

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

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## ANNEX I

### CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES

This annex sets out the criteria for classification in hazard...

1. PART 1: GENERAL PRINCIPLES FOR CLASSIFICATION AND LABELLING
  - 1.0. Definitions
  - 1.1. Classification of substances and mixtures
    - 1.1.0. Cooperation to meet the requirements in this Regulation
    - 1.1.1. The role and application of expert judgement and weight of...
      - 1.1.1.1. Where the criteria cannot be applied directly to available identified...
      - 1.1.1.2. The approach to classifying mixtures may include the application of...
      - 1.1.1.3. A weight of evidence determination means that all available information...
      - 1.1.1.4. For the purpose of classification for health hazards (Part 3)...
      - 1.1.1.5. For the purpose of classification for health hazards (Part 3)...
    - 1.1.2. Specific concentration limits, M-factors and generic cut-off values
      - 1.1.2.1. Specific concentration limits or M-factors shall be applied in accordance...
      - 1.1.2.2. Cut-off values
        - 1.1.2.2.1. Cut-off values indicate when the presence of a substance needs...
        - 1.1.2.2.2. The cut-off values referred to in Article 11 shall be...
    - 1.1.3. Bridging principles for the classification of mixtures where test data...
      - 1.1.3.1. Dilution
      - 1.1.3.2. Batching
      - 1.1.3.3. Concentration of highly hazardous mixtures
      - 1.1.3.4. Interpolation within one hazard category
      - 1.1.3.5. Substantially similar mixtures
      - 1.1.3.6. Review of classification where the composition of a mixture has...
      - 1.1.3.7. Aerosols
  - 1.2. Labelling
    - 1.2.1. General rules for the application of labels required by Article...
      - 1.2.1.1. Hazard pictograms shall be in the shape of a square...
      - 1.2.1.2. Hazard pictograms as laid down in Annex V shall have...
      - 1.2.1.3. Each hazard pictogram shall cover at least one fifteenth of...
      - 1.2.1.4. The dimensions of the label and of each pictogram shall...
  - 1.3. Derogations from labelling requirements for special cases
    - 1.3.1. Transportable gas cylinders

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- 1.3.2. Gas containers intended for propane, butane or liquefied petroleum gas...
      - 1.3.2.1. If propane, butane and liquefied petroleum gas or a mixture...
      - 1.3.2.2. No information concerning the effects on human health and the...
      - 1.3.2.3. For consumers, sufficient information shall be transmitted to enable them...
    - 1.3.3. Aerosols and containers fitted with a sealed spray attachment and...
    - 1.3.4. Metals in massive form, alloys, mixtures containing polymers, mixtures containing...
      - 1.3.4.1. Metals in massive form, alloys, mixtures containing polymers and mixtures...
      - 1.3.4.2. Instead, the supplier shall provide the information to downstream users...
    - 1.3.5. Explosives placed on the market with a view to obtaining...
    - 1.3.6. Substances or mixtures classified as corrosive to metals but not...
  - 1.4. Request for use of an alternative chemical name
    - 1.4.1. Requests for use of an alternative chemical name under Article...
    - 1.4.2. The choice of the chemical name(s) for mixtures intended for...
  - 1.5. Exemptions from labelling and packaging requirements
    - 1.5.1. Exemptions from Article 31 [(Article 29(1))]
      - 1.5.1.1. Where Article 29(1) applies, the label elements mentioned in Article...
      - 1.5.1.2. The label on any inner packaging shall contain at least...
    - 1.5.2. Exemptions from Article 17 [(Article 29(2))]
      - 1.5.2.1. Labelling of packages where the contents do not exceed 125 ml...
        - 1.5.2.1.1The hazard statements and the precautionary statements linked to the...
        - 1.5.2.1.2The precautionary statements linked to the hazard categories listed below...
        - 1.5.2.1.3The pictogram, the signal word, the hazard statement, and the...
      - 1.5.2.2. Labelling of soluble packaging for single use
      - 1.5.2.3. Section 1.5.2.2 shall not apply to substances or mixtures within...
      - 1.5.2.4. Labelling of inner packaging where the contents do not exceed...
        - 1.5.2.4.1The label elements required by Article 17 may be omitted...
        - 1.5.2.4.2Notwithstanding sections 1.5.1.2 and 1.5.2.4.1, the label on the inner...
      - 1.5.2.5. Section 1.5.2.4 shall not apply to substances or mixtures within...
2. PART 2: PHYSICAL HAZARDS
- 2.1. Explosives
    - 2.1.1. Definitions
      - 2.1.1.1. The class of explosives comprises
      - 2.1.1.2. For the purposes of this Regulation the following definitions shall...
    - 2.1.2. Classification criteria

- 2.1.2.1. Substances, mixtures and articles of this class are classified as...
- 2.1.2.2. Substances, mixtures and articles of this class, which are not...
- 2.1.2.3. Explosives, which are not classified as an unstable explosive, shall...
- 2.1.2.4. If explosives are unpackaged or repacked in packaging other than...
- 2.1.3. Hazard Communication
- 2.1.4. Additional Classification Considerations
  - 2.1.4.1. The classification of substances, mixtures and articles in the explosives...
    - Figure 2 Procedure for assignment to a division in the class of...
      - ( 1 ) See Chapter 3.3 of the UN RTDG, Model Regulations for...
    - Figure 2 Procedure for the classification of ammonium nitrate emulsion, suspension or...
  - 2.1.4.2. Screening procedure
    - Note:
  - 2.1.4.3. The acceptance procedure for the hazard class 'explosives' need not...
  - 2.1.4.4. In the case of mixtures containing any known explosives, the...
- 2.2. Flammable gases
  - 2.2.1. Definitions
  - 2.2.2. Classification criteria
    - 2.2.2.1. A flammable gas is classified in Category 1A, 1B or...
      - NOTE 1 Aerosols shall not be classified as flammable gases. See Section 2.3....
      - NOTE 2 In the absence of data allowing classification into Category 1B,...
      - NOTE 3 Spontaneous ignition for pyrophoric gases is not always immediate, and...
      - NOTE 4 In the absence of data on its pyrophoricity, a flammable...
  - 2.2.3. Hazard Communication
    - Figure 2 Flammable gases
      - ( 1 ) In the absence of data on its pyrophoricity, a flammable...
  - 2.2.4. Additional Classification Considerations
    - 2.2.4.1. Flammability shall be determined by tests or, for mixtures where...
    - 2.2.4.2. Pyrophoricity shall be determined at 54 °C in accordance with either...
    - 2.2.4.3. The classification procedure for pyrophoric gases need not be applied...
    - 2.2.4.4. Chemical instability shall be determined in accordance with the method...
- 2.3. Aerosols
  - 2.3.1. Definitions
  - 2.3.2. Classification criteria
    - 2.3.2.1. Aerosols shall be classified in one of the three categories...
    - 2.3.2.2. An aerosol shall be classified in one of the three...
      - Note:
  - 2.3.3. Hazard Communication

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- 2.3.4. Additional Classification Considerations
  - 2.3.4.1. The chemical heat of combustion ( $\Delta H_c$ ), in kilojoules...
- 2.4. Oxidising gases
  - 2.4.1. Definitions
  - 2.4.2. Classification criteria
    - 2.4.2.1. An oxidising gas shall be classified in a single category...  
Note:
  - 2.4.3. Hazard Communication
  - 2.4.4. Additional Classification Considerations
- 2.5. Gases under pressure
  - 2.5.1. Definition
    - 2.5.1.1. Gases under pressure are gases which are contained in a...
    - 2.5.1.2. The critical temperature is the temperature above which a pure...
  - 2.5.2. Classification criteria
    - 2.5.2.1. Gases under pressure shall be classified, according to their physical...
  - 2.5.3. Hazard Communication  
Note:
  - 2.5.4. Additional Classification Considerations
- 2.6. Flammable liquids
  - 2.6.1. Definition
  - 2.6.2. Classification criteria
    - 2.6.2.1. A flammable liquid shall be classified in one of the...  
Note:
  - 2.6.3. Hazard Communication
  - 2.6.4. Additional Classification Considerations
    - 2.6.4.1. For the classification of flammable liquids data on flash point...
    - 2.6.4.2. In the case of mixtures containing known flammable liquids in...
    - 2.6.4.3. One suitable method is described in Gmehling and Rasmussen (Ind....
    - 2.6.4.4. Possible test methods for determining the flash point of flammable...
    - 2.6.4.5. Liquids with a flash point of more than 35 °C and...
    - 2.6.4.6. Possible test methods for determining the initial boiling point of...
- 2.7. Flammable solids
  - 2.7.1. Definition
    - 2.7.1.1. A flammable solid means a solid which is readily combustible,...
  - 2.7.2. Classification criteria
    - 2.7.2.1. Powdered, granular or pasty substances or mixtures (except powders of...
    - 2.7.2.2. Powders of metals or metal alloys shall be classified as...
    - 2.7.2.3. A flammable solid shall be classified in one of the...  
Note 1:  
Note 2:
  - 2.7.3. Hazard Communication
- 2.8. Self-reactive substances and mixtures
  - 2.8.1. Definition
    - 2.8.1.1. Self-reactive substances or mixtures are thermally unstable liquid or solid...

- 2.8.1.2. A self-reactive substance or mixture is regarded as possessing explosive...
- 2.8.2. Classification criteria
  - 2.8.2.1. Any self-reactive substance or mixture shall be considered for classification...
  - 2.8.2.2. Mixtures of oxidising substances, meeting the criteria for classification as...
  - 2.8.2.3. Self-reactive substances and mixtures shall be classified in one of...
  - 2.8.2.4. Criteria for temperature control
- 2.8.3. Hazard Communication
- 2.8.4. Additional Classification Considerations
  - 2.8.4.1. The properties of self-reactive substances or mixtures which are decisive...
  - 2.8.4.2. The classification procedures for self-reactive substances and mixtures need not...
- 2.9. Pyrophoric liquids
  - 2.9.1. Definition
  - 2.9.2. Classification criteria
    - 2.9.2.1. A pyrophoric liquid shall be classified in a single category...
  - 2.9.3. Hazard Communication
  - 2.9.4. Additional Classification Considerations
    - 2.9.4.1. The classification procedure for pyrophoric liquids need not be applied...
- 2.10. Pyrophoric solids
  - 2.10.1. Definition
  - 2.10.2. Classification criteria
    - 2.10.2.1 A pyrophoric solid shall be classified in a single category...  
Note
  - 2.10.3. Hazard Communication
  - 2.10.4. Additional Classification Considerations
    - 2.10.4.1 The classification procedure for pyrophoric solids need not be applied...
- 2.11. Self-heating substances and mixtures
  - 2.11.1. Definition
    - 2.11.1.1 A self-heating substance or mixture is a liquid or solid...
    - 2.11.1.2 Self-heating of a substance or a mixture is a process...
  - 2.11.2. Classification criteria
    - 2.11.2.1 A substance or mixture shall be classified as a self-heating...
    - 2.11.2.2 A self-heating substance or mixture shall be classified in one...  
Note
    - 2.11.2.3 Substances and mixtures with a temperature of spontaneous combustion higher...
    - 2.11.2.4 Substances and mixtures with a spontaneous ignition temperature higher than...
  - 2.11.3. Hazard Communication
  - 2.11.4. Additional Classification Considerations
    - 2.11.4.1 For detailed schemes for the decision logic for classification and...
    - 2.11.4.2 The classification procedure for self-heating substances or mixtures need not...
- 2.12. Substances and mixtures which in contact with water emit flammable...
  - 2.12.1. Definition

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- 2.12.2. Classification criteria
  - 2.12.2.1 A substance or mixture which, in contact with water, emits...
    - Note:
    - 2.12.2.2 A substance or mixture shall be classified as a substance...
- 2.12.3. Hazard Communication
- 2.12.4. Additional Classification Considerations
  - 2.12.4.1 The classification procedure for this class need not be applied...
- 2.13. Oxidising liquids
  - 2.13.1. Definition
  - 2.13.2. Classification criteria
    - 2.13.2.1 An oxidising liquid shall be classified in one of the...
  - 2.13.3. Hazard Communication
  - 2.13.4. Additional Classification Considerations
    - 2.13.4.1 For organic substances or mixtures the classification procedure for this...
    - 2.13.4.2 For inorganic substances or mixtures the classification procedure for this...
    - 2.13.4.3 In the event of divergence between test results and known...
    - 2.13.4.4 In cases where substances or mixtures generate a pressure rise...
- 2.14. Oxidising solids
  - 2.14.1. Definition
  - 2.14.2. Classification criteria
    - 2.14.2.1 An oxidising solid shall be classified in one of the...
      - Note 1
      - Note 2
  - 2.14.3. Hazard Communication
  - 2.14.4. Additional Classification Considerations
    - 2.14.4.1 For organic substances or mixtures the classification procedure for this...
    - 2.14.4.2 For inorganic substances or mixtures the classification procedure for this...
    - 2.14.4.3 In the event of divergence between test results and known...
- 2.15. Organic peroxides
  - 2.15.1. Definition
    - 2.15.1.1 Organic peroxides means liquid or solid organic substances which contain...
    - 2.15.1.2 An organic peroxide is regarded as possessing explosive properties when...
  - 2.15.2. Classification criteria
    - 2.15.2.1 Any organic peroxide shall be considered for classification in this...
      - Note
      - 2.15.2.2 Organic peroxides shall be classified in one of the seven...
      - 2.15.2.3 Criteria for temperature control
  - 2.15.3. Hazard Communication
  - 2.15.4. Additional Classification Considerations
    - 2.15.4.1 Organic peroxides are classified by definition based on their chemical...
    - 2.15.4.2 Mixtures of already classified organic peroxides may be classified as...
- 2.16. Corrosive to metals

- 2.16.1. Definition
- 2.16.2. Classification criteria
  - 2.16.2.1 A substance or a mixture which is corrosive to metals...
    - Note
- 2.16.3. Hazard Communication
  - Note:
- 2.16.4. Additional Classification Considerations
  - 2.16.4.1 The corrosion rate can be measured according to the test...
- 2.17. Desensitised explosives
  - 2.17.1. Definitions and general considerations
    - 2.17.1.1 Desensitised explosives are solid or liquid explosive substances or mixtures...
    - 2.17.1.2 The hazard class of desensitised explosives comprises:
  - 2.17.2. Classification criteria
    - 2.17.2.1 Any explosive while in a desensitised state shall be considered...
    - 2.17.2.2 Desensitised explosives shall be classified and packaged for supply and...
  - 2.17.3. Hazard communication
  - 2.17.4. Additional classification considerations
    - Figure 2D.4.1 Desensitised explosives
    - 2.17.4.1 The classification procedure for desensitised explosives does not apply if:...
    - 2.17.4.2 The exothermic decomposition energy shall be determined using the explosive...
- 3. PART 3: HEALTH HAZARDS
  - 3.1. Acute toxicity
    - 3.1.1. Definitions
      - 3.1.1.1. Acute toxicity means serious adverse health effects (i.e., lethality) occurring...
      - 3.1.1.2. The hazard class Acute Toxicity is differentiated into:
    - 3.1.2. Criteria for classification of substances as acutely toxic
      - 3.1.2.1. Substances can be allocated to one of four hazard categories...
      - 3.1.2.2. Specific considerations for classification of substances as acutely toxic
        - 3.1.2.2.1 The preferred test species for evaluation of acute toxicity by...
      - 3.1.2.3. Specific considerations for classification of substances as acutely toxic by...
        - 3.1.2.3.1 Units for inhalation toxicity are a function of the form...
        - 3.1.2.3.2 Of particular importance in classifying for inhalation toxicity is the...
        - 3.1.2.3.3 In addition to classification for inhalation toxicity, if data are...
    - 3.1.3. Criteria for classification of mixtures as acutely toxic
      - 3.1.3.1. The criteria for classification of substances for acute toxicity as...
      - 3.1.3.2. For acute toxicity each route of exposure shall be considered...
      - 3.1.3.3. In order to make use of all available data for...
      - 3.1.3.4. Classification of mixtures where acute toxicity data are available for...

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- 3.1.3.4. ~~I~~Where the mixture itself has been tested to determine its...
  - 3.1.3.5. Classification of mixtures where acute toxicity data are available for...
    - 3.1.3.5. ~~I~~Where the mixture itself has not been tested to determine...
    - 3.1.3.5. ~~I~~f a tested mixture is diluted with a diluent that...
  - 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity...
    - 3.1.3.6. ~~I~~Data available for all ingredients
    - 3.1.3.6. ~~C~~lassification of mixtures when data are not available for all...
      - 3.1.3.6. ~~W~~here an ATE is not available for an individual ingredient...
      - 3.1.3.6. ~~I~~n the event that a component without any useable information...
      - 3.1.3.6. ~~I~~n the total concentration of the relevant ingredient(s) with unknown...  
Note 1
- 3.1.4. Hazard Communication
  - 3.1.4.1. Label elements shall be used for substances or mixtures meeting...  
Note 1  
Note 2
  - 3.1.4.2. The acute toxicity hazard statements differentiate the hazard based on...
- 3.2. Skin corrosion/irritation
  - 3.2.1. Definitions and general considerations
    - 3.2.1.1. Skin corrosion means the production of irreversible damage to the...
    - 3.2.1.2. In a tiered approach, emphasis shall be placed upon existing...
  - 3.2.2. Classification criteria for substances
    - 3.2.2.1. Classification based on standard animal test data
      - 3.2.2.1. ~~I~~Skin corrosion
        - 3.2.2.1. ~~I~~A substance is corrosive to skin when it produces destruction...
        - 3.2.2.1. ~~C~~orrosive substances shall be classified in Category 1 where data...
        - 3.2.2.1. ~~W~~hen data are sufficient substances shall be classified in one...
        - 3.2.2.1. ~~I~~Three sub-categories are provided within the corrosion category: sub-category 1A —...
        - 3.2.2.1. ~~I~~n the use of human data is discussed in Sections 3.2.1.2 and...
      - 3.2.2.1. ~~S~~kin irritation
        - 3.2.2.1. ~~I~~A substance is irritant to skin when it produces reversible...
        - 3.2.2.1. ~~A~~ single irritation category (Category 2) is presented in Table...
        - 3.2.2.1. ~~R~~eversibility of skin lesions is also considered in evaluating irritant...
        - 3.2.2.1. ~~A~~nimal irritant responses within a test can be variable, as...

- 3.2.2.1.2 The use of human data is discussed in Sections 3.2.1.2...
    - 3.2.2.2. Classification in a tiered approach
      - 3.2.2.2.1 A tiered approach to the evaluation of initial information shall...
      - 3.2.2.2.2 Existing human and animal data including information from single or...
      - 3.2.2.2.3 Acute dermal toxicity data may be used for classification. If...
      - 3.2.2.2.4 In vitro alternatives that have been validated and accepted shall...
      - 3.2.2.2.5 Likewise, pH extremes like  $\leq 2$  and  $\geq 11,5$  may indicate the...
      - 3.2.2.2.6 In some cases, sufficient information may be available from structurally...
      - 3.2.2.2.7 The tiered approach provides guidance on how to organize existing...
  - 3.2.3. Classification criteria for mixtures
    - 3.2.3.1. Classification of mixtures when data are available for the complete...
      - 3.2.3.1.1 The mixture shall be classified using the criteria for substances,...
      - 3.2.3.1.2 When considering testing of the mixture, classifiers are encouraged to...
    - 3.2.3.2. Classification of mixtures when data are not available for the...
      - 3.2.3.2.1 Where the mixture itself has not been tested to determine...
    - 3.2.3.3. Classification of mixtures when data are available for all ingredients...
      - 3.2.3.3.1 In order to make use of all available data for...
      - 3.2.3.3.2 In general, the approach to classification of mixtures as corrosive...
      - 3.2.3.3.3 Table 3.2.3 provides the generic concentration limits to be used to...
      - 3.2.3.3.4 Particular care must be taken when classifying certain types of...
      - 3.2.3.3.5 For mixtures containing strong acids or bases the pH shall...
      - 3.2.3.3.6 A mixture containing ingredients that are corrosive or irritant to...
      - 3.2.3.3.7 On occasion, reliable data may show that the skin corrosion/irritation...
      - 3.2.3.3.8 If there are data showing that (an) ingredient(s) is/are corrosive...
  - 3.2.4. Hazard Communication
    - 3.2.4.1. Label elements shall be used for substances or mixtures meeting...
- 3.3. Serious eye damage/eye irritation
  - 3.3.1. Definitions and general considerations
    - 3.3.1.1. Serious eye damage means the production of tissue damage in...
    - 3.3.1.2. In a tiered approach, emphasis shall be placed upon existing...

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- 3.3.2. Classification criteria for substances
  - 3.3.2.1. Classification based on standard animal test data
    - 3.3.2.1.1. Serious eye damage (Category 1)
      - 3.3.2.1.1.A. single hazard category (Category 1) is adopted for substances...
      - 3.3.2.1.1.B. The use of human data is discussed in Section 3.3.2.2 and...
    - 3.3.2.1.2. Eye irritation (Category 2)
      - 3.3.2.1.2.A. Substances that have the potential to induce reversible eye irritation...
      - 3.3.2.1.2.B. For those substances where there is pronounced variability among animal...
      - 3.3.2.1.2.C. The use of human data is addressed in Sections 3.3.2.2, and...
  - 3.3.2.2. Classification in a tiered approach
    - 3.3.2.2.1. A tiered approach to the evaluation of initial information shall...
    - 3.3.2.2.2. Existing human and animal data shall be the first line...
    - 3.3.2.2.3. In vitro alternatives that have been validated and accepted shall be...
    - 3.3.2.2.4. Likewise, pH extremes like  $\leq 2$  and  $\geq 11,5$ , may indicate serious...
    - 3.3.2.2.5. In some cases sufficient information may be available from structurally...
    - 3.3.2.2.6. The tiered approach provides guidance on how to organize existing...
- 3.3.3. Classification criteria for mixtures
  - 3.3.3.1. Classification of mixtures when data are available for the complete...
    - 3.3.3.1.1. The mixture shall be classified using the criteria for substances,...
    - 3.3.3.1.2. When considering testing of the mixture classifiers are encouraged to...
  - 3.3.3.2. Classification of mixtures when data are not available for the...
    - 3.3.3.2.1. Where the mixture itself has not been tested to determine...
  - 3.3.3.3. Classification of mixtures when data are available for all ingredients...
    - 3.3.3.3.1. In order to make use of all available data for...
    - 3.3.3.3.2. In general, the approach to classification of mixtures as seriously...
    - 3.3.3.3.3. Table 3.3.3 provides the generic concentration limits to be used to...
    - 3.3.3.3.4. Particular care must be taken when classifying certain types of...
    - 3.3.3.3.5. For mixtures containing strong acids or bases the pH shall...
    - 3.3.3.3.6. A mixture containing skin corrosive or serious eye damaging/eye irritating...
    - 3.3.3.3.7. On occasion, reliable data may show that the effects of...
    - 3.3.3.3.8. If there are data showing that (an) ingredient(s) may be...

- 3.3.4. Hazard Communication
  - 3.3.4.1. Label elements shall be used for substances or mixtures meeting...
- 3.4. Respiratory or skin sensitisation
  - 3.4.1. Definitions and general considerations
    - 3.4.1.1. Respiratory sensitisation means hypersensitivity of the airways occurring after inhalation...
    - 3.4.1.2. Skin sensitisation means an allergic response occurring after skin contact...
    - 3.4.1.3. For the purpose of section 3.4, sensitisation includes two phases:...
    - 3.4.1.4. For respiratory sensitisation, the pattern of induction followed by elicitation...
    - 3.4.1.5. Usually, for both skin and respiratory sensitisation, lower levels are...
    - 3.4.1.6. The hazard class Respiratory or Skin Sensitisation is differentiated into:...
  - 3.4.2. Classification criteria for substances
    - 3.4.2.1. Respiratory sensitisers
      - 3.4.2.1.1. ~~Hazard categories~~
        - 3.4.2.1.1.1. ~~R~~espiratory sensitisers shall be classified in Category 1 where data...
        - 3.4.2.1.1.2. ~~W~~here data are sufficient a refined evaluation according to 3.4.2.1.1.3...
        - 3.4.2.1.1.3. ~~E~~ffects seen in either humans or animals will normally justify...
        - 3.4.2.1.1.4. ~~S~~ubstances shall be classified as respiratory sensitisers in accordance with...
      - 3.4.2.1.2. ~~H~~uman evidence
        - 3.4.2.1.2.1. ~~E~~vidence that a substance can lead to specific respiratory hypersensitivity...
        - 3.4.2.1.2.2. ~~W~~hen considering the human evidence, it is necessary for a...
        - 3.4.2.1.2.3. ~~T~~he evidence referred to above could be:
        - 3.4.2.1.2.4. ~~C~~linical history shall include both medical and occupational history to...
        - 3.4.2.1.2.5. ~~T~~he results of positive bronchial challenge tests are considered to...
      - 3.4.2.1.3. ~~A~~nimal studies
        - 3.4.2.1.3.1. ~~D~~ata from appropriate animal studies which may be indicative of...
    - 3.4.2.2. Skin sensitisers
      - 3.4.2.2.1. ~~Hazard categories~~
        - 3.4.2.2.1.1. ~~S~~kin sensitisers shall be classified in Category 1 where data...
        - 3.4.2.2.1.2. ~~W~~here data are sufficient a refined evaluation according to section...
        - 3.4.2.2.1.3. ~~E~~ffects seen in either humans or animals will normally justify...
        - 3.4.2.2.1.4. ~~S~~ubstances shall be classified as skin sensitisers in accordance with...
      - 3.4.2.2.2. ~~H~~uman evidence



- 3.5.2.3.2 The system is hazard based, classifying substances on the basis...
    - 3.5.2.3.3 Classification for heritable effects in human germ cells is made...
    - 3.5.2.3.4 In vivo heritable germ cell mutagenicity tests, such as:
    - 3.5.2.3.5 In vivo somatic cell mutagenicity tests, such as:
    - 3.5.2.3.6 Mutagenicity/genotoxicity tests in germ cells, such as:
    - 3.5.2.3.7 Genotoxicity tests in somatic cells such as:
    - 3.5.2.3.8 In vitro mutagenicity tests such as:
    - 3.5.2.3.9 The classification of individual substances shall be based on the...
  - 3.5.3. Classification criteria for mixtures
    - 3.5.3.1. Classification of mixtures when data are available for all ingredients...
      - 3.5.3.1.1 The mixture shall be classified as a mutagen when at...
        - Note
    - 3.5.3.2. Classification of mixtures when data are available for the complete...
      - 3.5.3.2.1 Classification of mixtures will be based on the available test...
    - 3.5.3.3. Classification of mixtures when data are not available for the...
      - 3.5.3.3.1 Where the mixture itself has not been tested to determine...
  - 3.5.4. Hazard communication
    - 3.5.4.1. Label elements shall be used in accordance with Table 3.5.3,...
  - 3.5.5. Additional classification considerations
- 3.6. Carcinogenicity
  - 3.6.1. Definition
    - 3.6.1.1. Carcinogenicity means the induction of cancer or an increase in...
  - 3.6.2. Classification criteria for substances
    - 3.6.2.1. For the purpose of classification for carcinogenicity, substances are allocated...
    - 3.6.2.2. Specific considerations for classification of substances as carcinogens
      - 3.6.2.2.1 Classification as a carcinogen is made on the basis of...
      - 3.6.2.2.2 Classification of a substance as a carcinogen is a process...
      - 3.6.2.2.3 Strength of evidence involves the enumeration of tumours in human...
      - 3.6.2.2.4 Additional considerations (as part of the weight of evidence approach...
      - 3.6.2.2.5 The factors can be viewed as either increasing or decreasing...
      - 3.6.2.2.6 Some important factors which may be taken into consideration, when...
      - 3.6.2.2.7 A substance that has not been tested for carcinogenicity may...
      - 3.6.2.2.8 The classification shall take into consideration whether or not the...
      - 3.6.2.2.9 It is important that whatever is known of the physico-chemical,...
  - 3.6.3. Classification criteria for mixtures

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- 3.6.3.1. Classification of mixtures when data are available for all ingredients...
  - 3.6.3.1.1. The mixture will be classified as a carcinogen when at...
    - Note
    - Note 1
- 3.6.3.2. Classification of mixtures when data are available for the complete...
  - 3.6.3.2.1. Classification of mixtures will be based on the available test...
- 3.6.3.3. Classification of mixtures when data are not available for the...
  - 3.6.3.3.1. Where the mixture itself has not been tested to determine...
- 3.6.4. Hazard Communication
  - 3.6.4.1. Label elements shall be used in accordance with Table 3.6.3,...
- 3.7. Reproductive toxicity
  - 3.7.1. Definitions and general considerations
    - 3.7.1.1. Reproductive toxicity means adverse effects on sexual function and fertility...
    - 3.7.1.2. For the purpose of classification the hazard class Reproductive Toxicity...
    - 3.7.1.3. Adverse effects on sexual function and fertility
    - 3.7.1.4. Adverse effects on development of the offspring
    - 3.7.1.5. Adverse effects on or via lactation are also included in...
  - 3.7.2. Classification criteria for substances
    - 3.7.2.1. Hazard categories
      - 3.7.2.1.1. For the purpose of classification for reproductive toxicity, substances are...
    - 3.7.2.2. Basis of classification
      - 3.7.2.2.1. Classification is made on the basis of the appropriate criteria,...
      - 3.7.2.2.2. In the evaluation of toxic effects on the developing offspring,...
      - 3.7.2.2.3. For human evidence to provide the primary basis for a...
    - 3.7.2.3. Weight of evidence
      - 3.7.2.3.1. Classification as a reproductive toxicant is made on the basis...
      - 3.7.2.3.2. Toxicokinetic studies in animals and humans, site of action and...
      - 3.7.2.3.3. If, in some reproductive toxicity studies in experimental animals the...
      - 3.7.2.3.4. Data from animal studies ideally shall provide clear evidence of...
      - 3.7.2.3.5. If appropriate information is available it is important to try...
    - 3.7.2.4. Maternal toxicity
      - 3.7.2.4.1. Development of the offspring throughout gestation and during the early...
      - 3.7.2.4.2. Based on pragmatic observation, maternal toxicity may, depending on severity,...
      - 3.7.2.4.3. Classification shall not automatically be discounted for substances that produce...

- 3.7.2.4. ~~Some of the end points used to assess maternal effects...~~
      - 3.7.2.5. Animal and experimental data
        - 3.7.2.5.1 ~~A number of internationally accepted test methods are available; these...~~
        - 3.7.2.5.2 ~~Results obtained from Screening Tests (e.g. OECD Guidelines 421 —...~~
        - 3.7.2.5.3 ~~Adverse effects or changes, seen in short- or long-term repeated...~~
        - 3.7.2.5.4 ~~Evidence from in vitro assays, or non-mammalian tests, and from...~~
        - 3.7.2.5.5 ~~It is preferable that animal studies are conducted using appropriate...~~
        - 3.7.2.5.6 ~~Studies involving routes of administration such as intravenous or intraperitoneal...~~
        - 3.7.2.5.7 ~~There is general agreement about the concept of a limit...~~
        - 3.7.2.5.8 ~~In principle, adverse effects on reproduction seen only at very...~~
        - 3.7.2.5.9 ~~However, specification of the actual 'limit dose' will depend upon...~~
    - 3.7.3. Classification criteria for mixtures
      - 3.7.3.1. Classification of mixtures when data are available for all ingredients...
        - 3.7.3.1.1 ~~The mixture shall be classified as a reproductive toxicant when...~~
        - 3.7.3.1.2 ~~The mixture shall be classified for effects on or via...~~
      - 3.7.3.2. Classification of mixtures when data are available for the complete...
        - 3.7.3.2.1 ~~Classification of mixtures will be based on the available test...~~
      - 3.7.3.3. Classification of mixtures when data are not available for the...
        - 3.7.3.3.1 ~~Subject to paragraph 3.7.3.2.1, where the mixture itself has not...~~
    - 3.7.4. Hazard Communication
      - 3.7.4.1. Label elements shall be used for substances or mixtures meeting...
- 3.8. Specific target organ toxicity — single exposure
  - 3.8.1. Definitions and general considerations
    - 3.8.1.1. Specific target organ toxicity – single exposure means specific, non-lethal...
    - 3.8.1.2. Classification identifies the substance or mixture as being a specific...
    - 3.8.1.3. These adverse health effects produced by a single exposure include...
    - 3.8.1.4. Assessment shall take into consideration not only significant changes in...
    - 3.8.1.5. Specific target organ toxicity can occur by any route that...
    - 3.8.1.6. Specific target organ toxicity following a repeated exposure is classified...
    - 3.8.1.7. The hazard class Specific Target Organ Toxicity — Single Exposure...
  - 3.8.2. Classification criteria for substances

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- 3.8.2.1. Substances of Category 1 and Category 2
  - 3.8.2.1.1 Substances are classified for immediate or delayed effects separately, by...
  - 3.8.2.1.2 The relevant route or routes of exposure by which the...
  - 3.8.2.1.3 Classification is determined by expert judgement (see section 1.1.1), on...
  - 3.8.2.1.4 Weight of evidence of all data (see section 1.1.1), including...
  - 3.8.2.1.5 The information required to evaluate specific target organ toxicity comes...
  - 3.8.2.1.6 In exceptional cases, based on expert judgement, it is appropriate...
  - 3.8.2.1.7 Effects considered to support classification for Category 1 and 2...
    - 3.8.2.1.7.1 Classification is supported by evidence associating single exposure to the...
    - 3.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of...
    - 3.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much...
  - 3.8.2.1.8 Effects considered not to support classification for Category 1 and...
  - 3.8.2.1.9 Guidance values to assist with classification based on the results...
    - 3.8.2.1.9.1 In order to help reach a decision about whether a...
    - 3.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed...
    - 3.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has...
  - 3.8.2.1.10 Other considerations
    - 3.8.2.1.10.1 When a substance is characterised only by use of animal...
    - 3.8.2.1.10.2 When well-substantiated human data are available showing a specific target...
    - 3.8.2.1.10.3 Substance that has not been tested for specific target...
    - 3.8.2.1.10.4 Saturated vapour concentration shall be considered, where appropriate, as an...
- 3.8.2.2. Substances of Category 3: Transient target organ effects
  - 3.8.2.2.1 Criteria for respiratory tract irritation
  - 3.8.2.2.2 Criteria for narcotic effects
- 3.8.3. Classification criteria for mixtures
  - 3.8.3.1. Mixtures are classified using the same criteria as for substances,...
  - 3.8.3.2. Classification of mixtures when data are available for the complete...
    - 3.8.3.2.1 When reliable and good quality evidence from human experience or...
  - 3.8.3.3. Classification of mixtures when data are not available for the...

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- 3.8.3.3.1 Where the mixture itself has not been tested to determine...
- 3.8.3.4. Classification of mixtures when data are available for all components...
  - 3.8.3.4.1 Where there is no reliable evidence or test data for...
  - 3.8.3.4.2 These generic concentration limits and consequent classifications shall be applied...
  - 3.8.3.4.3 Mixtures shall be classified for either or both single- and...
  - Note 1
  - 3.8.3.4.4 Care shall be exercised when toxicants affecting more than one...
  - 3.8.3.4.5 Care shall be exercised when extrapolating toxicity of a mixture...
  - 3.8.3.4.6 In cases where the additivity approach is used for Category...
- 3.8.4. Hazard Communication
  - 3.8.4.1 Label elements shall be used in accordance with Table 3.8.4.,...
- 3.9. Specific target organ toxicity — repeated exposure
  - 3.9.1. Definitions and general considerations
    - 3.9.1.1. Specific target organ toxicity-repeated exposure means specific toxic effects on...
    - 3.9.1.2. Classification for target organ toxicity (repeated exposure) identifies the substance...
    - 3.9.1.3. These adverse health effects include consistent and identifiable toxic effects...
    - 3.9.1.4. Assessment shall take into consideration not only significant changes in...
    - 3.9.1.5. Specific target organ toxicity can occur by any route that...
    - 3.9.1.6. Non-lethal toxic effects observed after a single-event exposure are classified...
  - 3.9.2. Classification criteria for substances
    - 3.9.2.1. Substances are classified as specific target organ toxicants following repeated...
      - Note
      - 3.9.2.2. The relevant route or routes of exposure by which the...
      - 3.9.2.3. Classification is determined by expert judgement (see section 1.1.1), on...
      - 3.9.2.4. Weight of evidence of all data (see section 1.1.1), including...
      - 3.9.2.5. The information required to evaluate specific target organ toxicity comes...
      - 3.9.2.6. In exceptional cases, based on expert judgement, it is appropriate...
      - 3.9.2.7. Effects considered to support classification for specific target organ toxicity...
        - 3.9.2.7.1 Reliable evidence associating repeated exposure to the substance with a...
        - 3.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of...
        - 3.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much...
      - 3.9.2.8. Effects considered not to support classification for specific target organ...

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- 3.9.2.8. It is recognised that effects may be seen in humans...
- 3.9.2.9. Guidance values to assist with classification based on the results...
  - 3.9.2.9.1. In studies conducted in experimental animals, reliance on observation of...
  - 3.9.2.9.2. In order to help reach a decision about whether a...
  - 3.9.2.9.3. Thus, in animal studies, when significant toxic effects are observed...
  - 3.9.2.9.4. The decision to classify at all can be influenced by...
  - 3.9.2.9.5. The guidance values refer to effects seen in a standard...
  - 3.9.2.9.6. Thus classification in Category 1 is applicable, when significant toxic...
  - 3.9.2.9.7. Classification in Category 2 is applicable, when significant toxic effects...
  - 3.9.2.9.8. The guidance values and ranges mentioned in paragraphs 3.9.2.9.6 and...
  - 3.9.2.9.9. Thus it is feasible that a specific profile of toxicity...
- 3.9.2.10. Other considerations
  - 3.9.2.10.1. When a substance is characterised only by use of animal...
  - 3.9.2.10.2. When well-substantiated human data are available showing a specific target...
  - 3.9.2.10.3. A substance that has not been tested for specific target...
  - 3.9.2.10.4. Saturated vapour concentration shall be considered, where appropriate, as an...
- 3.9.3. Classification criteria for mixtures
  - 3.9.3.1. Mixtures are classified using the same criteria as for substances,...
  - 3.9.3.2. Classification of mixtures when data are available for the complete...
    - 3.9.3.2.1. When reliable and good quality evidence from human experience or...
  - 3.9.3.3. Classification of mixtures when data are not available for the...
    - 3.9.3.3.1. Where the mixture itself has not been tested to determine...
  - 3.9.3.4. Classification of mixtures when data are available for all components...
    - 3.9.3.4.1. Where there is no reliable evidence or test data for...
      - Note 1
    - 3.9.3.4.2. These generic concentration limits and consequent classifications apply to repeated-dose...
    - 3.9.3.4.3. Mixtures shall be classified for either or both single-and...
    - 3.9.3.4.4. Care shall be exercised when toxicants affecting more than one...
- 3.9.4. Hazard Communication
  - 3.9.4.1. Label elements shall be used in accordance with Table 3.9.5...
- 3.10. Aspiration hazard
  - 3.10.1. Definitions and general considerations
    - 3.10.1.1. These criteria provide a means of classifying substances or mixtures...

- 3.10.1.2 'Aspiration' means the entry of a liquid or solid substance...
- 3.10.1.3 Aspiration hazard means severe acute effects such as chemical pneumonia,...
- 3.10.1.4 Aspiration is initiated at the moment of inspiration, in the...
- 3.10.1.5 Aspiration of a substance or mixture can occur as it...
- 3.10.1.6 Specific considerations
  - 3.10.1.6A. review of the medical literature on chemical aspiration revealed...
  - 3.10.1.6B The classification criteria refer to kinematic viscosity. The following provides...
  - 3.10.1.6C Although the definition of aspiration in section 3.10.1.2 includes the...
  - 3.10.1.6D Classification of aerosol/mist products
- 3.10.2. Classification criteria for substances
  - Note:
- 3.10.3. Classification criteria for mixtures
  - 3.10.3.1 Classification when data are available for the complete mixture
  - 3.10.3.2 Classification when data are not available for the complete mixture:...
  - 3.10.3.2A Where the mixture itself has not been tested to determine...
  - 3.10.3.3 Classification when data are available for all components or only...
    - 3.10.3.3A Category 1
      - 3.10.3.3A.1 The 'relevant ingredients' of a mixture are those...
      - 3.10.3.3A.2 A mixture is classified as Category 1 when the sum...
      - 3.10.3.3A.3 In the case of a mixture which separates into two...
- 3.10.4. Hazard Communication
  - 3.10.4.1 Label elements shall be used for substances or mixtures meeting...
- 4. PART 4: ENVIRONMENTAL HAZARDS
  - 4.1. Hazardous to the aquatic environment
    - 4.1.1. Definitions and general considerations
      - 4.1.1.1. Definitions
      - 4.1.1.2. Basic elements
        - 4.1.1.2.1 Hazardous to the aquatic environment is differentiated into:
        - 4.1.1.2.2 The basic elements used for classification for aquatic environmental hazards...
        - 4.1.1.2.3 Preferably data shall be derived using the standardised test methods...
      - 4.1.1.3. Other considerations
        - 4.1.1.3.1 Classification of substances and mixtures for environmental hazards requires the...
        - 4.1.1.3.2 While the classification system applies to all substances and mixtures,...
    - 4.1.2. Classification criteria for substances
      - 4.1.2.1. The system for classification recognises that the intrinsic hazard to...

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- 4.1.2.2. The core classification system for substances consists of one short-term...
- 4.1.2.3. The criteria for classification of a substance in Acute 1...
- 4.1.2.4. The system also introduces a ‘ safety net ’ classification...
- 4.1.2.5. Substances with acute toxicities below 1 mg/l or chronic toxicities below...
- 4.1.2.6. The criteria for classifying and categorising substances as ‘ hazardous...
  - Note 1:
  - Note 2:
  - Note 3:
  - Note 4:
- 4.1.2.7. Aquatic toxicity
  - 4.1.2.7.1Acute aquatic toxicity is normally determined using a fish 96-hour...
  - 4.1.2.7.2For determining chronic aquatic toxicity for classification purposes data generated...
- 4.1.2.8. Bioaccumulation
  - 4.1.2.8.1Bioaccumulation of substances within aquatic organisms can give rise to...
- 4.1.2.9. Rapid degradability of organic substances
  - 4.1.2.9.1Substances that rapidly degrade can be quickly removed from the...
  - 4.1.2.9.2One way of demonstrating rapid degradation utilises the biodegradation screening...
  - 4.1.2.9.3Many degradation data are available in the form of degradation...
  - 4.1.2.9.4The criteria used reflect the fact that environmental degradation may...
  - 4.1.2.9.5Substances are considered rapidly degradable in the environment if one...
- 4.1.2.10Inorganic compounds and metals
  - 4.1.2.10.1For inorganic compounds and metals, the concept of degradability as...
  - 4.1.2.10.2Poorly soluble inorganic compounds and metals may be acutely or...
- 4.1.3. Classification criteria for mixtures
  - 4.1.3.1. The classification system for mixtures covers all classification categories which...
  - 4.1.3.2. The approach for classification of aquatic environmental hazards is tiered,...
    - Figure 4The tiered approach to classification of mixtures for short-term (acute) and...
  - 4.1.3.3. Classification of mixtures when toxicity data are available for the...
    - 4.1.3.3.1When the mixture as a whole has been tested to...
    - 4.1.3.3.2The long-term (chronic) hazard classification of mixtures requires additional information...
    - 4.1.3.3.3Classification for category Acute 1
    - 4.1.3.3.4Classification for categories Chronic 1, 2 and 3
    - 4.1.3.3.5Classification for category Chronic 4
  - 4.1.3.4. Classification of mixtures when toxicity data are not available for...

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- 4.1.3.4. ~~I~~Where the mixture itself has not been tested to determine...
- 4.1.3.4. ~~D~~Dilution: if a mixture is formed by diluting another tested...
- 4.1.3.4. ~~I~~If a mixture is formed by diluting another tested mixture...
- 4.1.3.5. Classification of mixtures when toxicity data are available for some...
  - 4.1.3.5. ~~I~~The classification of a mixture is based on summation of...
  - 4.1.3.5. ~~M~~Mixtures can be made of a combination of both components...
  - 4.1.3.5. ~~W~~When applying the additivity formula for part of the mixture,...
  - 4.1.3.5. ~~I~~f a mixture is classified in more than one way,...
  - 4.1.3.5. ~~S~~Summation method
    - 4.1.3.5. ~~R~~ationale
      - 4.1.3.5. ~~I~~n case of the substance classification categories Chronic 1 to...
      - 4.1.3.5. ~~W~~hen a mixture contains components classified as Acute 1 or...
    - 4.1.3.5. ~~C~~lassification procedure
      - 4.1.3.5. ~~I~~n 2.1. general a more severe classification for mixtures overrides a...
    - 4.1.3.5. ~~C~~lassification for category Acute 1
      - 4.1.3.5. ~~F~~irst, all components classified as Acute 1 are considered. If...
      - 4.1.3.5. ~~T~~he 2. classification of mixtures for short-term (acute) hazards based on...
    - 4.1.3.5. ~~C~~lassification for the categories Chronic 1, 2, 3 and 4...
      - 4.1.3.5. ~~F~~irst, all components classified as Chronic 1 are considered. If...
      - 4.1.3.5. ~~I~~n 2. cases where the mixture is not classified as Chronic...
      - 4.1.3.5. ~~I~~n 3. cases where the mixture is not classified either as...
      - 4.1.3.5. ~~I~~n 4. the mixture is still not classified in Chronic 1,...
      - 4.1.3.5. ~~T~~he 5. classification of mixtures for long-term (chronic) hazards, based on...
    - 4.1.3.5. ~~M~~ixtures with highly toxic components
      - 4.1.3.5. ~~A~~cute 1 and Chronic 1 components with toxicities below 1 mg/l...
- 4.1.3.6. Classification of mixtures with components without any useable information
  - 4.1.3.6. ~~I~~n the event that no useable information on short-term (acute)...
- 4.1.4. Hazard communication
  - 4.1.4.1. Label elements shall be used for substances or mixtures meeting...

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- 5. PART 5: ADDITIONAL HAZARDS
  - 5.1. Hazardous to the ozone layer
    - 5.1.1. Definitions and general considerations
      - 5.1.1.1. Ozone depleting potential (ODP) is an integrative quantity, distinct for...
    - 5.1.2. Classification criteria for substances
      - 5.1.2.1. A substance shall be classified as hazardous to the ozone...
    - 5.1.3. Classification criteria for mixtures
      - 5.1.3.1. Mixtures shall be classified as hazardous to the ozone layer...
    - 5.1.4. Hazard communication
      - 5.1.4.1. Label elements shall be used for substances or mixtures meeting...

## ANNEX II

### SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES

This Annex consists of 5 parts:

Part 1 contains special rules for the labelling of certain...

- 1. PART 1: SUPPLEMENTAL HAZARD INFORMATION
  - 1.1. Physical properties
    - 1.1.1. EUH001 — ‘Explosive when dry’
    - 1.1.2. EUH006 — ‘Explosive with or without contact with air’
    - 1.1.1. EUH014 — ‘Reacts violently with water’
    - 1.1.2. EUH018 — ‘In use, may form flammable/explosive vapour-air mixture’
    - 1.1.3. EUH019 — ‘May form explosive peroxides’
    - 1.1.4. EUH044 — ‘Risk of explosion if heated under confinement’
  - 1.2. Health properties
    - 1.2.1. EUH029 — ‘Contact with water liberates toxic gas’
    - 1.2.2. EUH031 — ‘Contact with acids liberates toxic gas’
    - 1.2.3. EUH032 — ‘Contact with acids liberates very toxic gas’
    - 1.2.4. EUH066 — ‘Repeated exposure may cause skin dryness or cracking’...
    - 1.2.5. EUH070 — ‘Toxic by eye contact’
    - 1.2.6. EUH071 — ‘Corrosive to the respiratory tract’
- 2. PART 2: SPECIAL RULES FOR SUPPLEMENTAL LABEL ELEMENTS FOR CERTAIN...
  - 2.1. Mixtures containing lead
  - 2.2. Mixtures containing cyanoacrylates
  - 2.3. Cements and cement mixtures
  - 2.4. Mixtures containing isocyanates
  - 2.5. Mixtures containing epoxy constituents with an average molecular weight  $\leq$ ...
  - 2.6. Mixtures sold to the general public which contain active chlorine...
  - 2.7. Mixtures containing cadmium (alloys) and intended to be used for...
  - 2.8. Mixtures containing at least one sensitising substance
  - 2.9. Liquid mixtures containing halogenated hydrocarbons
  - 2.10. Mixtures not intended for the general public
  - 2.11. Aerosols

3. PART 3: SPECIAL RULES ON PACKAGING
  - 3.1. Provisions relating to child-resistant fastenings
    - 3.1.1. Packaging to be fitted with child-resistant fastenings
      - 3.1.1.1. Packaging of whatever capacity containing a substance or mixture supplied...
      - 3.1.1.2. Packaging of whatever capacity containing a substance or mixture supplied...
      - 3.1.1.3. Where a substances or mixture has at least one of...
    - 3.1.2. Reclosable packages
    - 3.1.3. Non-reclosable packages
    - 3.1.4. Notes
      - 3.1.4.1. Evidence of conformity with the above standards may be certified...
      - 3.1.4.2. Specific cases
  - 3.2. Tactile Warnings
    - 3.2.1. Packaging to be fitted with a tactile warning
      - 3.2.1.1. Where substances or mixtures are supplied to the general public...
      - 3.2.1.2. Section 3.2.1.1 does not apply to transportable gas receptacles. Aerosols...
    - 3.2.2. Provisions relating to tactile warning
  - 3.3. Liquid consumer laundry detergents in soluble packaging for single use...
4. PART 4: SPECIAL RULE FOR LABELLING OF PLANT PROTECTION PRODUCTS...
5. PART 5: LIST OF HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH...

### ANNEX III

#### LIST OF HAZARD STATEMENTS, SUPPLEMENTAL HAZARD INFORMATION AND SUPPLEMENTAL LABEL ELEMENTS

1. Part 1: hazard statements
2. Part 2: supplemental hazard information
3. Part 3: supplemental label elements/information on certain certain substances and...

### ANNEX IV

#### LIST OF PRECAUTIONARY STATEMENTS

This Annex sets out a matrix listing the recommended precautionary...

To provide flexibility in the application of precautionary phrases, combinations...

Notwithstanding Article 22 the precautionary statements that appear on labels...

Where square brackets [...] appear around some text in a...

When a forward slash or diagonal mark [/] appears in...

When three full stops [...] appear in a precautionary statement...

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Where the text in column 5 indicates that a precautionary...

1. Part 1: Criteria for the selection of precautionary statements
2. Part 2: precautionary statements

## ANNEX V

### HAZARD PICTOGRAMS

#### INTRODUCTION

1. PART 1: PHYSICAL HAZARDS
  - 1.1. Symbol: exploding bomb
  - 1.2. Symbol: flame
  - 1.3. Symbol: flame over circle
  - 1.4. Symbol: gas cylinder
  - 1.5. Symbol: corrosion
  - 1.6. A pictogram is not required for the following physical hazard...
2. PART 2: HEALTH HAZARDS
  - 2.1. Symbol: skull and crossbones
  - 2.2. Symbol: corrosion
  - 2.3. Symbol: exclamation mark
  - 2.4. Symbol: health hazard
  - 2.5. A pictogram is not required for the following health hazard...
3. PART 3: ENVIRONMENTAL HAZARDS
  - 3.1. Symbol: environment
4. PART 4: ADDITIONAL HAZARDS
  - 4.1. Symbol: exclamation mark

## ANNEX VI

Mandatory classification and labelling for certain hazardous substances

Part 1 of this Annex provides an introduction to the...  
Part 2 of this Annex lays down general principles for...

...

1. PART 1: INTRODUCTION TO THE LIST OF MANDATORY CLASSIFICATIONS AND...
  - 1.1. Information listed for each entry
    - 1.1.1. Numbering of entries and identification of a substance
      - 1.1.1.1. Index numbers
      - 1.1.1.2. EC numbers
      - 1.1.1.3. CAS number
      - 1.1.1.4. Chemical name
      - 1.1.1.5. Entries for groups of substances
    - 1.1.2. Information related to the classification and labelling of each entry...
      - 1.1.2.1. Classification codes
        - 1.1.2.1.1. Hazard class and category codes
        - 1.1.2.1.2. Hazard statement codes
      - 1.1.2.2. Labelling codes

- 1.1.2.3. Specific concentration limits, M-factors and Acute Toxicity Estimates (ATE)
- 1.1.3. Notes assigned to an entry
  - 1.1.3.1. Notes relating to the identification, classification and labelling of substances...
    - Note A:
    - Note B:
    - Note C:
    - Note D:
    - Note E (Table 3.2):
    - Note F:
    - Note G:
    - Note H (Table 3.1):
    - Note H (Table 3.2):
    - Note J:
    - Note K:
    - Note L:
    - Note M:
    - Note N:
    - Note P:
    - Note Q:
    - Note R:
    - Note S:
    - Note T:
    - Note U (Table 3):
  - 1.1.3.2. Notes relating to the classification and labelling of mixtures
    - Note 1:
    - Note 2:
    - Note 3:
    - Note 5:
    - Note 7:
    - Note 8:
    - Note 9:
- 1.1.4. Information related to the classification and labelling of each entry...
  - 1.1.4.1. Classification codes
  - 1.1.4.2. Labelling codes
  - 1.1.4.3. Specific Concentration Limits
  - 1.1.4.4. Non-conformity with Table 3.1 for physical hazards
- 1.2. Classifications and hazard statements in Table 3 arising from translation...
  - 1.2.1. Minimum classification
  - 1.2.2. Route of exposure cannot be excluded
  - 1.2.3. Hazard statements for reproductive toxicity
  - 1.2.4. Correct classification for physical hazards could not be established
- 2. PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING
- 3. PART 3: HARMONISED CLASSIFICATION AND LABELLING TABLE

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## ANNEX VII

Translation table from classification under Directive  
67/548/EEC to classification under this Regulation

This Annex includes a table to assist translation of a...

1. Translation table

## ANNEX VIII

### HARMONISED INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE AND PREVENTATIVE MEASURES

#### PART A

#### GENERAL REQUIREMENTS

1. APPLICATION
  - 1.1. Importers and downstream users placing on the market mixtures for...
  - 1.2. Importers and downstream users placing on the market mixtures for...
  - 1.3. Importers and downstream users placing on the market mixtures for...
  - 1.4. Importers and downstream users having submitted information relating to hazardous...
  - 1.5. By way of derogation from Section 1.4, if one of...
2. PURPOSE, SCOPE AND DEFINITIONS
  - 2.1. This Annex sets out the requirements that importers and downstream...
  - 2.2. This Annex shall not apply to mixtures for scientific research...
  - 2.2a. In the case of bespoke paints, submitters may, without prejudice...
  - 2.3. In the case of mixtures with an end use not...
  - 2.4. For the purposes of this Annex, the following definitions shall...
3. SUBMISSION REQUIREMENTS
  - 3.1. Before placing mixtures on the market, submitters shall provide information...
  - 3.2. Where following receipt of a submission under Section 3.1 an...
  - 3.3. The submission shall be in the official language(s) of the...
  - 3.4. The intended use of the mixture shall be described in...
  - 3.5. A submission update shall be made without undue delay when...
4. GROUP SUBMISSION
  - 4.1. A single submission may be provided for more than one...
  - 4.2. A group submission shall only be permitted when all mixtures...
  - 4.3. By way of derogation from Section 4.2, a group submission...
  - 4.4. In the case of a group submission, the information required...
5. UNIQUE FORMULA IDENTIFIER (UFI)
  - 5.1. The submitter shall create a Unique Formula Identifier ('UFI') by...
  - 5.2. The UFI shall be preceded by the acronym ' UFI...
  - 5.3. Instead of including the UFI in the supplemental information on...
6. FORMATS AND TECHNICAL SUPPORT FOR SUBMISSION OF INFORMATION
  - 6.1. The Agency shall specify, maintain and update the UFI generator,...

- 6.2. The Agency shall provide technical and scientific guidance, technical support...

## PART B

### INFORMATION CONTAINED IN A SUBMISSION

1. IDENTIFICATION OF THE MIXTURE AND OF THE SUBMITTER
  - 1.1. Product identifier of the mixture
  - 1.2. Details of the submitter and contact point
  - 1.3. Name, telephone number and email address for rapid access to...
2. HAZARDS IDENTIFICATION AND ADDITIONAL INFORMATION
  - 2.1. Classification of the mixture
  - 2.2. Label elements
  - 2.3. Toxicological information
  - 2.4. Additional information
3. INFORMATION ON MIXTURE COMPONENTS
  - 3.1. General requirements
  - 3.2. Identification of mixture components
    - 3.2.1. Substances
    - 3.2.2. Mixture in mixture
    - 3.2.3. Identification by generic component identifiers
  - 3.3. Mixture components subject to submission requirements
  - 3.4. Concentration and concentration ranges of the mixture components
    - 3.4.1. Hazardous components of major concern for emergency health response and...
    - 3.4.2. Other hazardous components and components not classified as hazardous
  - 3.5. Grouping of components in an interchangeable component group
    - 3.5.1. Name of interchangeable component group and identification of grouped components...
    - 3.5.2. Concentration and concentration ranges of grouped components
  - 3.6. Mixtures complying with standard formulas
  - 3.7. Fuels
  - 3.8. Classification of mixture components
4. SUBMISSION UPDATE
  - 4.1. Conditions for submission update
  - 4.2. Content of the submission update

## PART C

### SUBMISSION FORMAT

1. SUBMISSION FORMAT
  - 1.1. Submission Format
  - 1.2. Identification of the mixture, submitter and contact point
  - 1.3. Classification of the mixture, label elements and toxicology
  - 1.4. Information on the mixture components and interchangeable component groups

## PART D

### STANDARD FORMULAS

1. CEMENT

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2. GYPSUM BINDER
3. READY MIXED CONCRETE

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- (1) [OJ C 204, 9.8.2008, p. 47.](#)
- (2) Opinion of the European Parliament of 3 September 2008 (not yet published in the Official Journal).
- (3) [OJ L 262, 27.9.1976, p. 169.](#)
- (4) [OJ L 213, 21.7.1982, p. 8.](#)
- (5) [OJ L 184, 15.7.1988, p. 61.](#)
- (6) [OJ L 40, 11.2.1989, p. 27.](#)
- (7) [OJ L 189, 20.7.1990, p. 17.](#)
- (8) [OJ L 169, 12.7.1993, p. 1.](#)
- (9) [OJ L 331, 7.12.1998, p. 1.](#)
- (10) [OJ L 84, 27.3.1999, p. 1.](#)
- (11) [OJ L 311, 28.11.2001, p. 1.](#)
- (12) [OJ L 311, 28.11.2001, p. 67.](#)
- (13) [OJ L 31, 1.2.2002, p. 1.](#)
- (14) [OJ L 268, 18.10.2003, p. 29.](#)
- (15) [OJ L 396, 30.12.2006, p. 1.](#) Corrected version in [OJ L 136, 29.5.2007, p. 3.](#)
- (16) [OJ 196, 16.8.1967, p. 1.](#)
- (17) [OJ L 200, 30.7.1999, p. 1.](#)
- (18) [OJ L 358, 18.12.1986, p. 1.](#)
- (19) [OJ L 142, 31.5.2008, p. 1.](#)
- (20) [OJ L 50, 20.2.2004, p. 44.](#)
- (21) [OJ L 230, 19.8.1991, p. 1.](#)
- (22) [OJ L 123, 24.4.1998, p. 1.](#)
- (23) [OJ C 364, 18.12.2000, p. 1.](#)
- (24) [OJ L 184, 17.7.1999, p. 23.](#)

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