit specified for each corrosive or irritant substance expressed as a percentage by weight to which is assigned the risk phrase R35, R34 or R38 in the preparation;

- (c) owing to their sensitizing effects by skin contact preparations containing at least one substance dangerous for supply to which is assigned phrase R43 (may cause sensitization by skin contact) that produces such effects in individual concentrations exceeding:

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- either the concentration specified in the approved supply list for the substance under consideration, or
- 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 the approved supply list or appear in it without concentration limits.

**13.** The following preparations shall be regarded as eye irritants—

- (a) preparations containing one or more substances classified or regarded as irritant to which is assigned the risk phrase R41 (risk of serious damage to eyes) or R36 (irritating to eyes) in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (b) preparations containing more than one substance classified or regarded as irritant to which is assigned the risk phrase R41 or R36 in individual concentrations not exceeding the limits specified either in the approved supply list 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 (R36) limit specified for that substance is 1 or more, i.e.—

$$\sum \left( \frac{P_{X_i, R41}}{L_{X_i, R36}} + \frac{P_{X_i, R36}}{L_{X_i, R41}} \right) \geq 1$$

where—

P<sub>X<sub>i</sub>,R41</sub> the percentage by weight of each irritant substance to which is assigned the risk phrase R41 in the preparation,

P<sub>X<sub>i</sub>,R36</sub> the percentage by weight of each irritant substance to which is assigned the risk phrase R36 in the preparation,

L<sub>X<sub>i</sub>,R36</sub> the irritant (R36) limit specified for each irritant substance expressed as a percentage by weight to which is assigned the risk phrase R41 or R36 in the preparation.

**14.** The following preparations shall be regarded as irritants for the respiratory system—

- (a) preparations containing one or more substances classified or regarded as irritant to which is assigned the risk phrase R37 (irritating to the respiratory system) in individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (b) preparations containing more than one substance classified or regarded as irritant to which is assigned the risk phrase R37 in individual concentrations not exceeding the limits specified either in the approved supply list 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 (R37) limit specified for that substance is 1 or more, i.e.—



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

where—

P<sub>Xi.R37</sub> the percentage by weight of each irritant substance to which is assigned the risk phrase R37 in the preparation,

L<sub>Xi.R37</sub> the irritant (R37) limit specified for each irritant substance expressed as a percentage by weight to which is assigned the risk phrase R37 in the preparation.

### **Classification by the conventional method as carcinogenic**

**15.**—(1) Preparations shall be regarded as carcinogenic and assigned at least the symbol and indication of danger “toxic” if they contain a substance producing such effects to which is assigned either the risk phrase R45 (may cause cancer) or R49 (may cause cancer by inhalation) which denotes carcinogenic substances in category 1 or category 2 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list 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 in the case of gases) where the substance or substances do not appear in the approved supply list or appear in it without concentration limits.

(2) Preparations shall be regarded as suspect for humans owing to their possible carcinogenic effects and assigned at least the symbol and indication of danger “harmful” if they contain a substance producing such effects to which is assigned the risk phrase R40 (possible risk of irreversible effects) which denotes carcinogenic substances in category 3 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits.

### **Classification by the conventional method as mutagenic**

**16.**—(1) Preparations shall be regarded as mutagenic and assigned at least the symbol and indication of danger “toxic” if they contain a substance producing such effects to which is assigned the risk phrase R46 (may cause heritable genetic damage) which denotes mutagenic substances in category 1 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits.

(2) Preparations shall be regarded as mutagenic and assigned at least the symbol and indication of danger “toxic” if they contain a substance producing such effects to which is assigned the risk phrase R46 (may cause heritable genetic damage) which denotes mutagenic substances in category 2 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list for the substance or substances under consideration, or

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- (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 the approved supply list or appear in it without concentration limits.
- (3) Preparations shall be regarded as suspect for humans because of their possible mutagenic effects and assigned at least the symbol and indication of danger “harmful” if they contain a substance producing such effects to which is assigned the risk phrase R40 (possible risk of irreversible effects) which denotes mutagenic substances in category 3 in a concentration equal to or exceeding—
  - (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits.

### **Classification by the conventional method as toxic for reproduction**

17.—(1) Preparations shall be regarded as toxic for reproduction and assigned at least the symbol and indication of danger “toxic” if they contain a substance producing such effects to which is assigned the appropriate risk phrase as ascertained from the approved classification and labelling guide which denotes substances toxic for reproduction in category 1 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits;
- (2) Preparations shall be regarded as having to be treated as toxic for reproduction and assigned at least the symbol and indication of danger “toxic” if they contain a substance producing such effects to which is assigned the appropriate risk phrase as ascertained from the approved classification and labelling guide which denotes substances toxic for reproduction in category 2 in a concentration equal to or exceeding—
- (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits.

(3) Preparations shall be regarded as having to be treated as toxic for reproduction and assigned at least the symbol and indication of danger “harmful” if they contain a substance producing such effects to which is assigned the appropriate risk phrase as ascertained from the approved classification and labelling guide which denotes substances toxic for reproduction in category 3 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list 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 the approved supply list or appear in it without concentration limits.

### **Lower limits of concentration**

**18.**—(1) For preparations to which this Schedule applies, no account shall be taken of substances, whether or not listed in the approved supply list, whether existing as impurities or as additives, if their concentration by weight is less than—

- (a) 0.1% for substances classified as very toxic, toxic, carcinogenic (category 1 or 2) or mutagenic (category 1 or 2);
- (b) 0.5% for substances classified as toxic for reproduction (category 1 or 2);
- (c) 1% for substances classified as harmful, corrosive, irritant, sensitizing, carcinogenic (category 3) or mutagenic (category 3); or
- (d) 5% for substances classified as toxic to reproduction (category 3),

unless lower limits are referred to in Part V of the approved supply list, or in the case of gases in Part II of this Schedule.

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

## **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**

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### 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.

TABLE I

Classification of the substance	Classification of the preparation		
	<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

Classification of the substance (gas)	Classification of the preparation		
	<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

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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, R40/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		
	<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> <sup>(†)</sup> obligatory
T with R39/route of exposure		concentration > 10% R39 <sup>(*)</sup> obligatory	1% < concentration < 10% R40 <sup>(*)</sup> <sup>(†)</sup> obligatory
Xn with R40/route of exposure			concentration > 10% R40 <sup>(*)</sup> <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**

Classification of the substance (gas)	Classification of the preparation		
	<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> <sup>(†)</sup> obligatory
T with R39/route of exposure		concentration > 5% R39 <sup>(*)</sup> obligatory	0.5% < concentration < 5% R40 <sup>(*)</sup> <sup>(†)</sup> obligatory
Xn with R40/route of exposure			concentration > 5% R40 <sup>(*)</sup> <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.

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## 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**

<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.

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### 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.

**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 > 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.

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TABLE IVA

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37, R38</i>
<i>C with R35</i>	concentration > 1% R35 obligatory	0.2% < concentration < 1% R34 obligatory	(*) 0.02% < concentration < 0.2% R37 obligatory
<i>C with R34</i>		concentration > 5% R34 obligatory	(*) 0.5% < concentration < 5% R37 obligatory
<i>Xi with R41</i>			concentration > 5% R41 obligatory 0.5% < concentration < 5% R36 obligatory
<i>Xi with R36, R37, R38</i>			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.	