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EN

ANNEXES I – VI

ANNEX I

Annex I to Regulation (EC) No 1272/2008 is amended as follows:

1. Part 1 is amended as follows:

(a) In section 1.1.2.2.2 Table 1.1 is replaced by the following:

'Table 1.1

Generic cut-off values

Hazard class	Generic cut-off values to be taken into account
Acute Toxicity:	
- Category 1-3 - Category 4	0,1 % 1 %
Skin corrosion/Irritation	1 %(1)
Serious damage to eyes/eye irritation	1 %(2)
Specific target organ toxicity, single exposure, Category 3	1 %(3)
Aspiration toxicity	1 %
Hazardous to Aquatic Environment	
- Acute Category 1	0,1 %(4)
- Chronic Category 1	0,1 %(4)
- Chronic Category 2-4	1 %'
(1) Or < 1 % where relevant, see 3.2.3.3.1. (2) Or < 1 % where relevant, see 3.3.3.3.1. (3) Or <1 % where relevant, see 3.8.3.4.6. (4) Or < 0,1 % where relevant, see 4.1.3.1.	

(b) Section 1.1.3.7. is replaced by the following:

'1.1.3.7. *Aerosols*

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.4, 3.8 and 3.9, an aerosol form of a mixture shall be classified in the same hazard

category as the tested non-aerosolised form of the mixture, provided that the added propellant does not affect the hazardous properties of the mixture upon spraying.'

(c) Section 1.3.2.1. is replaced by the following:

'1.3.2.1. If propane, butane and liquefied petroleum gas or a mixture containing these substances classified in accordance with the criteria of this Annex, is placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope of EN 417 as fuel gases which are only released for combustion (current edition of EN 417, relating to 'Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances; construction, inspection, testing and marking'), these cylinders or cartridges need be labelled only with the appropriate pictogram and the hazard and precautionary statements concerning flammability.'

2. Part 2 is amended as follows:

(a) In section 2.1.1.1., point (c) is replaced by the following:

'(c) substances, mixtures and articles not mentioned in points (a) and (b) above, which are manufactured with the view to producing a practical explosive or pyrotechnic effect.'

(b) In section 2.1.2.2., point (f) is replaced by the following:

'(f) Division 1.6 Extremely insensitive articles which do not have a mass explosion hazard:

- articles which predominantly contain extremely insensitive substances or mixtures;
- and which demonstrate a negligible probability of accidental initiation or propagation.'

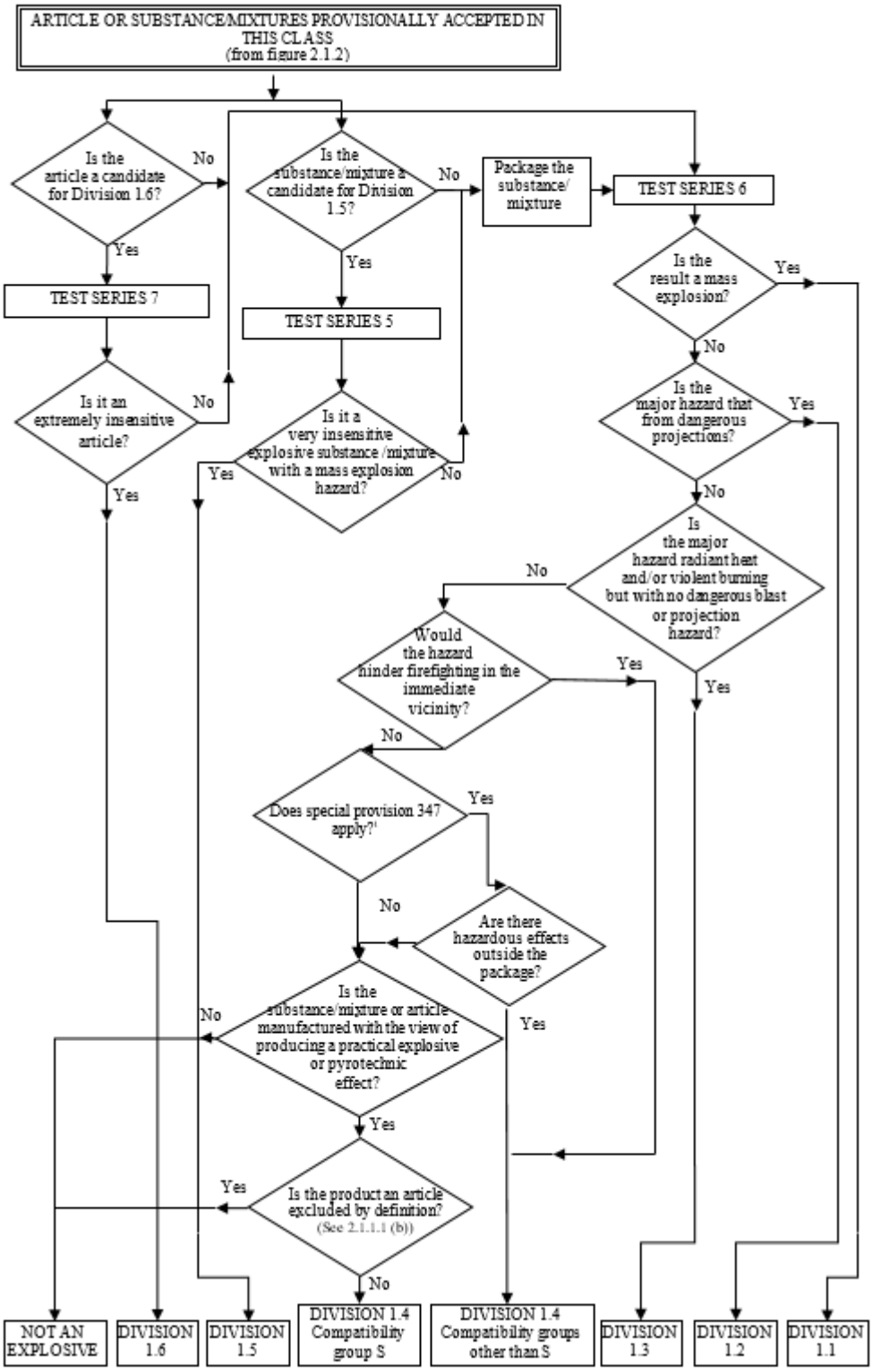
(c) In section 2.1.4.1., the third paragraph is replaced by the following:

'Some explosive substances and mixtures are wetted with water or alcohols, diluted with other substances or dissolved or suspended in water or other liquid substances to suppress or reduce their explosives properties. They may be a candidate for classification as desensitised explosives (see Section 2.17).'

(d) In section 2.1.4.1., figure 2.1.3 is replaced by the following:
'

'Figure 2.1.3

Procedure for assignment to a division in the class of explosives (Class 1 for transport)



[1]*See Chapter 3.3 of the UN RTDG, Model Regulations for details.'*

(e) Section 2.1.4.3. is amended as follows:

(i) the introductory wording is replaced by the following:

'2.1.4.3. The acceptance procedure for the hazard class "explosives" need not be applied if:'

(ii) point (c) is replaced by the following:

‘(c) For an organic substance, or a homogenous mixture of organic substances, containing a chemical group (or groups) associated with explosive properties:
– the exothermic decomposition energy is less than 500 J/g, or
– the onset of exothermic decomposition is 500 ºC or above
as indicated in Table 2.1.3.’

(iii) Table 2.1.3 is added to 2.1.4.3 (c):

‘Table 2.1.3

Decision to apply the acceptance procedure for the hazard class “Explosives” for an organic substance or a homogenous mixture of organic substances

Decomposition energy (J/g)	Decomposition onset temperature (°C)	Apply acceptance procedure? (Yes/No)
< 500	< 500	No
< 500	≥ 500	No
≥ 500	< 500	Yes
≥ 500	≥ 500	No

The exothermic decomposition energy may be determined using a suitable calorimetric technique (see section 20.3.3.3 of the *UN RTDG, Manual of Tests and Criteria).*’

(f) In section 2.2. the title is replaced by the following:

‘2.2. Flammable gases’

(g) In section 2.2., section 2.2.1. is replaced by the following:

‘2.2.1.1. Flammable gas means a gas or gas mixture having a flammable range with air at 20 °C and a standard pressure of 101,3 kPa.

2.2.1.2. A pyrophoric gas means a flammable gas that is liable to ignite spontaneously in air at a temperature of 54 ºC or below.’

2.2.1.3. A chemically unstable gas means a flammable gas that is able to react explosively even in the absence of air or oxygen.’

(h) Section 2.2.2.1. and 2.2.2.2. are replaced by the following:

‘2.2.2.1. A flammable gas is classified in Category 1A, 1B or 2 in accordance with Table 2.2.1. Flammable gases that are pyrophoric and/or chemically unstable are always classified in Category 1A.’

Table 2.2.1: Criteria for categorisation of flammable gases

Category		Criteria
1A	Flammable gas	Gases, which at 20 °C and a standard pressure of 101,3 kPa:

			(a) are ignitable when in a mixture of 13 % or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless of the lower flammability limit unless data show they meet the criteria for Category 1B
	Pyrophoric gas		Flammable gases that ignite spontaneously in air at a temperature of 54 ºC or below
	Chemically unstable gas	A	Flammable gases which are chemically unstable at 20 °C and a standard pressure of 101,3 kPa
		B	Flammable gases which are chemically unstable at a temperature greater than 20 °C and/or a pressure greater than 101,3 kPa
1B	Flammable gas		Gases which meet the flammability criteria for Category 1A, but which are not pyrophoric, nor chemically unstable, and which have at least either: (a) a lower flammability limit of more than 6 % by volume in air; or (b) a fundamental burning velocity of less than 10 cm/s;
2	Flammable gas		Gases, other than those of Category 1A or 1B, which, at 20 °C and a standard pressure of 101,3 kPa, have a flammable range while mixed in air

.

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, a flammable gas that meets the criteria for Category 1A is classified by default in Category 1A.

NOTE 3: Spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay.

NOTE 4: In the absence of data on its pyrophoricity, a flammable gas mixture shall be classified as a pyrophoric gas if it contains more than 1% (by volume) of pyrophoric component(s).'

(i) In section 2.2.3., Table 2.2.3. is replaced by the following:

‘Table 2.2.2
Label elements for flammable gases

	Category 1A	Gases categorised as 1A by meeting pyrophoric or unstable gas A/B criteria			Category 1B	Category 2
		Pyrophoric gas	Chemically unstable gas			
			Category A	Category B		
GHS Pictogram						No pictogram
Signal Word	Danger	Danger	Danger	Danger	Danger	Warning
Hazard Statement	H220: Extremely flammable gas	H220: Extremely flammable gas. H232 May ignite spontaneously if exposed to air	H220: Extremely flammable gas. H230: May react explosively even in the absence of air	H220: Extremely flammable gas. H231: May react explosively even in the absence of air at elevated pressure and/or temperature	H221: Flammable gas	H221: Flammable gas
Precautionary Statement Prevention	P210	P210 P222 P280	P202 P210	P202 P210	P210	P210
Precautionary Statement	P377	P377	P377	P377	P377	P377

Response	P381	P381	P381	P381	P381	P381
Precautionary Statement Storage	P403	P403	P403	P403	P403	P403
Precautionary Statement Disposal						

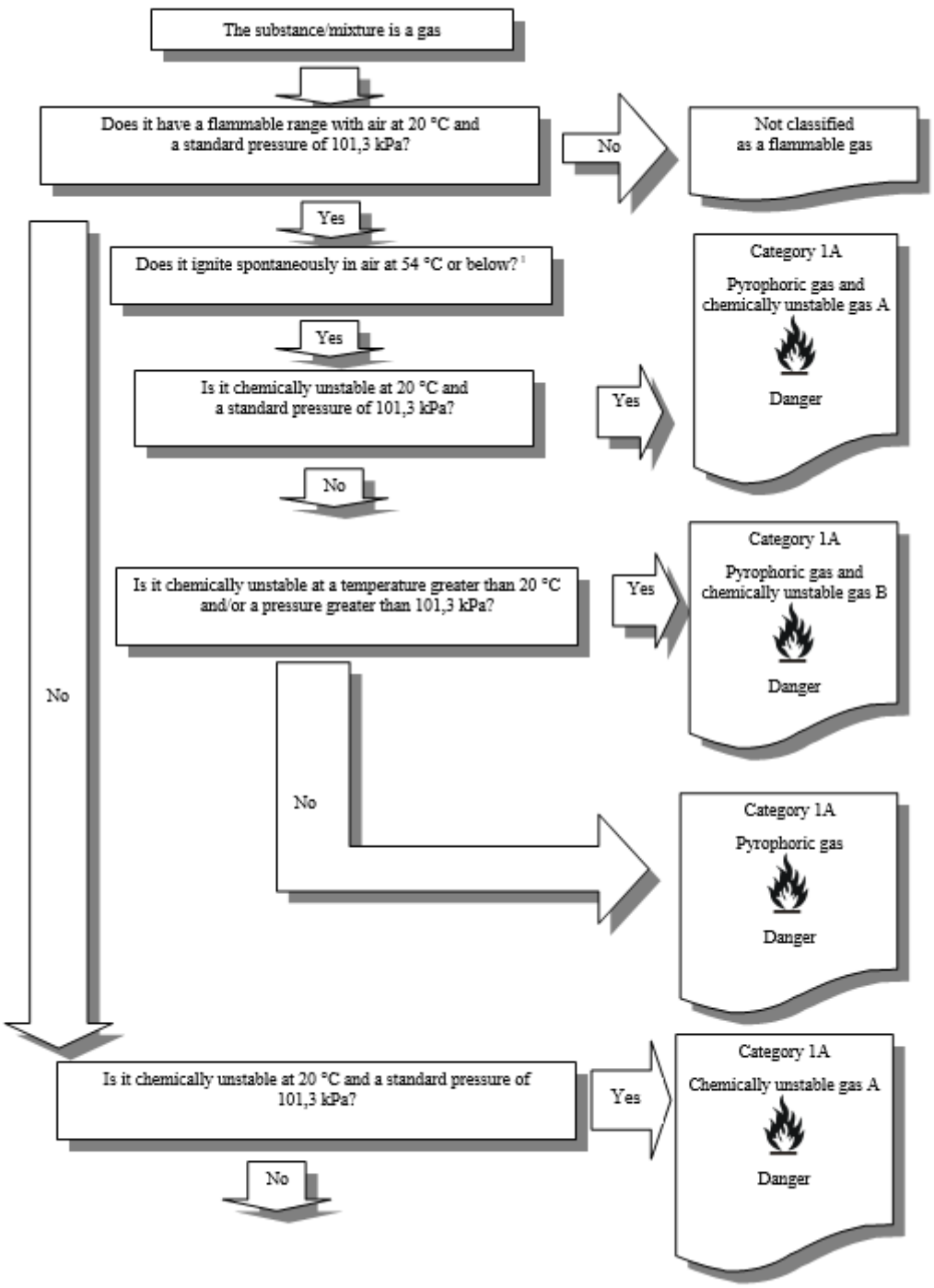
The classification procedure is set out in the following decision logic (see Figure 2.2.1).'

(j) In section 2.2.3., the following paragraph is added after Table 2.2.2.:

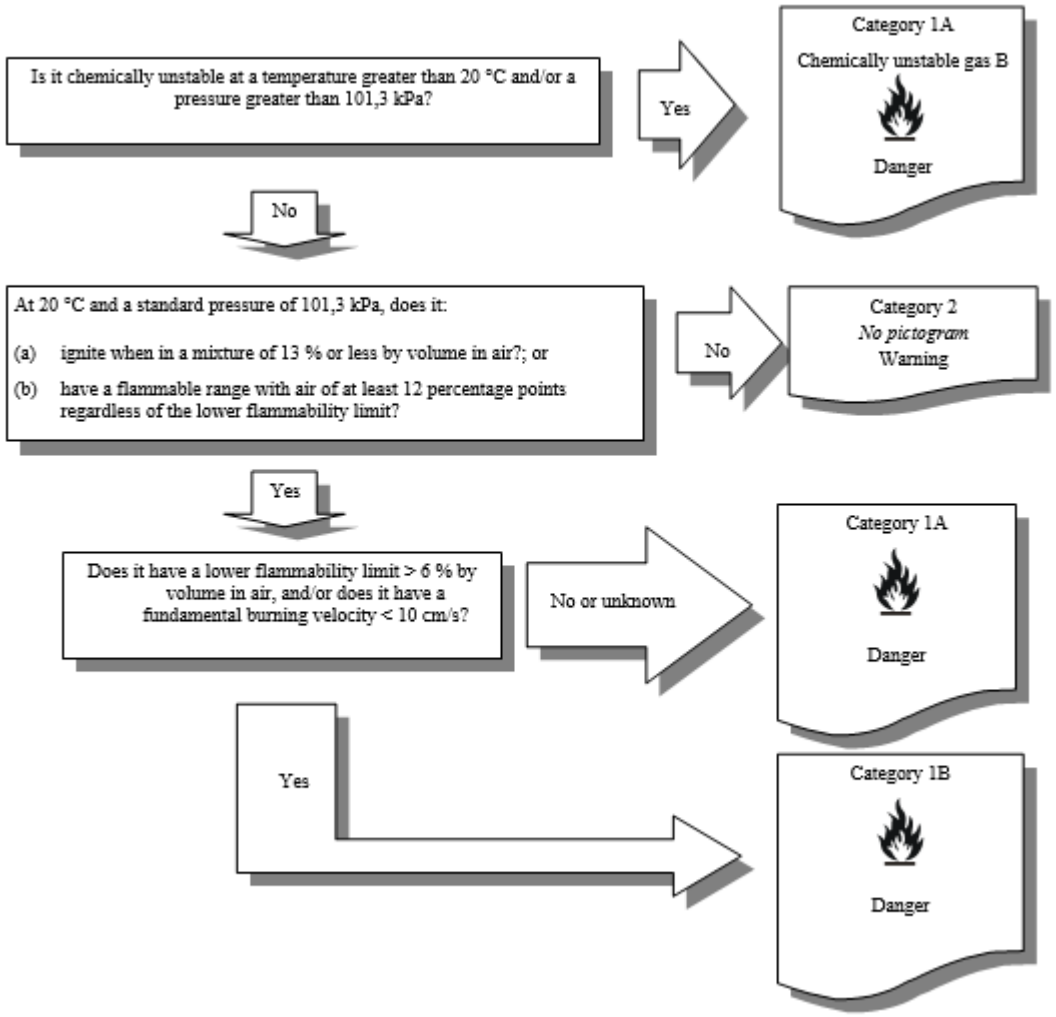
'If a flammable gas or gas mixture is classified as pyrophoric and/or chemically unstable, then all relevant classification(s) shall be communicated on the safety data sheet as specified in Annex II of Regulation (EC) No 1907/2006, and the relevant hazard communication elements included on the label.'

(k) In section 2.2.3., Figure 2.2.1. is replaced with the following:

'Figure 2.2.1
Flammable gases



[1]*In the absence of data on its pyrophoricity, a flammable gas mixture shall be classified as a pyrophoric gas if it contains more than 1% (by volume) of pyrophoric component(s).*



,

(l) In section 2.2.3., Figure 2.2.2. is deleted.

(m) Section 2.2.4. is amended as follows:

Section 2.2.4.1. is replaced by the following:

‘2.2.4.1. Flammability shall be determined by tests or, for mixtures where there are sufficient data available, by calculation in accordance with the methods adopted by ISO (see ISO 10156 as amended, “Gases and gas mixtures — Determination of fire potential and oxidising ability for the selection of cylinder valve outlets" and, if using fundamental burning velocity for Category 1B, see ISO 817 as amended "Refrigerants-Designation and safety classification, Annex C:- Method of test for burning velocity measurement of flammable gases"). Instead of the test apparatus according to ISO 10156 as amended, the test apparatus for the tube method according to clause 4.2 of EN 1839 as amended (Determination of explosion limits of gases and vapours) may be used.’

The following sections 2.2.4.2. and 2.2.4.3. are inserted:

‘2.2.4.2. Pyrophoricity shall be determined at 54 °C in accordance with either IEC 60079-20-1 ed1.0 (2010-01) “Explosive atmospheres – Part 20-1: Material characteristics

for gas and vapour classification – Test methods and data" or DIN 51794 "Determining the ignition temperature of petroleum products".

2.2.4.3. The classification procedure for pyrophoric gases need not be applied when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 54 ºC or below. Flammable gas mixtures, which have not been tested for pyrophoricity and contain more than one percent pyrophoric components, shall be classified as a pyrophoric gas. Expert judgement on the properties and physical hazards of pyrophoric gases and their mixtures shall be used in assessing the need for classification of flammable gas mixtures containing one percent or less pyrophoric components. In this case, testing need only be considered if expert judgement indicates a need for additional data to support the classification process.'

(n) Section 2.2.4.2. is renumbered as follows:

'2.2.4.4.'

(o) The text before paragraphs (a) to (d) in section 2.6.4.2. is replaced by the following:

'2.6.4.2. In the case of mixtures[1] containing known flammable liquids in defined concentrations, although they may contain non-volatile components e.g. polymers, additives, the flash point need not be determined experimentally if the calculated flash point of the mixture, using the method given in 2.6.4.3 below, is at least 5 °C[2] greater than the relevant classification criterion and provided that:

[1]*Up to now, the calculation method is validated for mixtures containing up to six volatile components. These components may be flammable liquids like hydrocarbons, ethers, alcohols, esters (except acrylates), and water. It is however not yet validated for mixtures containing halogenated, sulphurous, and/or phosphoric compounds as well as reactive acrylates.*

[2]*If the calculated flash point is less than 5 °C greater than the relevant classification criterion, the calculation method may not be used and the flash point shall be determined experimentally.'*

(p) Section 2.7.2.2. is replaced by the following:

'2.7.2.2. Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample (100 mm) in 10 min or less.'

(q) In section 2.12.2.1. Table 2.12.1. is replaced by the following:

'Table 2.12.1

Criteria for substances and mixtures, which in contact with water, emit flammable gases

Category	Criteria
1	Any substance or mixture which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 litres per kilogram of substance over any one minute.
2	Any substance or mixture which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 litres per kilogram of substance per hour, and

	which does not meet the criteria for Category 1.
3	Any substance or mixture which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is greater than 1 litre per kilogram of substance per hour, and which does not meet the criteria for Categories 1 and 2.

Note:
The test shall be performed on the substance or mixture in its physical form as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.'

(r) The following section 2.17. is added:

'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 which are phlegmatised to suppress their explosive properties in such a manner that they do not mass explode and do not burn too rapidly and therefore may be exempted from the hazard class "Explosives" (see also paragraph 3 in section 2.1.4.1)[1]

[1] *Unstable explosives as defined in Section 2.1 can also be stabilised by desensitisation and consequently may be classified as desensitised explosives, provided all criteria of Section 2.17 are met. In this case the desensitised explosive shall be tested according to test series 3 (Part I of the UN RTDG, Manual of Tests and Criteria) because information about its sensitiveness to mechanical stimuli is likely to be important for determining conditions for safe handling and use. The results shall be communicated in the safety data sheet.*

2.17.1.2. The hazard class of desensitised explosives comprises:

(a) Solid desensitised explosives: explosive substances or mixtures, which are wetted with water or alcohols or are diluted with other substances, to form a homogeneous solid mixture to suppress their explosive properties.

NOTE: This includes desensitisation achieved by formation of hydrates of the substances.

(b) Liquid desensitised explosives: explosive substances or mixtures, which are dissolved or suspended in water or other liquid substances, to form a homogeneous liquid mixture to suppress their explosive properties.

2.17.2. *Classification criteria*

2.17.2.1. Any explosive while in a desensitised state shall be considered in this class unless, in that state:

(a) It is intended to produce a practical explosive or pyrotechnic effect;

(b) It has a mass explosion hazard according to test series 6 (a) or 6 (b) or the corrected burning rate according to the burning rate test described in part V, subsection 51.4 of the *UN RTDG, Manual of Tests and Criteria* is greater than 1200 kg/min; or

(c) The exothermic decomposition energy is less than 300 J/g.

NOTE 1: Substances or mixtures, which meet the criterion (a) or (b) in their desensitised state shall be classified as explosives (see Section 2.1). Substances or mixtures which meet the criterion (c) may fall within the scope of other physical hazard classes.

NOTE 2: The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see section 20, sub-section 20.3.3.3 in Part II of the UN RTDG, Manual of Tests and Criteria).

2.17.2.2. Desensitised explosives shall be classified and packaged for supply and use in one of the four categories of this class depending on the corrected burning rate (A_c) using the test "burning rate test (external fire)" described in Part V, sub-section 51.4 of the *UN RTDG, Manual of Tests and Criteria*, according to Table 2.17.1:

Table 2.17.1.
Criteria for desensitised explosives

Category	Criteria
1	Desensitised explosives with a corrected burning rate (A_C) equal to or greater than 300 kg/min but not more than 1200 kg/min
2	Desensitised explosives with a corrected burning rate (A_C) equal to or greater than 140 kg/min but less than 300 kg/min
3	Desensitised explosives with a corrected burning rate (A_C) equal to or greater than 60 kg/min but less than 140 kg/min
4	Desensitised explosives with a corrected burning rate (A_C) less than 60 kg/min

Note 1: Desensitised explosives shall be prepared so that they remain homogeneous and do not separate during normal storage and handling, particularly if desensitised by wetting. The manufacturer/supplier shall give information in the safety data sheet about the shelf-life and instructions on verifying desensitisation. Under certain conditions the content of desensitising agent (e.g. phlegmatiser, wetting agent or treatment) may decrease during supply and use, and thus, the hazard potential of the desensitised explosive may increase. In addition, the safety data sheet shall include advice on avoiding increased fire, blast or protection hazards when the substance or mixture is not sufficiently desensitised.

Note 2: Explosive properties of desensitised explosives shall be determined by test series 2 of the UN RTDG, Manual of Tests and Criteria, and shall be communicated in the safety data sheet.

Note 3: For the purposes of storage, supply and use, desensitised explosives do not fall additionally within the scope of Sections 2.1 (explosives), 2.6 (flammable liquids) and 2.7 (flammable solids).

2.17.3. Hazard communication

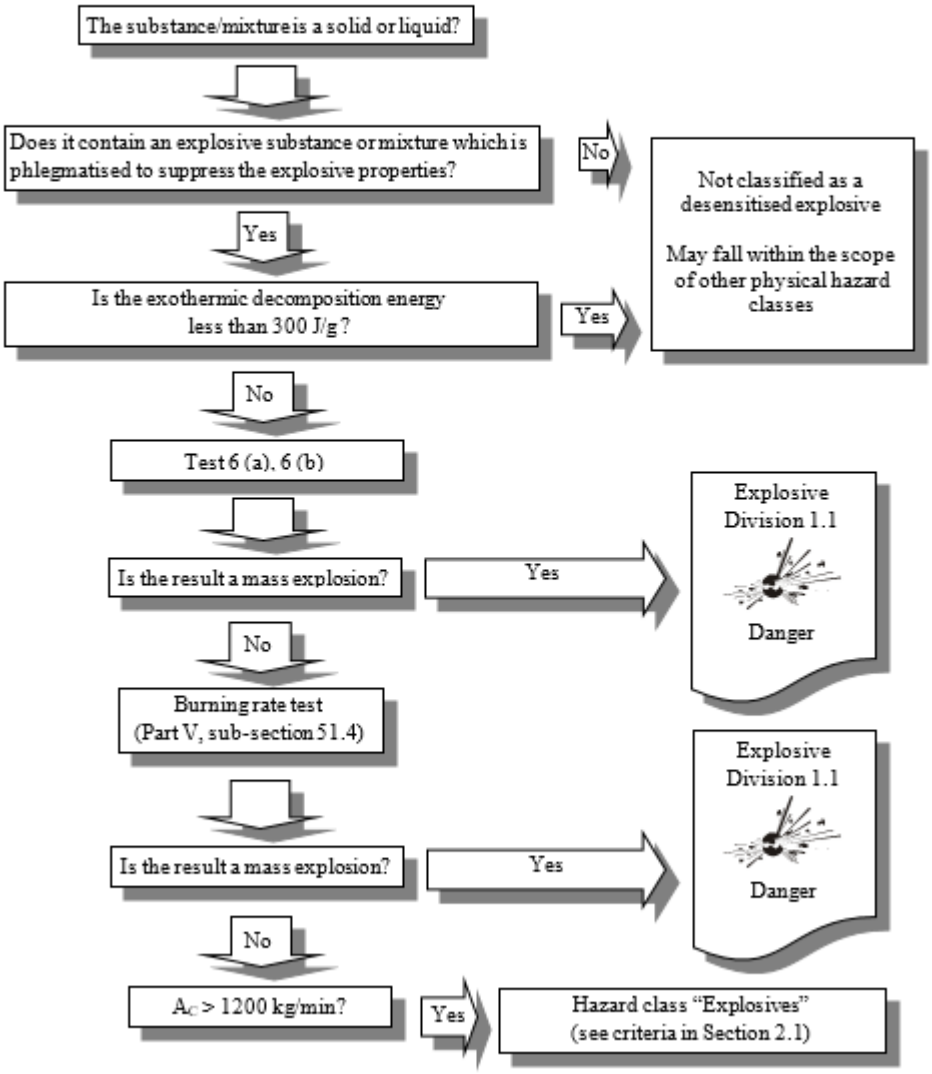
Label elements shall be used for liquid or solid substances or mixtures meeting the criteria for classification in this hazard class in accordance with Table 2.17.2.

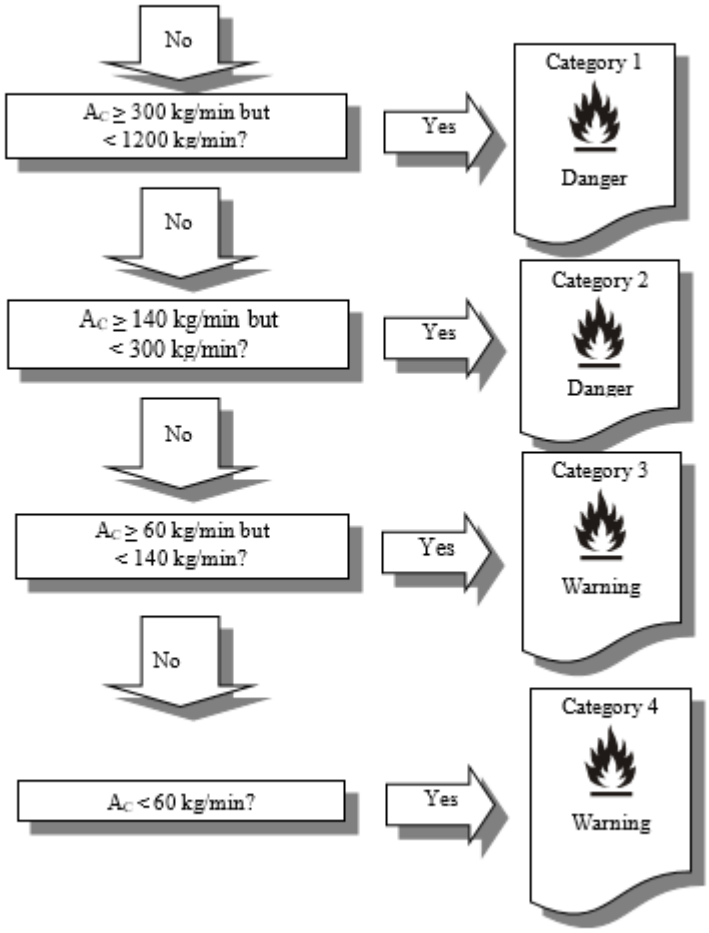
Table 2.17.2.
Label elements for desensitised explosives

	Category 1	Category 2	Category 3	Category 4
GHS Pictogram				
Signal word	Danger	Danger	Warning	Warning
Hazard statement	H206 Fire, blast or projection hazard; increased risk of explosion if desensitising agent is reduced	H207 Fire or projection hazard; increased risk of explosion if desensitising agent is reduced	H207 Fire or projection hazard; increased risk of explosion if desensitising agent is reduced	H208: Fire hazard; increased risk of explosion if desensitising agent is reduced
Precautionary statement Prevention	P210 P212 P230 P233 P280	P210 P212 P230 P233 P280	P210 P212 P230 P233 P280	P210 P212 P230 P233 P280
Precautionary Statement Response	P370 + P380+ P375	P370 + P380+ P375	P370 + P380+ P375	P371 + P380 + P375
Precautionary Statement Storage	P401	P401	P401	P401
Precautionary Statement Disposal	P501	P501	P501	P501

2.17.4. Additional classification considerations

Figure 2.17.1.
Desensitised explosives





2.17.4.1. The classification procedure for desensitised explosives does not apply if:

(a) The substances or mixtures contain no explosives according to the criteria in Section 2.1; or

(b) The exothermic decomposition energy is less than 300 J/g.

2.17.4.2. The exothermic decomposition energy shall be determined using the explosive already desensitised (i.e.: the homogenous solid or liquids mixture formed by the explosive and the substance(s) used to suppress its explosive properties). The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see Section 20, sub-section 20.3.3.3 in Part II of the *UN RTDG, Manual of Tests and Criteria*).'

3. Part 3 is amended as follows:

(a) Section 3.1.1.1. is replaced by the following:

'3.1.1.1. Acute toxicity means serious adverse health effects (i.e., lethality) occurring after a single or short-term oral, dermal or inhalation exposure to a substance or mixture.'

(b) In section 3.1.2.1., the introductory paragraph is replaced by the following:

‘3.1.2.1. Substances can be allocated to one of four hazard categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in the table below. Acute toxicity values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation) values or as acute toxicity estimates (ATE). While some *in vivo* methods determine LD_{50}/LC_{50} values directly, other newer *in vivo* methods (e.g. using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category. Explanatory notes are shown following Table 3.1.1.’

(c) In section 3.1.2.1. the title of Table 3.1.1. is replaced by the following:

‘*Table 3.1.1.*
Acute toxicity estimate (ATE) values and criteria for acute toxicity hazard categories.’

(d) Section 3.2.1.1. is replaced by the following:

‘3.2.1.1. Skin corrosion means the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.

Skin irritation means the production of reversible damage to the skin occurring after exposure to a substance or mixture.’

(e) Section 3.3.1.1. is replaced by the following:

‘3.3.1.1. Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.

Eye irritation means the production of changes in the eye, which are fully reversible, occurring after the exposure of the eye to a substance or mixture.’

(f) Section 3.4.1.1. is replaced by the following:

‘3.4.1.1. Respiratory sensitisation means hypersensitivity of the airways occurring after inhalation of a substance or a mixture.’

(g) Section 3.4.1.2. is replaced by the following:

‘3.4.1.2. Skin sensitisation means an allergic response occurring after skin contact with a substance or a mixture.’

(h) Section 3.4.2.1.3.1. is replaced by the following:

‘3.4.2.1.3.1. Data from appropriate animal studies[1] which may be indicative of the potential of a substance to cause sensitisation by inhalation in humans[2] may include:

(a) measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice;

(b) specific pulmonary responses in guinea pigs.

[1] *At present, recognised and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

[2] *The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventative measures, these substances are considered respiratory sensitisers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyper-reactivity, they shall not be considered as respiratory sensitisers.'*

(i) In section 3.4.3.3.2. , Table 3.4.6, *Note 1* is replaced by the following:

> *'Note 1:*
>
> This concentration limit for elicitation is used for the application of the special labelling requirements of section 2.8 of Annex II to protect already sensitised individuals. A SDS is required for the mixture containing a component at or above this concentration. For sensitising substances with a specific concentration limit, the concentration limit for elicitation shall be set at a tenth of the specific concentration limit.'

(j) Section 3.5.1.1. is replaced by the following:

'3.5.1.1. Germ cell mutagenicity means heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.'

(k) Section 3.5.1.1. is renumbered as follows:

'3.5.1.2. A mutation means a permanent change in the amount or structure of the genetic material in a cell. The term 'mutation' applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including specific base pair changes and chromosomal translocations). The term 'mutagenic' and 'mutagen' will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.'

(l) Section 3.5.1.2. is renumbered as follows:

'3.5.1.3. The more general terms 'genotoxic' and 'genotoxicity' apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non- physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.'

(m) Section 3.5.2.3.5. is replaced by the following:

'3.5.2.3.5. In vivo somatic cell mutagenicity tests, such as:

- mammalian bone marrow chromosome aberration test;
- mammalian erythrocyte micronucleus test'

(n) Section 3.6.1.1. is replaced by the following:

'3.6.1.1. Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture. Substances and mixtures which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected

human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans.
Classification of a substance or mixture as posing a carcinogenic hazard is based on its intrinsic properties and does not provide information on the level of the human cancer risk with the use of the substance or mixture may represent.'

(o) Section 3.7.1.1. is replaced by the following:

'3.7.1.1. Reproductive toxicity refers to adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture. The definitions presented below are adapted from those agreed as working definitions in IPCS/EHC Document N°225, Principles for Evaluating Health Risks to Reproduction Associated with Exposure to Chemicals. For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in Germ Cell Mutagenicity (Section 3.5), since in the present classification system it is considered more appropriate to address such effects under the separate hazard class of germ cell mutagenicity.

In this classification system, reproductive toxicity is subdivided into two main headings:

(a) adverse effects on sexual function and fertility;

(b) adverse effects on development of the offspring.

Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, substances and mixtures with these effects shall be classified as with a general hazard statement.'

(p) Section 3.7.2.5.1. is replaced by the following:

'3.7.2.5.1. A number of internationally accepted test methods are available; these include methods for developmental toxicity testing (e.g. OECD Test Guideline 414) and methods for one or two-generation toxicity testing (e.g. OECD Test Guidelines 415, 416, 443).'

(q) Section 3.8.1.1. is replaced by the following:

'3.8.1.1. Specific target organ toxicity – single exposure means specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in sections 3.1 to 3.7 and 3.10 are included (see also section 3.8.1.6).'

(r) Section 3.8.3.4.1. is replaced by the following:

'3.8.3.4.1. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant (single

exposure) and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively.'

(s) In section 3.8.3.4. section 3.8.3.4.6. is added:

'3.8.3.4.6. In cases where the additivity approach is used for Category 3 ingredients, the "relevant ingredients" of a mixture are those which are present in concentrations ≥1 % (w/w for solids, liquids, dusts, mists, and vapours and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration <1 % is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects.'

(t) Section 3.9.1.1. is replaced by the following:

'3.9.1.1. Specific target organ toxicity-repeated exposure means specific toxic effects on target organs occurring after repeated exposure to a substances or mixture. All significant health effects that can impair function, reversible and irreversible, immediate and/or delayed are included. However, other specific toxic effects that are specifically addressed in sections 3.1 to 3.8 and 3.10 are not included here.'

(u) Section 3.9.3.4.1. is replaced by the following:

'3.9.3.4.1. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following repeated exposure when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant (repeated exposure) and is present at or above the appropriate generic concentration limit as laid out in Table 3.9.4 for Category 1 and 2 respectively.'

(v) Section 3.10.1.3. is replaced by the following:

'3.10.1.3. Aspiration hazard means severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.'

(w) In section 3.10.3.3. a new section is added :

'3.10.3.3.1.1. The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1 %.'

(x) Section 3.10.3.3.1.1. is renumbered and replaced by the following:

'3.10.3.3.1.2. A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥10 % and the mixture has a kinematic viscosity ≤20.5 mm^2/s, measured at 40 °C.'

(y) Section 3.10.3.3.1.2. is renumbered and replaced by the following:

'3.10.3.3.1.3. In the case of a mixture which separates into two or more distinct layers, the entire mixture is classified as Category 1 if in any distinct layer the sum of the concentrations of Category 1 ingredients is ≥ 10 %, and it has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40 °C.'

Part 4 is amended as follows:

(a) Section 4.1.3.5.5.3.1. is replaced by the following:

‘4.1.3.5.5.3.1. First, all components classified as Acute 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is ≥25 % the whole mixture is classified as Acute 1.’

ANNEX II

Annex II to Regulation (EC) No 1272/2008 is amended as follows:

1. Part I is amended as follows:

(a) the following entry is deleted:

‘EUH001 — ‘Explosive when dry’ For explosive substances and mixtures as referred to in section 2.1 of Annex I, placed on the market wetted with water or alcohols or diluted with other substances to suppress their explosive properties.’

(b) In section 2.10. the third indent is replaced by the following:

‘- ≥ one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with a specific concentration limit, or’

ANNEX III

Annex III to Regulation (EC) No 1272/2008 is amended as follows:

1. Part 1 is amended as follows:

(a) The following Hazard Statements are added to Table 1.1:

‘H206	Language	2.17, Desensitised explosives, Hazard Category 1
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Fire, blast or projection hazard; increased risk of explosion if desensitising agent is reduced’
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	

	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

H207	Language	2.17, Desensitised explosives, Hazard Category 2, 3
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Fire or projection hazard; increased risk of explosion if desensitising agent is reduced
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

H208	Language	2.17, Desensitised explosives, Hazard Category 4
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Fire hazard; increased risk of explosion if desensitising agent is reduced
	FR	

	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

‘H232	Language	2.2 Flammable gases, Hazard Category 1A, pyrophoric gas
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	May ignite spontaneously if exposed to air’
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

(b) Table 1.1 is amended as follows:

(i) The top row of the entry concerning H220 is replaced by the following:

‘H220	Language	2.2 – Flammable gases, Hazard Category 1A’

(ii) The top row of the entry concerning H221 is replaced by the following:

‘H221	Language	2.2 – Flammable gases, Hazard Category 1B, 2’

(iii) The top row of the entry concerning H230 is replaced by the following:

‘H230	Language	2.2 - Flammable gases, Hazard Category 1A, chemically unstable gas A’

(iv) The top row of the entry concerning H231 is replaced by the following:

‘H231	Language	2.2 - Flammable gases, Hazard Category 1A, chemically unstable gas B’

(c) The 10th row of the entry concerning H314 is replaced by the following:

	‘FR	Provoque de graves brûlures de la peau et de graves lésions des yeux.’

2. Part 2 is amended as follows:

(a) In Table 2.1. the entry for EUH 001 is deleted.

ANNEX IV

Annex IV to Regulation (EC) No 1272/2008 is amended as follows:

(1) The first introductory paragraph of Annex IV is replaced by the following:

‘This Annex sets out a matrix listing the recommended precautionary statements for each hazard class and hazard category by type of precautionary statement. The matrix guides the selection of appropriate precautionary statements, and includes elements for all categories of precautionary action. All specific elements relating to particular hazard classes shall be used. In addition, general precautionary statements not linked to a certain hazard class or category shall also be used where relevant.

To provide flexibility in the application of precautionary phrases, combinations or consolidations of precautionary statements are encouraged to save label space and improve readability. The matrix and the Tables in Part 1 of this Annex include a number of combined precautionary statements. However, these are only examples and suppliers may further combine and consolidate phrases where this contributes to clarity and comprehensibility of label information in accordance with Articles 22 and 28(3).

Notwithstanding Article 22 the precautionary statements that appear on labels or in safety data sheets may incorporate minor textual variations from those set out in this Annex where these variations assist in communicating safety information and the safety advice is not diluted or compromised. These may include spelling variations, synonyms or other equivalent terms appropriate to the region where the product is supplied and used.’

(a) Table 6.1 is amended as follows:

(i) The entry concerning code P103 is replaced by the following:

‘P103	Read carefully and follow all instructions	As appropriate		Consumer products – *omit where P202 is used’*

(b) Table 6.2 is amended as follows:

(i) The entries concerning codes P201 and P202 are replaced by the following:

‘P201	Obtain special instructions before use.	Explosives (section 2.1)	Unstable explosive	
		Germ cell mutagenicity (section 3.5)	1A,1B, 2	Consumer products – *omit where P202 is used’*
		Carcinogenicity (section 3.6)	1A,1B, 2	
		Reproductive toxicity (section 3.7)	1A,1B, 2	
		Reproductive toxicity — effects on or via lactation (section 3.7)	Additional category	
P202	Do not handle until all safety precautions have been read and understood	Flammable gases (section 2.2)	A, B (chemically unstable gases)	
		Germ cell mutagenicity (section 3.5)	1A,1B, 2	
		Carcinogenicity (section 3.6)	1A,1B, 2	
		Reproductive toxicity (section 3.7)	1A,1B, 2	
		Reproductive toxicity, effects on or via lactation (section 3.7)	Additional category	

(ii) The entry concerning code P210 is replaced by the following:

‘P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	Explosives (section 2.1)	Divisions 1.1, 1.2, 1.3, 1.4, 1.5	
		Flammable gases (section 2.2)	1A, 1B, 2	
		Aerosols (section 2.3)	1, 2, 3	
		Flammable liquids (section 2.6	1, 2, 3	
		Flammable solids (section 2.7)	1, 2	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F’	
		Desensitised explosives (section 2.17)	1, 2, 3, 4’	

(iii) The entry concerning code P212 is inserted:

‘P212	Avoid heating under confinement or reduction of the desensitising agent	Desensitised explosives (section 2.17)	1, 2, 3, 4’	

(iv) The entry concerning code P222 is replaced by the following:

‘P222	Do not allow contact with air.	Flammable gases (section 2.2)	Pyrophoric gas	*– if emphasis of the hazard statement is deemed necessary.’*
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	

(v) The entry concerning code P230 is replaced by the following:

‘P230	Keep wetted with ...	Explosives (section 2.1)	Divisions 1.1, 1.2, 1.3, 1.5	Manufacturer/ supplier to specify appropriate material – *for substances and mixtures which are wetted, diluted, dissolved or suspended with a phlegmatiser in order to suppress their explosive properties*
		Desensitised explosives (section 2.17)	1, 2, 3, 4	Manufacturer/ supplier to specify appropriate material’

(vi) The entry concerning code P233 is replaced by the following:

‘P233	Keep container tightly closed.	Flammable liquids (section 2.6)	1, 2, 3	- if the liquid is volatile and may generate an explosive atmosphere
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Desensitised explosives (section 2.17)	1, 2, 3, 4	
		Acute toxicity – inhalation (section 3.1)	1, 2, 3	- if the chemical is volatile and may generate a hazardous atmosphere’
		Specific target organ toxicity – single exposure; respiratory tract irritation (section 3.8)	3	
		Specific target organ toxicity – single exposure; narcotic effects (section 3.8)	3	

(vii) The entry concerning code P280 is replaced by the following:

‘P280	Wear protective gloves/protective clothing/eye protection/face protection/ hearing protection/…	Explosives (section 2.1)	Unstable explosive and divisions 1.1, 1.2, 1.3, 1.4, 1.5	Manufacturer/ supplier to specify the appropriate type of personal protective equipment.
		Flammable gases (section 2.2)	Pyrophoric gas	
		Flammable liquids (section 2.6)	1, 2, 3	
		Flammable solids (section 2.7)	1, 2	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Self-heating substances and mixtures (section 2.11)	1, 2	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2, 3	
		Oxidizing liquids (section 2.13)	1, 2, 3	
		Oxidizing solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F	
		Desensitised explosives (section 2.17)	1, 2, 3, 4	
		Acute toxicity – dermal (section 3.1)	1, 2, 3, 4	– *Specify protective gloves/clothing.* Manufacturer/ supplier may further specify type of equipment where appropriate.
		Skin corrosion (section 3.2)	1A, 1B, 1C	– *Specify protective gloves/clothing and eye/face protection.* Manufacturer/ supplier may further specify type of equipment where appropriate.
		Skin irritation (section 3.2)	2	– *Specify protective*

		Skin sensitization (section 3.4)	1, 1A, 1B	*gloves.* Manufacturer/ supplier may further specify type of equipment where appropriate.
		Serious eye damage (section 3.3)	1	– *Specify eye/face protection.* Manufacturer/ supplier may further specify type of equipment where appropriate.
		Eye irritation (chapter 3.3)	2	
		Germ cell mutagenicity (chapter 3.5)	1A, 1B, 2	Manufacturer/ supplier to specify the appropriate type of personal protective equipment.'
		Carcinogenicity (section 3.6)	1A, 1B, 2	
		Reproductive toxicity (section 3.7)	1A, 1B, 2	

(b) Table 6.3 is amended as follows:

(i) The entries concerning code P301 and P302 are replaced by the following:

'P301	IF SWALLOWED:	Acute toxicity – oral (section 3.1)	1, 2, 3, 4	
		Skin corrosion (section 3.2)	1, 1A, 1B, 1C	
		Aspiration Hazard (section 3.10)	1	
P302	IF ON SKIN:	Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2	
		Acute toxicity – dermal (section 3.1)	1, 2, 3, 4	
		Skin irritation (section 3.2)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B'	

(ii) The entry concerning code P332 is replaced by the following:

'P332	If skin irritation occurs:	Skin irritation (section 3.2)	2	may be omitted if P333 is given on the

				label.’

(iii) The entry concerning codes P370 and 371 are replaced by the following:

‘P370	In case of fire:	Explosives (section 2.1)	Unstable explosives and divisions 1.1, 1.2, 1.3, 1.4, 1.5	
		Oxidising gases (section 2.4)	1	
		Flammable liquids (section 2.6)	1, 2, 3	
		Flammable solids (section 2.7)	1, 2	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2, 3	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic Peroxides (section 2.15)	Types A, B, C, D, E, F	
		Desensitised explosives (section 2.17)	1, 2, 3’	
‘P371	In case of major fire and large quantities:	Oxidising liquids (section 2.13)	1	
		Oxidising solids (section 2.14)	1	
		Desensitised explosives (section 2.17)	4’	

(iv) The entry concerning code P375 is replaced by the following:

'P375	Fight fire remotely due to the risk of explosion.	Explosives (section 2.1)	Division 1.4	- for explosives of division 1.4 (compatibility group S) in transport packaging.’

		Self-reactive substances and mixtures (section 2.8)	Type B	
		Oxidising liquids (section 2.13)	1	
		Oxidising solids (section 2.14)	1	
		Organic peroxides (section 2.15)	Type B	
		Desensitised explosives (section 2.17)	1, 2, 3, 4’	

(v) The entry concerning code P377 is replaced by the following:

‘P377	Leaking gas fire: Do not extinguish, unless leak can be stopped safely.	Flammable gases (section 2.2)	1A, 1B, 2’	

(vi) The entry concerning code P380 is replaced by the following:

‘P380	Evacuate area.	Explosives (section 2.1)	Unstable explosives, Divisions 1.1, 1.2, 1.3, 1.4, 1.5	
		Self-reactive substances and mixtures (section 2.8)	Types A, B	
		Oxidising liquids (section 2.13)	1	
		Oxidising solids (section 2.14)	1	
		Organic peroxides (section 2.15)	Types A, B’	
		Desensitised explosives (section 2.17)	1, 2, 3, 4’	

(vii) The entry concerning code P381 is replaced by the following:

‘P381	In case of leakage eliminate all ignition sources	Flammable gases (section 2.2)	1A, 1B, 2’	

(viii) The entry concerning code P301 + P312 is replaced by the following:

‘P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/ …/if you feel unwell	Acute toxicity – oral (section 3.1)	4	…Manufacturer/ supplier to specify the appropriate source of emergency medical advice’

(ix) The entry concerning code P302 + P352 is replaced by the following:

‘P302 + P352	IF ON SKIN: Wash with plenty of water/….	Acute toxicity – dermal (section 3.1)	1, 2, 3, 4	…Manufacturer/ supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.’
		Skin irritation (section 3.2)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B	

(x) The entries concerning codes P370 + P380 + P375 and P371 + P380 + P375 are replaced by the following:

‘P370 + P380 + P375	In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.	Explosives (section 2.1)	Division 1.4	- for explosives of division 1.4 (compatibility group S) in transport packaging’
		Desensitised explosives (section 2.17)	1, 2, 3	
P371 + P380 + P375	In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.	Oxidising liquids (section 2.13)	1	
		Oxidising solids (section 2.14)	1	
		Desensitised explosives (section 2.17)	4	

(d) Table 6.4 is amended as follows:

(i) The entry concerning code P401 is replaced by the following:

'P401	Store in accordance with …	Explosives (section 2.1)	Unstable explosives and Divisions 1.1, 1.2, 1.3, 1.4, 1.5	**…** Manufacturer/ supplier to specify local/regional/ national/ international regulations as applicable. ’
		Desensitised explosives (section 2.17)	1, 2, 3, 4	

(ii) The entry concerning code P403 is replaced by the following:

‘P403	Store in a well-ventilated place.	Flammable gases (section 2.2)	1A, 1B, 2	
		Oxidising gases (section 2.4)	1	
		Gases under pressure (section 2.5)	Compressed gas	
			Liquefied gas	
			Refrigerated liquefied gas	
			Dissolved gas	
		Flammable liquids (section 2.6)	1, 2, 3	- for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.
		Organic peroxides (section 2.15)		
		Acute toxicity – inhalation (section 3.1)	1, 2, 3	– if the substance or mixture is

		Specific target organ toxicity – single exposure; respiratory tract irritation (section 3.8)	3	volatile and may generate a hazardous atmosphere.'
		Specific target organ toxicity – single exposure; narcotic effects (section 3.8)	3	

(e) Table 6.5 is amended as follows:

(i) The entry concerning code P501 is replaced by the following:

'P501	Dispose of contents/container to **...**	Flammable liquids (section 2.6)	1, 2, 3	……in accordance with local/regional/ national/ international regulation (to be specified). Manufacturer/ supplier to specify whether disposal requirements apply to contents, container or both**.'**
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2, 3	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F	
		Desensitised explosives (section 2.17)	1, 2, 3, 4	
		Acute toxicity – oral (section 3.1)	1, 2, 3, 4	
		Acute toxicity – dermal (section 3.1)	1, 2, 3, 4	
		Acute toxicity – inhalation (section 3.1)	1, 2, 3	
		Skin corrosion (section 3.2)	1, 1A, 1B, 1C	
		Respiratory sensitisation (section 3.4)	1, 1A, 1B	
		Skin sensitisation (section 3.4)	1, 1A, 1B	
		Germ cell mutagenicity (section 3.5)	1A, 1B, 2	
		Carcinogenicity (section 3.6)	1A, 1B, 2	
		Reproductive toxicity	1A, 1B, 2	

		(section 3.7)		
		Specific target organ toxicity – single exposure (section 3.8)	1, 2	
		Specific target organ toxicity – single exposure; respiratory tract irritation (section 3.8)	3	
		Specific target organ toxicity – single exposure; narcotic effects (section 3.8)	3	
		Specific target organ toxicity – repeated exposure (section 3.9)	1, 2	
		Aspiration hazard (section 3.10)	1	
		Hazardous to the aquatic environment – acute aquatic hazard (section 4.1)	1	
		Hazardous to the aquatic environment – chronic aquatic hazard (section 4.1)	1, 2, 3, 4	

(ii) The following new entry is inserted after code P502:

‘P503	Refer to manufacturer/ supplier/… for information on disposal/recovery/ recycling	Explosives (chapter 2.1)	Unstable explosives and Divisions 1.1, 1.2, 1.3, 1.4, 1.5	… Manufacturer/ supplier to specify appropriate source of information in accordance with local/regional/ national/ international regulations as applicable.’

(f) Table 1.2. is amended as follows:

(i) The following new entry is inserted:

‘P212	Avoid heating under confinement or reduction of the desensitising agent

ANNEX V

Annex V to Regulation (EC) No 1272/2008 is amended as follows:

1. Part 1, section 1.2 is amended as follows:

   a) 'In column 2, the sentence "Flammable gases, hazard category 1" is replaced by '"Flammable gases, hazard categories 1A, 1B".'
   b) In column 2, the sentence ' "Section 2.17 Desensitised explosives, hazard categories 1, 2, 3, 4" is added after the last entry.'

ANNEX VI

1. Part 1 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

a) In Table 1.1 the row concerning Flammable gases is replaced by the following:

'Flammable gases	Flam. Gas 1A Flam. Gas 1B Flam. Gas 2 Pyr. Gas Chem. Unst. Gas A Chem. Unst. Gas B'

b) In Table 1.1 the following row is added after the row "Substance or mixture corrosive to metals":

'Desensitised explosives	Desen. Expl. 1 Desen. Expl. 2 Desen. Expl. 3 Desen. Expl. 4'