

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 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, mutagenic or teratogenic effects, 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 in accordance with 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 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 the Notification of New Substances Regulations 1982(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.I. 1982/1496, amended by S.I. 1984/1244, 1985/1333, 1986/890, 1991/1914.

(6) A substance referred to in sub-paragraph (4) above must be treated on the same basis as the other substances present in the preparation when applying the method of evaluation by calculation, if the labelling gave 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.—

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

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

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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 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.—

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

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,

PX_n the percentage by weight of each harmful substance in the preparation,

LX_n 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) 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

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- (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 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 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—

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- (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 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 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.—

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

where—

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

L_{Xi.R41} 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 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 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—

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

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

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

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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—
- (i) —either the concentration specified in the approved supply list for the substance under consideration, or
 - (ii) —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.—

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

where—

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

PXi.R36 the percentage by weight of each irritant substance to which is assigned the risk phrase R36 in the preparation,

LXi.R36 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;

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- (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.—

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

where—

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

$L_{Xi.R37}$ 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 “harmful” if they contain a substance producing such effects to which is assigned the risk

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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 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 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 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 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 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 or toxic; or
- (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 of this Schedule.

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