1.1.3.1. Notes relating to the identification, classification and labelling of substances

Note A: Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3.

In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Note C: Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.

In this case the supplier must state on the label whether the substance is a specific isomer or a mixture of isomers.

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3.

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

Note E: (Table 3.2):

Substances with specific effects on human health (see Chapter 4 of Annex VI to Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word 'Also'.

- Note F: This substance may contain a stabiliser. If the stabiliser changes the hazardous properties of the substance, as indicated by the classification in Part 3, classification and labelling should be provided in accordance with the rules for classification and labelling of hazardous mixtures.
- Note G: This substance may be marketed in an explosive form in which case it must be evaluated using the appropriate test methods. The classification and labelling provided shall reflect the explosive properties.
- Note H: (Table 3.1):

The classification and labelling shown for this substance applies to the hazardous property(ies) indicated by the hazard statement(s) in combination with the hazard class(es) and category(ies) shown. The requirements of Article 4 for manufacturers, importers or downstream users of this substance apply to all other hazard classes and categories. For hazard classes where the route of exposure or the nature of the effects leads to a differentiation of the classification of the hazard class, the manufacturer, importer or downstream user is required to consider the routes of exposure or the nature of the effects not already considered. The final label shall follow the requirements of Article 17 and of section 1.2 of Annex I.

(Table 3.2):

The classification and label shown for this substance applies to the dangerous property(ies) indicated by the risk phrase(s) in combination with the category(ies) of danger shown. Manufacturers, importers and downstream users of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of section 7 of Annex VI to Directive 67/548/EEC.

- Note J: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EINECS No 200-753-7). This note applies only to certain complex coal- and oilderived substances in Part 3.
- Note K: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (EINECS No 203-450-8). If the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P210-P403 (Table 3.1) or the S-phrases (2-)9-16 (Table 3.2) should apply. This note applies only to certain complex oil-derived substances in Part 3.

- Note L: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346 'Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions Dimethyl sulphoxide extraction refractive index method', Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3.
- Note M: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (EINECS No 200-028-5). This note applies only to certain complex coalderived substances in Part 3.
- Note N: The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. This note applies only to certain complex oilderived substances in Part 3.
- Note P: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EINECS No 200-753-7).

When the substance is not classified as a carcinogen at least the precautionary statements (P102-)P260-P262-P301 + P310-P331 (Table 3.1) or the S-phrases (2-)23-24-62 (Table 3.2) shall apply.

This note applies only to certain complex oil-derived substances in Part 3.

- Note Q: The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:
 - a short term biopersistence test by inhalation has shown that the fibres longer than 20 μ m have a weighted half-life less than 10 days; or
 - a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 μ m have a weighted half-life less than 40 days; or
 - an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or
 - absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.
- Note R: The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter less two standard geometric errors greater than $6~\mu m$.
- Note S: This substance may not require a label according to Article 17 (see section 1.3 of Annex I) (Table 3.1).

This substance may not require a label according to Article 23 of Directive 67/548/EEC (see section 8 of Annex VI to that Directive) (Table 3.2).

Note T:

This substance may be marketed in a form which does not have the physical hazards as indicated by the classification in the entry in Part 3. If the results of the relevant method or methods in accordance with Part 2 of Annex I of this Regulation show that the specific form of substance marketed does not exhibit this physical property or these physical hazards, the substance shall be classified in accordance with the result or results of this test or these tests. Relevant information, including reference to the relevant test method(s) shall be included in the safety data sheet.

Note U: (Table 3.1):

When put on the market gases have to be classified as 'Gases under pressure', in one of the groups compressed gas, liquefied gas, refrigerated liquefied gas or dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case by case.

1.1.3.2. Notes relating to the classification and labelling of mixtures

Note 1: The concentration stated or, in the absence of such concentrations, the generic concentrations of this Regulation (Table 3.1) or the generic concentrations of Directive 1999/45/EC (Table 3.2), are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.

Note 2: The concentration of isocyanate stated is the percentage by weight of the free monomer calculated with reference to the total weight of the mixture.

Note 3: The concentration stated is the percentage by weight of chromate ions dissolved in water calculated with reference to the total weight of the mixture.

Note 4: No longer in use

Note 5: The concentration limits for gaseous mixtures are expressed as volume per volume percentage.

Note 6: No longer in use

Note 7: Alloys containing nickel are classified for skin sensitisation when the release rate of 0,5 µg Ni/cm₂/week, as measured by the European Standard reference test method EN 1811, is exceeded.