Explanation of the notes relating to the identification, classification and labelling of substances

Correct as amended through the 29th ATP: Source is 28th ATP text (which replaced previous versions), except Note K, amended in 29th ATP

Note A:
The name of the substance must appear on the label in the form of one of the designations given in Annex I (see Article 23(2)(a)).
In Annex I, use is sometimes made of a general description such as .. compounds. or .. salts.. In this case, the manufacturer or any other person who markets such a substance is required to state on the label the correct name, due account being taken of the chapter entitled .Nomenclature. of the Foreword:
Example: for $BeCl_2$ (Einecs No 232-116-4): beryllium chloride.
The Directive also requires that the symbols, indications of danger, R- and S-phrases to be used for each substance shall
be those shown in Annex I (Article 23(2)(c), (d) and (e)).
For substances belonging to one particular group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in the appropriate entry in Annex I.
For substances belonging to more than one group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in both the appropriate entries given in Annex I. In cases where two different classifications are given in the two entries for the same hazard, the classification reflecting the more severe hazard classification is used.
Example:
for substance AB - no individual entry in Annex I:
Annex I group entry for compounds of A:
Repr. Cat. 1; R61 Repr. Cat. 3; R62 Xn; R20/22 R33 N; R50-53
Annex I group entry for compounds of B:
Carc. Cat.1; R45 T; R23/25 N; R51-53
Classification of substance AB thus becomes:
Carc. Cat. 1; R45 Repr. Cat. 1; R61 Repr. Cat. 3; R62 T; R23/25 R33 N; R50-53.

Note B:
Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different labelling since the hazards vary at different concentrations.
In Annex I entries with Note B have a general designation of the following type: .nitric acid .%..
In this case the manufacturer or any other person who markets such a substance in aqueous solution must state the percentage concentration of the solution on the label.
Example: nitric acid 45 %.
Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
The use of additional data (e.g. specific gravity, degrees Baumé) or descriptive phrases (e.g. fuming or glacial) is permissible.

Note C:
Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.
In Annex I, a general designation of the following type is sometimes used: .xylenol..
In this case the manufacturer or any other person who markets such a substance must state on the label whether the substance is a specific isomer (a) or a mixture of isomers (b).
Example: (a) 2,4-dimethylphenol
(b) xylenol (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 Annex I to this Directive.
However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed by the words .non-stabilised..
Example: methacrylic acid (non-stabilised).

Note E:
Substances with specific effects on human health (see Chapter 4 of Annex VI) 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..
Examples: R45-23 .May cause cancer. Also toxic by inhalation.
R46-27/28 .May cause heritable genetic damage. Also very toxic in contact with skin and if
swallowed..

Note F:
This substance may contain a stabiliser. If the stabiliser changes the dangerous properties of the substance, as indicated
by the label in Annex I, a label should be provided in accordance with the rules for the labelling of dangerous preparations.

Note G:
This substance may be marketed in an explosive form in which case it must be evaluated using the appropriate test methods and a label should be provided reflecting its explosive property.

Note H:
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. The requirements of Article 6 of this Directive on manufacturers, distributors and importers of this substance apply to all other aspects of classification and labelling. The final label shall follow the requirements of section 7 of Annex VI of this Directive.
This note applies to **certain coal- and oil-derived substances** and to certain entries for groups of substances in Annex I.

Note J:
The classification as a carcinogen 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 oil-derived substances** in Annex I.

Note K: (as amended by 29th ATP)
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
S-phrases (2-)9-16 should apply. This note applies to **certain complex oil-derived substances** in Annex I.

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. This note applies only to **certain complex oil-derived substances** in Annex I.

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 coal-derived substances** in Annex I.

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 oil-derived substances** in Annex I.

Note P:
The classification as a carcinogen 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 classified as a carcinogen, Note E shall also apply.
When the substance is not classified as a carcinogen at least the S-phrases (2-)23-24-62 shall apply.
This note applies only to **certain complex oil-derived substances** in Annex I.

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 µm 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 µm 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 µm.

Note S:
This substance may not require a label according to Article 23 (see section 8 of Annex VI).

Explanation of the notes relating to the labelling of preparations

The significance of the notes that appear to the right of the concentration limits is as follows:

Note 1:
The concentration stated or, in the absence of such concentrations, the general concentrations of Directive 1999/45/EC are the percentages by weight of the metallic element calculated with reference to the total weight of the preparation.

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 preparation.

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 preparation.

Note 4:
Preparations containing these substances have to be classified as harmful with R65 if they meet the criteria in section 3.2.3 in Annex VI.[i]

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

Note 6:
Preparations containing these substances have to be assigned R67 if they meet the criteria in section 3.2.8 in Annex VI.

This note will no longer apply from the date on which the criteria for the use of R67 provided for in Directive 1999/45/EC enter into force.