

## SCHEDULE 4

### 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”, “carcinogenic”, “mutagenic” or “teratogenic”.

##### 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 labelling guide.

(2) Subject to sub-paragraph (3), preparations shall be classified as explosive, oxidizing, extremely flammable, highly flammable or flammable when they satisfy the criteria referred to in sub-paragraph (1) for the category of danger.

(3) 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 paragraphs 5 to 17 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) shall be assessed in accordance with the conventional method.

(3) Where the health effects have been assessed by both methods, the results of the method set out in sub-paragraph (1)(b) shall be used for classifying the preparation except in the case of carcinogenic, mutagenic or teratogenic effects, when the conventional method set out in sub-paragraph (1)(a) shall 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 preparation of a known composition classified in accordance with the method set out in sub-paragraph (1)(b), a new health effect assessment either by the method set out in sub-paragraph (1)(a) or (1)(b) 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 in accordance with the following table—

<i>Initial concentration range of the constituent</i>	<i>Permitted variation in actual concentration of the constituent</i>
$\leq 2.5\%$	$\pm 15\%$
$> 2.5 \leq 10\%$	$\pm 10\%$
$> 10 \leq 25\%$	$\pm 6\%$
$> 25 \leq 50\%$	$\pm 5\%$
$> 50 \leq 100\%$	$\pm 2.5\%$

- (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) Where the health effects are assessed by the conventional method in accordance with paragraph 4(1)(a) the appropriate concentration limits shall be assigned in accordance with sub-paragraph (2) or (3).

(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, the appropriate concentration limits shall be assigned in accordance with this Part.

(3) Where the substances concerned are dangerous for supply and do not appear in the approved list as dangerous for supply or appear there without the concentration limits, the appropriate concentration limits shall be assigned in accordance with Part II.

(4) In its application to preparations that are gases, this Part shall be modified so that any reference to a concentration expressed as a percentage by weight shall be construed as a reference to a concentration expressed as the same percentage by volume.

(5) Where a preparation contains at least one substance which, in accordance with the Notification of New Substances Regulations (Northern Ireland) 1985(1) bears the warning “Caution — Substance not yet fully tested”, the label of the preparation must bear the label “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.

(1) [S.R. 1985 No. 63](#), as amended by [S.R. 1986 No. 188](#) and [S.R. 1991 No. 472](#)

(6) A substance which is a gas shall be treated on the same basis as the other substances present in the preparation when applying the method of assessment by calculation, if an indication of at least one of the health effects appears on the label.

**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 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 1 of Part II (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 supply list or in paragraph 1 of Part II (Table I or Table IA in the case of gases), if the sum of the quotients obtained by dividing the percentage by weight of each very toxic substance in the preparation by the very toxic limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,

$L_{T+}$  is 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 11 (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 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 1 of Part II (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 or toxic in individual concentrations not exceeding the

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limits specified in the approved supply list or in paragraph 1 of Part II (Table I or Table IA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each very toxic or toxic substance in the preparation by the toxic limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,

$P_T$  is the percentage by weight of each toxic substance in the preparation,

$L_T$  is 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 (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;
- (d) owing to their severe 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 (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 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 1 of Part II (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, toxic or harmful in individual concentrations not exceeding the limits specified in the approved supply list or in paragraph I of Part II (Table I or Table IA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each very toxic, toxic or harmful substance in the preparation by the harmful limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,

$P_T$  is the percentage by weight of each toxic substance in the preparation,

$P_{Xn}$  is the percentage by weight of each harmful substance in the preparation,

$L_{Xn}$  is the 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 (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;
- (d) owing to their severe 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 (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 (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) 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 individual concentrations exceeding—
  - (i) either the concentration specified in the approved supply list for the substance or substances under consideration, or

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- (ii) the concentration specified in paragraph 4 of Part II (Table IV or Table IVA in the case of gases) where the substance or substances do not appear in the approved 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 (Table IV or Table IVA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each very corrosive substance in the preparation by the corrosive (R35) limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{C,R35}$  is the percentage by weight of each very corrosive substance to which is assigned the risk phrase R35 in the preparation,

$L_{C,R35}$  is the corrosive (R35) limit specified for each very corrosive substance expressed as a percentage by weight.

10. The following preparations shall 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 (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 in individual concentrations not exceeding the limits specified either in the approved supply list or in paragraph 4 of Part II (Table IV or Table IVA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each corrosive substance in the preparation by the corrosive (R34) limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{C,R35}$  is the percentage by weight of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C,R34}$  is the percentage by weight of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$L_{C,R34}$  is 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—

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- (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 (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 or irritant to which is assigned the risk phrase R41 in individual concentrations not exceeding the limits specified either in the approved supply list or in paragraph 4 of Part II (Table IV or Table IVA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each irritant substance in the preparation by the irritant (R41) limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{X_i, R41}$  is the percentage by weight of each irritant substance to which is assigned the risk phrase R41 in the preparation,

$L_{X_i, R41}$  is the irritant (R41) limit specified for each irritant substance expressed as a percentage by weight to which is assigned the risk phrase R41 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 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 (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 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 (Table IV or Table IVA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant (R38) limit specified for that substance is 1 or more, that is to say,

$$\sum \left( \frac{P_{C, R35}}{L_{X_i, R38}} + \frac{P_{C, R34}}{L_{X_i, R38}} + \frac{P_{X_i, R38}}{L_{X_i, R41}} \right) \geq 1$$

where—

$P_{C, R35}$  is the percentage by weight of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C, R34}$  is the percentage by weight of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

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$P_{Xi.R38}$  is the percentage by weight of each irritant substance to which is assigned the risk phrase R38 in the preparation,

$L_{Xi.R38}$  is 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 the risk phrase R43 (may cause sensitization by skin contact) that produces such effects in individual concentrations exceeding—
- (i) either the concentration specified in the approved supply list of the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 5 of Part II (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.

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 (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 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 (Table IV or Table IVA in the case of gases) if the sum of the quotients obtained by dividing the percentage by weight of each irritant substance in the preparation by the irritant (R36) limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{Xi.R41}$  is the percentage by weight of each irritant substance to which is assigned the risk phrase R41 in the preparation,

$P_{Xi.R36}$  is the percentage by weight of each irritant substance to which is assigned the risk phrase R36 in the preparation,

$L_{Xi.R36}$  is 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 substances under consideration, or



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- (ii) the concentration specified in paragraph 4 of Part II (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 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 (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage by weight of each irritant substance in the preparation by the irritant (R37) limit specified for that substance is 1 or more, that is to say,

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

where—

$P_{Xi.R37}$  is the percentage by weight of each irritant substance to which is assigned the risk phrase R37 in the preparation,

$L_{Xi.R37}$  is 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 or Part II (Table VI OF 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 (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.

#### **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

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- (b) the concentration specified in paragraph 6 of Part II, (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 having to be treated as mutagenic 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 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
  - (b) the concentration specified in paragraph 6 of Part II (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.
- (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 (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.

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

17.—(1) Preparations shall be regarded as teratogenic 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 R47 (may cause birth defects) which denotes teratogenic 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 (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 having to be treated as teratogenic 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 R47 (may cause birth defects) which denotes teratogenic substances in category 2 in a concentration equal to or exceeding—

- (a) either the concentration specified in the approved supply list of the substance or substances under consideration; or
- (b) the concentration specified in paragraph 6 of Part II (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.

#### **Lower limits of concentration**

18.—(1) Subject to sub-paragraph (2), in relation to 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 or toxic; or

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(b) 1% for substances classified as harmful, corrosive or irritant, unless in either case lower limits are referred to in Part V of the approved supply list, or in the case of gases in Part II.

(2) Where any substance has more than one health effect each of these effects shall be characterised by its appropriate specific concentration limit.