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Legislation

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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE

of 29 July 1983

adapting to technical progress for the fifth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(83/467/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹⁾, as last amended by Directive 79/831/EEC ⁽²⁾, and in particular Article 19 thereof,

Whereas experience shows that it is necessary to adapt the list of dangerous substances in Annex I to Directive 67/548/EEC in the light of present scientific and technical knowledge, so as to enter further substances on the list, to explain certain criteria for the classification of these substances and to revise the classification and labelling of some of them;

Whereas Article 2 of Directive 67/548/EEC defines as dangerous *inter alia* explosive, oxidizing, extremely flammable, highly flammable, very toxic, toxic, harmful, corrosive and irritant substances and preparations according to general criteria; whereas Article 16 lays down the symbols and indications of danger to be used for the labelling of such substances and preparations; whereas these symbols and

indications of danger are illustrated in Annex II of Directive 67/548/EEC; whereas, to take into account the new categories of danger included in the Directive, Annex II must be amended;

Whereas Annexes III and IV to Directive 67/548/EEC define the indications of special risks (R phrases) and safety advice (S phrases); whereas, in view of the advances in knowledge, certain special risks can be better identified and certain safety advice better formulated; whereas, under these circumstances, Annexes III and IV need to be amended;

Whereas Articles 5 and 8 (2) of Directive 67/548/EEC lay down provisions on the packaging and provisional labelling of dangerous substances not contained in Annex I thereof; whereas these provisions must, in particular, be in accordance with the criteria laid down in part II (B) of Annex VI, which lays down the definition of corrosion criteria and irritation criteria, and part II (D), which contains a guide to the labelling of dangerous substances and the criteria for the choice of phrases indicating the special risks (R phrases) and the safety advice (S phrases) assigned to dangerous substances; whereas in these circumstances Annex VI must be expanded;

Whereas the provisions of this Directive are in conformity with the opinion of the Committee on the adaptation to technical progress of the Directives for the elimination of technical barriers to trade in dangerous substances and preparations,

⁽¹⁾ OJ No 196, 16. 8. 1967, p. 1.

⁽²⁾ OJ No L 259, 15. 10. 1979, p. 10.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is hereby amended as follows:

- 1. The general remark in the preamble to Annex I (List of dangerous substances) is expanded as follows:
‘More particularly in the case of salts (under any denomination such as mentioned in Annex I), these are considered in Annex I both in their anhydrous and their hydrated form unless expressly specified to the contrary.’
- 2. The substance mentioned in Annex I to this Directive shall be added to Annex I (List of dangerous substances).
- 3. The following corrections are made to Annex I (List of dangerous substances):

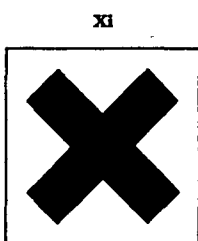
Reference No	Substance	Error	Corrections
603-072-00-7	1,4-Bis(2,3-epoxypropoxy) butane (Butanedioldiglycidyl ether)	R: 20/21-36/38-40	R: 20/21-36/38-43
607-106-00-1	8,9-Dinorborn-5-ene-2,3-dicarboxylic anhydride (In the English language the designation of this substance in Directive 81/957/EEC is incorrect.)	R: 22-36/37/38-43 (In all languages except French.)	R: 22-36/37/38-42
612-059-00-5	3,6-Diazaoctanethylenediamine (Triethylenetetramine)	R: 21/34-43	R: 21-34-43
615-005-01-6	Diphenylmethane-4,4'-diisocyanate, Isomeres and homologues, blending of (1) and (2)	S: the numbers are missing	S: 26-28-38-45
615-006-00-4	Toluene-2,4-di-isocyanate (1) Toluene-2,6-di-isocyanate (2) Mixtures of (1) and (2)	Only in the French language: designation of the substance is incorrect	Only in the French language: 2,4-Diisocyanate de toluyène (1) 2,6-Diisocyanate de toluyène (2) Mélanges de (1) et (2)

4. Annex I (List of dangerous substances) is amended as follows:

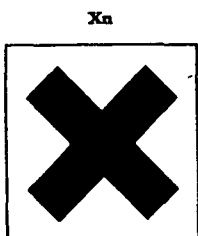
(1) No 607-107-00-7 2-Ethylhexyl acrylate
After R: 37/38 add: -43

(2) No 615-011-00-1 Hexamethylene-di-isocyanate
The statements of special risk phrases are replaced by the following:
R: 23-36/37/38-42/43

(3) No 601-023-00-4 Ethylbenzene
The symbol



is replaced by the symbol



The statements of special risks and safety advice are replaced by the following:

R: 11-20
S: 16-24/25-29

5. Annex II is replaced by Annex II to this Directive.

6. Annex III (Nature of the special risks attaching to dangerous substances) is amended as follows:

(1) The following phrases are added:

R 41 Risiko for alvorlig øjenskade.
Gefahr ernster Augenschäden.
Κίνδυνος σοβαρών οφθαλμικών βλαβών.
Risk of serious damage to eyes.
Risque de lésions oculaires graves.
Rischio di gravi lesioni oculari.
Gevaar voor ernstig oogletsel.

- R 44 Eksplosionsfarlig ved opvarmning under indeslutning.
Explosionsgefahr bei Erhitzen unter Einschuß.
Κίνδυνος εκρήξεως εάν θερμανθεί σε κλειστή ατμόσφαιρα.
Risk of explosion if heated under confinement.
Risque d'explosion si chauffé en ambiance confinée.
Rischio di esplosione per riscaldamento in ambiente confinato.
Ontploffingsgevaar bij verwarming in afgesloten toestand.
- R 45 Kan fremkalde kræft.
Kann Krebs erzeugen.
Μπορεί να προκαλέσει καρκίνο.
May cause cancer.
Peut causer le cancer.
Può provocare il cancro.
Kan kanker veroorzaken.
- R 46 Kan forårsage arvelige genetiske skader.
Kann vererbare Schäden verursachen.
Μπορεί να προκαλέσει κληρονομικές γενετικές βλάβες.
May cause heritable genetic damage.
Peut causer des altérations génétiques héréditaires.
Può provocare alterazioni genetiche ereditarie.
Kan erfelijke genetische schade veroorzaken.
- R 47 Kan medføre fosterskader.
Kann Mißbildungen verursachen.
Μπορεί να προκαλέσει εκ γενετής παραμορφώσεις.
May cause birth defects.
Peut causer des malformations congénitales.
Può provocare malformazioni congenite.
Kan geboortefwijkingen veroorzaken.
- R 48 Alvorlig sundhedsfare ved længere tids påvirkning.
Gefahr ernster Gesundheitsschäden bei längerer Exposition.
Κίνδυνος σοβαρής βλάβης για την υγεία κατόπιν παρατεταμένης εκθέσεως.
Danger of serious damage to health by prolonged exposure.
Risque d'effets graves pour la santé en cas d'exposition prolongée.
Pericolo di gravi danni per la salute in caso di esposizione prolungata.
Gevaar voor ernstige schade aan de gezondheid bij langdurige blootstelling.

- (2) In the German language the term 'explosionsfähig' is replaced by the term 'explosionsgefährlich' in phrases R 1, R 2, R 4 and R 16; the term 'leicht explosionsfähig' is replaced by the term 'besonders explosionsgefährlich' in phrase 3. The term 'hochgiftige' is replaced by the term 'sehr giftige' in phrase R 32.

7. Annex IV (Safety advice concerning dangerous chemical substances) is amended as follows:

- (1) The following phrases are deleted:

- S 10: Keep contents wet.
S 11: Avoid contact with air.
S 31: Keep away from explosive materials.

(2) The following phrases are added:

- S 46 Ved indtagelse, kontakt omgående læge og vis denne beholder eller etiket.
Bei Verschlucken sofort ärztlichen Rat einholen und Verpackung oder Etikett vorzeigen.
Σε περίπτωση καταπόσεως, να ζητηθεί αμέσως ιατρική συμβουλή και να επιδειχθεί το δοχείο ή η ετικέτα.
If swallowed, seek medical advice immediately and show this container or label.
En cas d'ingestion consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
In caso d'ingestione consultare immediatamente il medico e mostrargli il contenitore o l'etichetta.
In geval van inslikken onmiddellijk een arts raadplegen en verpakking of etiket tonen.
- S 47 Må ikke opbevares ved temperaturer på over ... °C (angives af fabrikanten).
Nicht bei Temperaturen über ... °C aufbewahren (vom Hersteller anzugeben).
Διατηρείται σε θερμοκρασία ίση ή κατώτερη των ... °C (προς προσδιορισμό από τον κατασκευαστή).
Keep at temperature not exceeding ... °C (to be specified by the manufacturer).
Conserver à une température ne dépassant pas ... °C (à préciser par le fabricant).
Conservare a temperatura non superiore a ... °C (da precisare da parte del fabbricante).
Bewaren bij een temperatuur beneden ... °C (aan te geven door de fabrikant).
- S 48 Holdes befugtet med ... (passende middel angives af fabrikanten).
Feucht halten mit ... (geeignetes Mittel vom Hersteller anzugeben).
Διατηρείται υγρό με ... (κατάλληλο υγρό που πρέπει να καθοριστεί από τον κατασκευαστή).
Keep wetted with ... (appropriate material to be specified by the manufacturer).
Maintenir humide avec ... (moyen approprié à préciser par le fabricant).
Mantenere umido con ... (mezzo appropriato da precisare da parte del fabbricante).
Inhoud vochtig houden met ... (middel aan te geven door de fabrikant).
- S 49 Må kun opbevares i den originale emballage.
Nur im Originalbehälter aufbewahren.
Διατηρείται μόνο μέσα στο αρχικό δοχείο.
Keep only in the original container.
Conserver uniquement dans le récipient d'origine.
Conservare soltanto nel recipiente originale.
Uitsluitend in de oorspronkelijke verpakking bewaren.

- S 50 Må ikke blandes med ... (angives af fabrikanten),
 Nicht mischen mit ... (vom Hersteller anzugeben).
 Να μην αναμιχθεί με ... (καθορίζεται από τον κατασκευαστή).
 Do not mix with ... (to be specified by the manufacturer).
 Ne pas mélanger avec ... (à spécifier par le fabricant).
 Non mescolare con ... (da specificare da parte del fabbricante).
 Niet vermengen met ... (aan te geven door de fabrikant).
- S 51 Må kun bruges på steder med god ventilation.
 Nur in gut gelüfteten Bereichen verwenden.
 Χρησιμοποιείται μόνο σε χώρους με πολύ καλό αερισμό.
 Use only in well ventilated areas.
 Utiliser seulement dans des zones bien ventilées.
 Usare soltanto in luogo ben ventilato.
 Uitsluitend op goed geventileerde plaatsen gebruiken.
- S 52 Bør ikke anvendes til større flader i beboelses- eller opholdsrum
 Nicht großflächig für Wohn- und Aufenthaltsräume zu verwenden.
 Να μη χρησιμοποιηθεί σε ευρείες επιφάνειες σε κατοικούμενους χώρους.
 Not recommended for interior use on large surface areas.
 Ne pas utiliser sur de grandes surfaces dans les locaux habités.
 Non utilizzare su grandi superfici in locali abitati.
 Niet voor gebruik op grote oppervlakken in woon- en verblijfruimtes.

(3) The following combinations are added to the combinations of S-phrases:

- S 3/14 Opbevares køligt og adskilt fra ... (uforligelige stoffer angives af fabrikanten).
 An einem kühlen, von ... entfernten Ort aufbewahren (die Stoffe, mit denen Kontakt vermieden werden muß, sind vom Hersteller anzugeben).
 Διατηρείται σε δροσερό μέρος μακριά από ... (ασύμβατα υλικά που υποδεικνύονται από τον κατασκευαστή).
 Keep in a cool place away from ... (incompatible materials to be indicated by the manufacturer).
 Conserver dans un endroit frais à l'écart des ... (matières incompatibles à indiquer par le fabricant).
 Conservare in luogo fresco lontano da ... (materiali incompatibili da precisare da parte del fabbricante).
 Bewaren op een koele plaats verwijderd van ... (stoffen, waarmee contact vermeden dient te worden, aan te geven door de fabrikant).
- S 3/9/14 Opbevares køligt, godt ventileret og adskilt fra ... (uforligelige stoffer angives af fabrikanten).
 An einem kühlen, gut gelüfteten Ort, entfernt von ... aufbewahren (die Stoffe, mit denen Kontakt vermieden werden muß, sind vom Hersteller anzugeben).

Διατηρείται σε δροσερό και καλά αεριζόμενο μέρος μακριά από ... (ασύμβατα υλικά που υποδεικνύονται από τον κατασκευαστή).

Keep in a cool, well ventilated place away from ... (incompatible materials to be indicated by the manufacturer).

Conserver dans un endroit frais et bien ventilé à l'écart des ... (matières incompatibles à indiquer par le fabricant).

Conservare in luogo fresco e ben ventilato lontano da ... (materiali incompatibili da precisare da parte del fabbricante).

Bewaren op een koele, goed geventileerde plaats verwijderd van ... (stoffen, waarmee contact vermeden dient te worden, aan te geven door de fabrikant).

S 3/9/49 Må kun opbevares i originalemballagen på et køligt, godt ventileret sted.

Nur im Originalbehälter an einem kühlen, gut gelüfteten Ort aufbewahren.

Διατηρείται μόνο μέσα στο αρχικό δοχείο σε δροσερό και καλά αεριζόμενο μέρος.

Keep only in the original container in a cool well ventilated place.

Conserver uniquement dans le récipient d'origine dans un endroit frais et bien ventilé.

Conservare soltanto nel contenitore originale in luogo fresco e ben ventilato.

Uitsluitend in de oorspronkelijke verpakking bewaren op een koele, goed geventileerde plaats.

S 3/9/14/49 Må kun opbevares i originalemballagen på et køligt, godt ventileret sted og adskilt fra ... (uforligelige stoffer angives af fabrikanten).

Nur im Originalbehälter an einem kühlen, gut gelüfteten Ort, entfernt von ... aufbewahren (die Stoffe, mit denen Kontakt vermieden werden muß, sind vom Hersteller anzugeben).

Διατηρείται μόνο μέσα στο αρχικό δοχείο σε δροσερό και καλά αεριζόμενο μέρος από ... (ασύμβατα υλικά που υποδεικνύονται από τον κατασκευαστή).

Keep only in the original container in a cool well ventilated place away from ... (incompatible materials to be indicated by the manufacturer).

Conserver uniquement dans le récipient d'origine dans un endroit frais et bien ventilé à l'écart de ... (matières incompatibles à indiquer par le fabricant).

Conservare soltanto nel contenitore originale in luogo fresco e ben ventilato lontano da ... (materiali incompatibili da precisare da parte del fabbricante).

Uitsluitend in de oorspronkelijke verpakking bewaren op een koele, goed geventileerde plaats verwijderd van ... (stoffen, waarmee contact vermeden dient te worden, aan te geven door de fabrikant).

S 47/49 Må kun opbevares i originalemballagen ved en temperatur på ikke over ... °C (angives af fabrikanten).

Nur im Originalbehälter bei einer Temperatur von nicht über ... °C (vom Hersteller anzugeben) aufbewahren.

Διατηρείται μόνο μέσα στο αρχικό δοχείο σε θερμοκρασία ίση ή κατώτερη των ... °C (προς προσδιορισμό από τον κατασκευαστή).

Keep only in the original container at temperature not exceeding ... °C (to be specified by the manufacturer).

Conserver uniquement dans le récipient d'origine à température ne dépassant pas ... °C (à préciser par le fabricant).

Conservare soltanto nel contenitore originale a temperatura non superiore a ... °C (da precisare da parte del fabbricante).

Uitsluitend in de oorspronkelijke verpakking bewaren bij een temperatuur beneden ... °C (aan te geven door de fabrikant).

8. Part II (B) of Annex VI is replaced by the following:

'B. Save where otherwise provided in separate Directives on dangerous preparations, substances and preparations shall be classified as corrosive or as irritant according to the following criteria:

(a) **Corrosion criteria**

A substance or a preparation is considered to be corrosive if, when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least one animal during the test for skin irritation cited in Annex V or during an equivalent method or if the result can be predicted, for example from strongly acid or alkaline reactions.

(b) **Irritation criteria**

A substance or a preparation is considered to be irritant if it causes inflammation of the skin or ocular lesions corresponding to the evaluation of the parameters given below:

1. *Inflammation of the skin*

(i) Inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours and corresponds to the following values determined on the rabbit according to the cutaneous irritation test method cited in Annex V:

- the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is two or more,
- or, in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of two or more calculated for each animal separately has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.

(ii) If practical experience shows the substances and preparations to be capable of inducing a sensitization reaction in a substantial number of persons by skin contact, or on the basis of a positive response in experimental animals.

In the case of the test method for skin sensitization detailed in Annex V or in the case of other adjuvant-type test methods a response in at least 30 % of the animals is considered positive. For any other test method a response in at least 15 % of the animals is considered positive.

2. *Ocular lesion*

Ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours and correspond to the following values

determined on the rabbit according to the eye irritation test method cited in Annex V:

- the mean value of the scores for each type of lesion, calculated over all the animals tested, is one of the following:
 - cornea opacity two or more
 - iris lesion one or more
 - redness of conjunctivae 2,5 or more
 - oedema of conjunctivae (chemosis) two or more
- or, in the case where the Annex V test has been completed using three animals, either cornea opacity, iris lesion, redness of conjunctive or oedema of conjunctive (chemosis) equivalent to a mean value such as is quoted above, but calculated for each animal separately, has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) and for an effect should be used in calculating the respective means values.'

9. Part II (D) of Annex VI is replaced by Annex III to this Directive.

Article 2

Member States shall adopt and publish before 1 January 1985 the measures needed to comply with this Directive and shall immediately inform the Commission thereof.

They shall apply these measures by 1 January 1986 at the latest.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 29 July 1983.

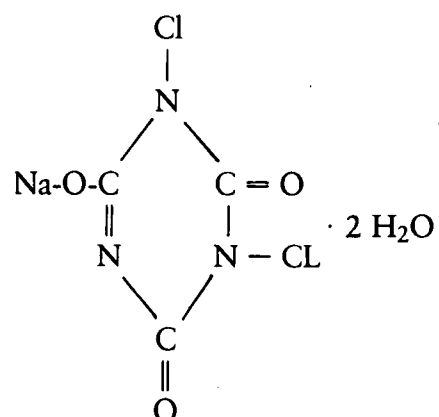
For the Commission

Karl-Heinz NARJES

Member of the Commission

BILAG I — ANHANG I — ΠΑΡΑΡΤΗΜΑ I — ANNEX I — ANNEXE I — ALLEGATO I — BIJLAGE I

Cas No



Cas No 613-030-01-7

Dichlorisocyanursyre, natriumsalt dihydrat

Natriumdichlorisocyanuratdihydrat

Διένυδρο άλας νατρίου του διχλώροϊσοκυανουρικού οξέος

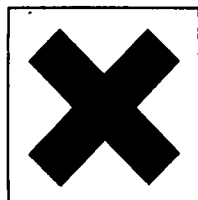
Sodium dichloroisocyanurate, dihydrate

Sel de sodium de l'acide dichloroisocyanurique dihydraté

Dicloroisocianurato sodico biidrato

Natriumdichloorisocyanuraatdihydraat

Xn



R: 22-31-36/37

S: 8-26-41

BILAG II — ANHANG II — ΠΑΡΑΡΤΗΜΑ II — ANNEX II — ANNEXE II — ALLEGATO II — BIJLAGE II**BILAG II****Faresymboler og farebetegnelser****ANHANG II****Gefahrensymbole und -bezeichnungen****ΠΑΡΑΡΤΗΜΑ II****Σύμβολα και ενδείξεις κινδύνου****ANNEX II****Symbols and indications of danger****ANNEXE II****Symboles et indications de danger****ALLEGATO II****Simboli e indicazioni di rischio****BIJLAGE II****Gevaarsymbolen en -aanduidingen**

Bemærk: Bogstaverne E, O, F, F+, T, T+, C, Xn, Xi indgår ikke i symbolet.

Anmerkung: Die Buchstaben E, O, F, F+, T, T+, C, Xn, Xi, sind nicht Bestandteil des Gefahrensymbols.

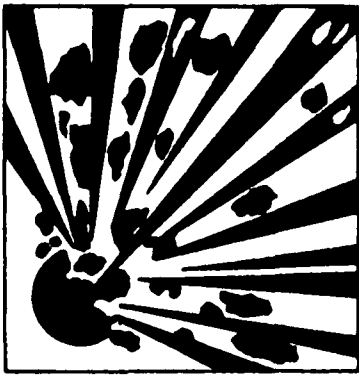
Σημείωση: Τα γράμματα E, O, F, F+, T, T+, C, Xn, Xi δεν αποτελούν μέρος του συμβόλου.

Note: The letters E, O, F, F+, T, T+, C, Xn, Xi do not form part of the symbol.

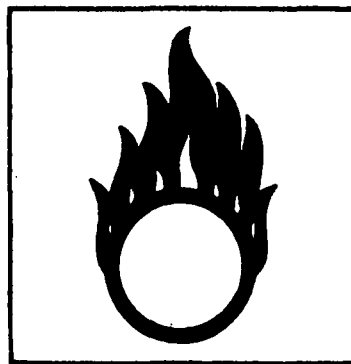
Remarque: Les lettres E, O, F, F+, T, T+, C, Xn, Xi ne font pas partie du symbole.

Nota: Le lettere E, O, F, F+, T, T+, C, Xn, Xi non fanno parte del simbolo.

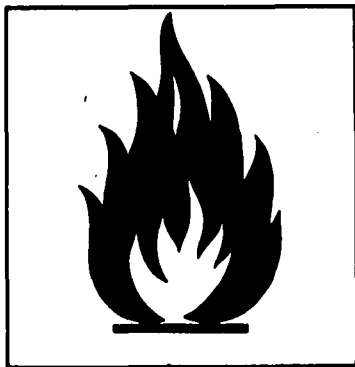
Opmerking: De letters E, O, F, F+, T, T+, C, Xn, Xi maken geen deel uit van het symbool.

E

Eksplisiv
Explosionsgefährlich
Εκρηκτικό
Explosive
Explosif
Esplosivo
Ontploffbaar

O

Brandnærende (oxiderende)
Brandfördernd
Οξειδωτικό
Oxidizing
Comburant
Comburente
Oxyderend

F

Let antændelig
Leichtentzündlich
Λίαν εύφλεκτο
Highly flammable
Facilement inflammable
Facilmente infiammabile
Licht ontvlambaar

F +

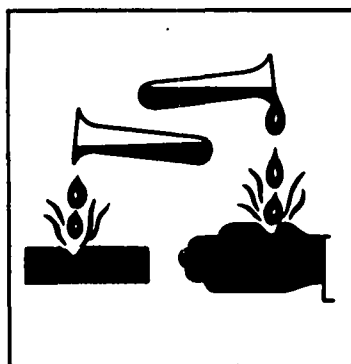
Yderst let antændelig
Hochentzündlich
Εξόχως εύφλεκτο
Extremely flammable
Extrêmement inflammable
Estremamente infiammabile
Zeer licht ontvlambaar

T

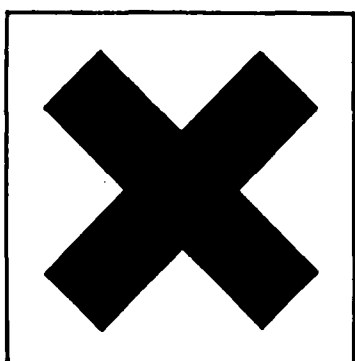
Giftig
Giftig
Τοξικό
Toxic
Toxique
Tossico
Vergiftig

T +

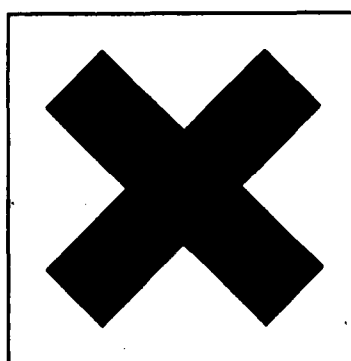
Meget giftig
Sehr giftig
Λίαν τοξικό
Very toxic
Très toxique
Molto tossico
Zeer vergiftig

C

Ætsende
Ätzend
Διαβρωτικό
Corrosive
Corrosif
Corrosivo
Corrosief

Xn

Sundhedsskadelig
Gesundheitsschädlich
Επιβλαβές
Harmful
Nocif
Nocivo
Schadelijk

Xi

Lokalirriterende
Reizend
Ερεθιστικό
Irritant
Irritant
Irritante
Irriterend

ANNEX III**'ANNEX VI, PART II (D)'****Guide to the classification and labelling of dangerous substances and preparations; criteria for the choice of phrases indicating special risks (R phrases) and safety advice (S phrases)****CONTENTS**

- 1. General introduction**
- 2. Classification as dangerous and choice of risk phrases**
 - 2.1. Introduction
 - 2.2. Physico-chemical properties
 - 2.3. Toxicological properties
 - 2.4. Criteria for classification, choice of symbols, indication of danger and choice of risk phrases
 - 2.4.1. Explosive
 - 2.4.2. Oxidizing
 - 2.4.3. Extremely flammable
 - 2.4.4. Highly flammable
 - 2.4.5. Flammable
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- 3. Additional criteria concerning specific effects of substances on health**
 - 3.1. Procedure for the classification of substances which may possibly have the effects mentioned in this chapter
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1. GENERAL INTRODUCTION

1.1. The information provided in this document is intended as a guide for all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations. It sets out the general principles governing the classification and labelling of substances and preparations referred to in Article 3 (3) of Directive 67/548/EEC, bearing in mind the exceptions mentioned in Article 3 (3) — 'save where contrary requirements for dangerous preparations are specified in separate Directives'.

1.2. The labelling requirements of this Directive and the separate Directives on dangerous preparations are intended to provide a primary means by which the general public and persons at work are given essential information about dangerous substances and preparations. The label draws the attention of persons handling or using substances and preparations to the inherent danger of certain such materials.

The label may also serve to draw attention to more comprehensive product information on safety and use available in other forms.

1.3. The label takes account of all potential hazards which are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, e.g. diluted. The most severe hazards are highlighted by symbols, such hazards and those arising from other dangerous properties are specified in standard risk phrases, and safety phrases give advice on necessary precautions.

The information is completed by the name of the substance under an internationally recognized chemical nomenclature, and the name and address of the manufacturer, or the distributor or the importer.

1.4. With respect to substances referred to in the second subparagraph of Article 5 (2) of Directive 67/548/EEC, the labelling applied by the manufacturer or his representative remains valid until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

2. CLASSIFICATION AS DANGEROUS AND CHOICE OF RISK PHRASES

2.1. Introduction

The object of classification is to identify all the toxicological and physico-chemical properties of substances and preparations which may constitute a risk during normal handling or use.

- As regards substances for which the information specified in Annex VII is required, most of the necessary data for classification and labelling appear in the 'base set'. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII).
- As regards other substances (e.g. those referred to in Article 5 (2)), the data required for classification and labelling may if necessary be obtained from a number of different sources, for example the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and the literature or information derived from practical experience.

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V. In other cases, the available

data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling criteria.

2.2 Physico-chemical properties

2.2.1. The test methods relating to explosive, oxidizing and flammable properties included in Annex V to this Directive serve to give specific meaning to the general definitions given in Article 2 (2) (a) to (e). Criteria follow directly from the test methods in Annex V as far as they are mentioned.

2.2.2. If adequate information is available to demonstrate in practice that the physico-chemical properties of substances and preparations (apart from organic peroxides) are different from those revealed by the test methods given in Annex V, then such substances and preparations should be classified according to the hazard they present, if any, to those handling the substances and preparations or to other persons.

2.2.3. Organic peroxides are classified as dangerous on the basis of their structure (e.g. R-O-O-H; R₁-O-O-R₂). In general terms, organic peroxides shall be classified as oxidizing, and labelled as under 2.4.2, unless:

- tests carried out in accordance with the methods given in Annex V show the organic peroxide, in the form in which it is placed on the market, to have explosive properties, as under 2.4.1, or
- the organic peroxide is so diluted or phlegmatized that it has neither explosive, oxidizing nor flammable properties.

2.3 Toxicological properties

2.3.1. Classification is concerned with both the acute and long-term effects of these substances and preparations, whether resulting from a single instance of exposure or repeated or prolonged exposure.

2.3.2. Substances and preparations should generally be classified in accordance with the acute toxicity of the marketed product, expressed as LD₅₀ or LC₅₀ as determined by tests on experimental animals. Reference values are given in part I of Annex VI.

If the facts show the existence of effects other than the acute effects indicated by experiments with animals, e.g. carcinogenic, mutagenic, allergenic, sub-acute or chronic effects, the substances or preparations shall be classified according to the magnitude of these effects.

If adequate evidence is available to demonstrate in practice that the toxic effect of substances and preparations on man is, or is likely to be different from that suggested by the experimental results obtained in animal tests then such substances and preparations should be classified according to their toxicity in man.

2.3.3. When the classification is to be established from experimental results obtained in animal tests, the results should have validity for man in that the tests reflect, in an appropriate way, the risks to man.

2.4 Criteria for classification, choice of symbols, indication of danger and choice of risk phrases

Classification must cover both the toxicological and the physico-chemical properties of substances and preparations. The object of choosing risk phrases is to ensure that the specific nature of the potential dangers identified in classification are expressed on the label. For this purpose it is necessary to consider the criteria given for the choice of symbol(s) and risk phrases in each of the sections 2.4.1 to 2.4.11 and chapter 3, for example classification under 2.4.6 does not imply that the sections such as 2.4.7 or 2.4.9 can be ignored.

The criteria are applicable to gaseous substances and preparations but only in so far as they may be subject to the packaging and labelling provisions of this Directive or the separate Directive on preparations.

Notwithstanding the criteria given under 2.4.3, 2.4.4 and 2.4.5, substances and preparations in the form of aerosols shall be subject to the flammability criteria set out in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC.

2.4.1. *Explosive*

Substances and preparations shall be classified as explosive and assigned the symbol 'E' and the indication of danger 'explosive' in accordance with the results of the tests given in Annex V and in so far as the substances and preparations are explosive as placed on the market. One risk phrase is obligatory, it is to be specified on the basis of the following:

- R 2 **Risk of explosion by shock, friction, fire or other sources of ignition**
— substances and preparations including certain organic peroxides but excepting those set out below.
- R 3 **Extreme risk of explosion by shock, friction, fire or other sources of ignition**
— substances and preparations which are particularly sensitive such as picric acid salts, PETN and certain undiluted organic peroxides such as dibenzoyl peroxide.

2.4.2. *Oxidizing*

Substances and preparations shall be classified as oxidizing and assigned the symbol 'O' and the indication of danger 'oxidizing' in accordance with the results of the tests given in Annex V (see also 2.2.3). One risk phrase is obligatory, it is to be specified on the basis of the test results but subject to the following:

- R 11 **Highly flammable**
— organic peroxides which have flammable properties even when not in contact with other combustible material.
- R 8 **Contact with combustible material may cause fire**
— other oxidizing substances and preparations which may cause fire or enhance the risk of fire when in contact with combustible material.
- R 9 **Explosive when mixed with combustible material**
— other substances and preparations which become explosive when mixed with combustible materials, e.g. certain chlorates.

2.4.3. *Extremely flammable*

Substances and preparations shall be classified as extremely flammable and assigned the symbol 'F+' and the indication of danger 'extremely flammable' in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the following criteria:

- R 12 **Extremely flammable**
— Liquid substances and preparations which have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C.

2.4.4. *Highly flammable*

Substances and preparations shall be classified as highly flammable and assigned the symbol 'F' and the indication of danger 'highly flammable' in accordance with the results of the tests given in Annex V. Risk phrases shall be assigned in accordance with the following criteria:

- R 17 **Spontaneously flammable in air**
 — substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy.
- R 11 **Highly flammable**
 — solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition;
 — liquid substances and preparations having a flash point below 21 °C but are not extremely flammable.
- R 12 **Extremely flammable**
 — gaseous substances and preparations which are flammable in air at normal pressure.
- R 13 **Extremely flammable liquefied gas**
 — gaseous substances and preparations which are flammable in air at normal pressure when put on the market in liquefied form.
- R 15 **Contact with water liberates highly flammable gases**
 — substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities, at a minimum rate of 1 litre/kg/h.

2.4.5. *Flammable*

Substances and preparations shall be classified as flammable in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the criteria mentioned below.

- R 10 **Flammable**
 — liquid substances and preparations having a flash point equal to or greater than 21 °C, and less than or equal to 55 °C.
- However, in practice it has been shown that a preparation having a flash point equal to or greater than 21 °C and less than or equal to 55 °C need not be classified as flammable if the preparation could not in any way support combustion and only so long as there is no reason to fear risks to those handling these preparations or to other persons.

2.4.6. *Very toxic*

Substances and preparations shall be classified as very toxic and assigned the symbol 'T+' and the indication of danger 'very toxic' in accordance with the criteria given in part I of Annex VI, as specified below.

Risk phrases shall be assigned in accordance with the following criteria:

- R 28 **Very toxic if swallowed**
 — acute toxicity results:
 LD₅₀ oral, rat: ≤ 25 mg/kg
- R 27 **Very toxic in contact with skin**
 — acute toxicity results:
 LD₅₀ dermal, rat or rabbit: ≤ 50 mg/kg
- R 26 **Very toxic by inhalation**
 — acute toxicity results:
 LC₅₀ inhalation, rat: ≤ 0,5 mg/litre/4 h
- R 39 (*) **Danger of very serious irreversible effects**
 — Strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).

(*) R 26, R 27 or R 28 is also to be assigned to indicate route of administration/exposure.

2.4.7. Toxic

Substances and preparations shall be classified as toxic and assigned the symbol 'T' and the indication of danger 'toxic' in accordance with the criteria given in part I of Annex VI, as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

R 25 Toxic if swallowed

- acute toxicity results:
 LD_{50} oral, rat: $25 < LD_{50} \leq 200$ mg/kg

R 24 Toxic in contact with skin

- acute toxicity results:
 LD_{50} dermal, rat or rabbit: $50 < LD_{50} \leq 400$ mg/kg

R 23 Toxic by inhalation

- acute toxicity results:
 LC_{50} inhalation, rat: $0,5 < LC_{50} \leq 2$ mg/litre/4 h

R 39 (*) Danger of very serious irreversible effects

- strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).

R 48 (*) Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure, by an appropriate route, at levels significantly lower than those quoted in section 2.4.8 (see also 2.3.2 and 2.3.3).

2.4.8. Harmful

Substances and preparations shall be classified as harmful and assigned the symbol 'Xn' and the indication of danger 'harmful' in accordance with the criteria given in part I of Annex VI as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

R 22 Harmful if swallowed

- acute toxicity results:
 LD_{50} oral, rat: $200 < LD_{50} \leq 2\,000$ mg/kg

R 21 Harmful in contact with skin

- acute toxicity results:
 LD_{50} dermal, rat or rabbit: $400 < LD_{50} \leq 2\,000$ mg/kg

R 20 Harmful by inhalation

- acute toxicity results:
 LC_{50} inhalation, rat: $2 < LC_{50} \leq 20$ mg/litre/4 h

R 40 () Possible risk of irreversible effects**

- strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).

(*) R 23, R 24 or R 25 is also to be assigned to indicate route of administration/exposure.

(**) R 20, R 21 or R 22 is also to be assigned to indicate route of administration/exposure.

R 48 (*) Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route, at levels of the order of (see also 2.3.2 and 2.3.3):
 - oral, rat ≤ 50 mg/kg (body weight)/day (**),
 - dermal, rat or rabbit ≤ 100 mg/kg (body weight)/day (**),
 - inhalation, rat $\leq 0,5$ mg/litre 6 h/day (**),

These guide values can apply directly when severe lesions have been observed in a sub-chronic (90 days) toxicity study, but also serve as a guide when interpreting the results of sub-acute (28 days) or chronic (two years) toxicity tests.

R 42 May cause sensitization by inhalation

- if practical evidence is available which shows the substances and preparations to be capable of inducing a sensitization reaction in humans by inhalation, at a greater frequency than would be expected from the response of a normal population.

2.4.9. Corrosive

Substances and preparations shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive' in accordance with the criteria given in Annex VI (B). Risk phrases shall be assigned in accordance with the following criteria:

R 35 Causes severe burns

- if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted.

R 34 Causes burns

- if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted.

2.4.10. Irritant

Non-corrosive substances and preparations shall be classified as irritant and assigned the symbol 'Xi' and the indication of danger 'irritant' in accordance with the criteria given in Annex VI (B) and as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

R 38 Irritating to skin

- if, when applied to healthy intact animal skin for up to four hours, significant inflammation is caused and which is present 24 hours or more after the end of the exposure period.

Inflammation is significant, if the mean value of the scores is two or more for either erythema and eschar formation or oedema formation. The same shall be the case where the test has been completed using three animals if the score for either erythema and eschar formation or oedema formation observed in two or more animals is equivalent to the value of two or more.

R 36 Irritating to eyes

- if, when applied to the eye of the animal, significant ocular lesions are caused and which are present 24 hours or more after instillation of the test material.

Ocular lesions are significant, if the means of the scores have any of the values: cornea opacity equal to or greater than two but less than three; iris lesion equal to or greater than one but not greater than 1,5; redness of the conjunctivae equal to or greater than 2,5; oedema of the conjunctivae (chemosis) equal to or greater than 2. The same shall be the case where the test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than one but less than two and for redness of conjunctivae the value should be equal to three.

(*) R 20, R 21 or R 22 is also to be assigned to indicate route of administration/exposure.

(**) These values are not intended to influence in any way the choice of dose levels in carrying out the tests of Annex V.

R 41 (*) Risk of serious damage to eyes

- if when applied to the eye of the animal severe ocular lesions are caused and which are present 24 hours or more after instillation of the test material.

Ocular lesions are severe if the means of the scores have any of the values:

cornea opacity equal to or greater than three; iris lesion greater than 1,5. The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:

cornea opacity equal to or greater than three; iris lesion equal to two.

R 43 May cause sensitization by skin contact

- if practical experience shows the substances and preparations to be capable of inducing a sensitization reaction in a substantial number of persons by skin contact, or on the basis of a positive response in experimental animals.

In the case of the test method for skin sensitization detailed in Annex V or in the case of other adjuvant-type test methods, a response of at least 30 % of the animals is considered positive. For any other test method a response of at least 15 % of the animals is considered positive.

R 37 Irritating to respiratory system

- substances and preparations which cause serious irritation to the respiratory system, based normally on practical observation.

2.4.11. Other properties

Additional risk phrases shall be assigned to substances and preparations, classified by virtue of 2.4.1 to 2.4.10 above, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

R 1 Explosive when dry

For explosive substances and preparations put on the market in solution or in a wetted form; e.g. nitrocellulose with more than 12,6 % nitrogen.

R 4 Forms very sensitive explosive metallic compounds

For substances and preparations which may form sensitive explosive metallic derivatives, e.g. picric acid, styphnic acid.

R 5 Heating may cause an explosion

For thermally unstable substances and preparations not classified as explosive, e.g. perchloric acid > 50 %.

R 6 Explosive with or without contact with air

For substances and preparations which are unstable at ambient temperatures, e.g. acetylene.

R 7 May cause fire

For reactive substances and preparations: e.g. fluorine, sodium hydrosulphite.

R 14 Reacts violently with water

For substances and preparations which react violently with water, e.g. acetyl chloride, alkali metals, titanium tetrachloride.

R 16 Explosive when mixed with oxidizing substances

For substances and preparations which react explosively with an oxidizing agent, e.g. red phosphorus.

R 18 In use, may form flammable/explosive vapour-air mixture

For preparations not in themselves classified as flammable, which contain volatile components which are flammable in air.

(*) The use of R 34 or R 35 precludes the use of R 41.

- R 19 May form explosive peroxides**
For substances and preparations which may form explosive peroxides during storage, e.g. diethyl ether, 1,4-dioxan.
- R 29 Contact with water liberates toxic gas**
For substances and preparations which in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts, e.g. aluminium phosphide, phosphorus pentasulphide.
- R 30 Can become highly flammable in use**
For preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components.
- R 31 Contact with acids liberates toxic gas**
For substances and preparations which react with acids to evolve toxic gases in dangerous amounts; e.g. sodium hypochlorite, barium polysulphides. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.
- R 32 Contact with acids liberates very toxic gas**
For substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; e.g. salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.
- R 33 Danger of cumulative effects**
For substances and preparations when accumulation in the human body is likely and may cause some concern which, however, is not sufficient to justify the use of R 48.

Previously assigned to substances of Annex I and preparations which were likely to cause damage to health by prolonged exposure or which were likely to be retained and then accumulated within the human body. Now to be progressively replaced when appropriate by R 48.
- R 44 Risk of explosion if heated under confinement**
For substances and preparations not in themselves classified as explosive in accordance with 2.4.1 above but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances which would decompose explosively if heated in a steel drum do not show this effect if heated in less-strong containers.

3. ADDITIONAL CRITERIA CONCERNING SPECIFIC EFFECTS OF SUBSTANCES ON HEALTH

For the record: further guidance applicable to preparations will be published later.

- 3.1. Procedure for the classification of substances which may possibly have the effects mentioned in this chapter**
- 3.1.1. If a manufacturer or his representative has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in section 3.2, 3.3 or 3.4, he or his representative shall provisionally label the substance with R 40 and assign at least the symbol 'Xn' unless the conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 indicate the need for a more severe classification.**
- 3.1.2. Furthermore, the manufacturer or his representative is requested to submit as soon as possible a document summarizing all relevant information to one Member State in which the substance is placed on the market. This summary document should include a bibliography containing all relevant references and may include any relevant unpublished data.**

- 3.1.3. In order to obtain as quickly as possible a harmonized classification for the Community by the procedure defined in Article 21, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

Any Member State which has good reason to believe that the suggested classification and labelling is inappropriate as far as the carcinogenic, mutagenic or teratogenic effects are concerned shall notify the Commission thereof.

- 3.1.4. The provisional labelling applied by a manufacturer or his representative shall remain valid until the entry into force of a decision on the inclusion or non-inclusion of the substance concerned in Annex I.

3.2. Carcinogenic substances

- 3.2.1. For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

- 3.2.2. The following specific risk phrases apply:

Categories 1 and 2:

R 45 May cause cancer

Category 3:

R 40 Possible risk of irreversible effects

- 3.2.3. The following classifications and symbols apply:

Categories 1 and 2: at least: Toxic

Category 3: Harmful

The conclusions reached by application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need of a more severe classification.

3.3. Mutagenic substances

- 3.3.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be mutagenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Category 2

Substances which should be regarded as if they are mutagenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

- appropriate animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible mutagenic effects but in respect of which the available information does not satisfactorily demonstrate heritable genetic damage. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in category 2.

3.3.2. The following specific risk phrases apply:

Categories 1 and 2:

R 46 **May cause heritable genetic damage**

Category 3:

R 40 **Possible risk of irreversible effects**

3.3.3. The following classifications and symbols apply:

Category 1: at least: **Toxic**

Categories 2 and 3: **Harmful**

The conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need for a more severe classification.

3.4. **Teratogenic substances**

3.4.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into two categories:

Category 1

Substances known to be teratogenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and subsequent non-heritable birth defects in offspring.

Category 2

Substances which should be regarded as if they are teratogenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in non-heritable birth defects in offspring, generally on the basis of:

- appropriate animal studies,
- other relevant information.

3.4.2. The following specific risk phrases apply:

Categories 1 and 2

R 47 **May cause birth defects**

3.4.3. The following classifications and symbols apply:

Category 1: at least: Toxic

Category 2: Harmful

The conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need for a more severe classification.

4. CHOICE OF SAFETY ADVICE PHRASES

Safety advice phrases (S phrases) shall be assigned to substances and preparations in accordance with the following general criteria:

S 1 Keep locked up

- Applicability
 - Very toxic and toxic substances and preparations.
- Criteria for use
 - Recommended for very toxic and toxic substances and preparations likely to be used by members of the general public.

S 2 Keep out of reach of children

- Applicability
 - All dangerous substances and preparations.
- Criteria for use
 - *Obligatory* only for all dangerous substances and preparations likely to be used by members of the general public or likely to be used in places to which the general public have access unless there is no reason to fear any danger particularly to children.

S 3 Keep in a cool place

- Applicability
 - Organic peroxides.
 - Other dangerous substances and preparations having a boiling point ≤ 40 °C.
- Criteria for use
 - *Obligatory* for organic peroxides unless S 47 is used.
 - Recommended for other dangerous substances and preparations having a boiling point ≤ 40 °C.

S 4 Keep away from living quarters

- Applicability
 - Very toxic and toxic substances and preparations.
- Criteria for use
 - Normally limited to very toxic and toxic substances and preparations when desirable to supplement S 13; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters.

S 5 Keep contents under ... (appropriate liquid to be specified by the manufacturer)

- Applicability
 - Spontaneously flammable solid substances and preparations.
- Criteria for use
 - Normally limited to special cases, e.g. sodium, potassium or white phosphorous.

- S 6 **Keep under . . . (inert gas to be specified by the manufacturer)**
- Applicability
 - Dangerous substances and preparations which must be kept under an inert atmosphere.
 - Criteria for use
 - Normally limited to special cases, e.g. certain organo metallic compounds.
- S 7 **Keep container tightly closed**
- Applicability
 - Organic peroxides.
 - Substances and preparations which can give off very toxic, toxic, harmful; extremely flammable or highly flammable vapours.
 - Substances and preparations which on contact with moisture give off highly flammable gases.
 - Highly flammable solids.
 - Criteria for use
 - *Obligatory* for organic peroxides in the combination of S 3/7/9.
 - Recommended for the other fields of application mentioned above.
- S 8 **Keep container dry**
- Applicability
 - Substances and preparations which may react violently with water.
 - Substances and preparations which on contact with water liberate highly flammable gases.
 - Substances and preparations which on contact with water liberate very toxic or toxic gases.
 - Criteria for use
 - Normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R 14, R 15 in particular, and R 29.
- S 9 **Keep container in a well-ventilated place**
- Applicability
 - Organic peroxides.
 - Volatile substances and preparations which may give off very toxic, toxic or harmful vapours.
 - Extremely flammable or highly flammable liquids and gases.
 - Criteria for use
 - *Obligatory* for organic peroxides in the combination S 3/7/9.
 - Recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours.
 - Recommended for extremely flammable or highly flammable liquids or gases.
- S 12 **Do not keep the container sealed**
- Applicability
 - Substances and preparations which will by giving off gases or vapours be liable to burst the container.
 - Criteria for use
 - Normally limited to the special cases mentioned above.

S 13 Keep away from food, drink and animal feedingstuffs

- Applicability
 - Very toxic, toxic and harmful substances and preparations.
- Criteria for use
 - Recommended when such substances and preparations are likely to be used by members of the general public.

S 14 Keep away from . . . (incompatible materials to be indicated by the manufacturer)

- Applicability
 - Organic peroxides.
- Criteria for use
 - *Obligatory* for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to produce a particular risk.

S 15 Keep away from heat

- Applicability
 - Substances and preparations which may decompose or which may react spontaneously under the effect of heat.
- Criteria for use
 - Normally limited to special cases, e.g. monomers but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 16 Keep away from sources of ignition — No smoking

- Applicability
 - Extremely flammable or highly flammable liquids and gases.
- Criteria for use
 - Recommended for the substances and preparations mentioned above but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 17 Keep away from combustible material

- Applicability
 - Substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material.
- Criteria for use
 - Available for use in special cases; e.g. to emphasize R 8 and R 9.

S 18 Handle and open container with care

- Applicability
 - Substances and preparations liable to produce an overpressure in the container.
 - Substances and preparations which may form explosive peroxides.
- Criteria for use
 - Normally limited to the abovementioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by members of the general public.

S 20 When using do not eat or drink

- Applicability
 - Very toxic, toxic and corrosive substances and preparations.
- Criteria for use
 - Normally limited to special cases (e.g. arsenic and arsenic compounds; fluoracetates) in particular when any of these are likely to be used by members of the general public.

S 21 When using do not smoke

- Applicability
 - Substances and preparations which produce toxic products on combustion.
- Criteria for use
 - Normally limited to special cases (e.g. halogenated compounds).

S 22 Do not breathe dust

- Applicability
 - All solid dangerous substances and preparations.
- Criteria for use
 - Recommended for those substances and preparations mentioned above which are liable to form inhalable dusts, and when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have been ascribed. However may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.

S 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)

- Applicability
 - All liquid or gaseous dangerous substances and preparations.
- Criteria for use
 - Recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.
 - Recommended for substances and preparations in the form of aerosols which are likely to be used by members of the general public.

S 24 Avoid contact with skin

- Applicability
 - All dangerous substances and preparations.
- Criteria for use
 - Recommended when it is necessary to draw the attention of the user to skin contact risks, not mentioned in the risk phrases which have to be ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 43.

S 25 Avoid contact with eyes

- Applicability
 - Corrosive or irritant substances and preparations.
- Criteria for use
 - Normally limited to special cases, i.e. when it is considered essential to emphasize the risk to eyes denoted by use of R 34, R 35, R 36 or R 41. Thus important if these substances and preparations are likely to be used by members of the general public and eye or face protection may not be available.

- S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
- Applicability
 - Corrosive or irritant substances and preparations.
 - Criteria for use
 - *Obligatory* for corrosive substance and preparations and those to which R 41 has already been ascribed.
 - *Recommended* for irritant substances to which the risk phrase R 36 has already been ascribed.
- S 27 Take off immediately all contaminated clothing
- Applicability
 - Organic peroxides.
 - Very toxic, toxic or corrosive substances and preparations.
 - Criteria for use
 - *Obligatory* for organic peroxides.
 - *Recommended* for very toxic and toxic substances and preparations which are easily absorbed by the skin and for corrosive substances and preparations unless safety phrase S 36 can be considered sufficient by itself.
- S 28 After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer)
- Applicability
 - Very toxic, toxic or corrosive substances and preparations.
 - Criteria for use
 - *Recommended* for the substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid.
- S 29 Do not empty into drains
- Applicability
 - Extremely or highly flammable liquids.
 - Criteria for use
 - *Recommended* for those extremely or highly flammable liquids which are immiscible with water. The intention is to avoid accidents (e.g. fire, explosion) and not to emphasize general pollution problems.
- S 30 Never add water to this product
- Applicability
 - Substances and preparations which react violently with water.
 - Criteria for use
 - Normally limited to special cases (e.g. sulphuric acid) and may be used, as appropriate to give the clearest possible information, either to emphasize R 14 or as an alternative to R 14.
- S 33 Take precautionary measures against static discharges
- Applicability
 - Extremely or highly flammable substances and preparations.
 - Criteria for use
 - *Recommended* for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by members of the general public.

S 34 Avoid shock and friction

- Applicability
 - Explosive substances and preparations.
- Criteria for use
 - *Obligatory* for and normally limited to explosive organic peroxides.

S 35 This material and its container must be disposed of in a safe way

- Applicability
 - Explosive substances and preparations.
 - Very toxic and toxic substances and preparations.
- Criteria for use
 - *Obligatory* for explosive substances and preparations other than organic peroxides.
 - Recommended for very toxic and toxic substances and preparations, particularly when such substances and preparations are likely to be used by members of the general public.

S 36 Wear suitable protective clothing

- Applicability
 - Very toxic, toxic or harmful substances and preparations.
 - Corrosive substances and preparations.
- Criteria for use
 - Recommended for substances and preparations used in industry which are:
 - very toxic, toxic or corrosive, and/or
 - harmful and easily absorbed by the skin and/or
 - liable to damage health by prolonged exposure.

S 37 Wear suitable gloves

- Applicability
 - Very toxic, toxic, harmful or corrosive substances and preparations.
 - Organic peroxides.
 - Substances and preparations irritating to the skin.
- Criteria for use
 - Recommended for very toxic, toxic and corrosive substances and preparations, when S 36 is not used (e.g. viz general public).
 - Recommended for organic peroxides as combination S 37/39.
 - Recommended for substances and preparations irritating to the skin particularly when R 38 is not shown on the label.

S 38 In case of insufficient ventilation wear suitable respiratory equipment

- Applicability
 - Very toxic or toxic substances and preparations.
- Criteria for use
 - Normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

S 39 Wear eye/face protection

- Applicability
 - Organic peroxides.
 - Corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes.
 - Very toxic and toxic substances and preparations.
- Criteria for use
 - Recommended for organic peroxides as the combination S 37/39.
 - Recommended for the corrosive substances and preparations mentioned above, in particular when there is a risk of splashing.
 - Normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.

S 40 To clean the floor and all objects contaminated by this material use ... (to be specified by the manufacturer)

- Applicability
 - All dangerous substances and preparations.
- Criteria for use
 - Normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g. where absorption by powdered material, dissolution by solvent etc. is necessary) and where it is important for health and or safety reasons to provide a warning on the label.

S 41 In case of fire and/or explosion do not breathe fumes

- Applicability
 - Dangerous substances and preparations which on combustion give off very toxic or toxic gases.
- Criteria for use
 - Normally limited to special cases.

S 42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)

- Applicability
 - Substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken.
- Criteria for use
 - Normally limited to special cases.

S 43 In case of fire use ... (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add: Never use water)

- Applicability
 - Extremely flammable, highly flammable and flammable substances and preparations.
- Criteria for use
 - *Obligatory* for substances and preparations which in contact with water or damp air, evolve highly flammable gases.
 - Recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.

S 44 If you feel unwell seek medical advice (show the label where possible)

- Applicability
 - Toxic substances and preparations.
- Criteria for use
 - *Obligatory* for the substances and preparations mentioned above when used in industry and not likely to be used by members of the general public.

- S 45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
- Applicability
 - Very toxic substances and preparations.
 - Toxic substances and preparations.
 - Criteria for use
 - *Obligatory* for the very toxic substances and preparations mentioned above.
 - *Obligatory* for toxic substances and preparations mentioned above when likely to be used by members of the general public.
- S 46 If swallowed, seek medical advice immediately and show this container or label
- Applicability
 - All dangerous substances and preparations other than those which are toxic or very toxic.
 - Criteria for use
 - *Obligatory* for all dangerous substances and preparations mentioned above which are likely to be used by members of the general public, unless there is no reason to fear any danger from swallowing, particularly by children.
- S 47 Keep at temperature not exceeding ... °C (to be specified by the manufacturer)
- Applicability
 - Substances and preparations which become unstable at a certain temperature.
 - Criteria for use
 - Normally limited to special cases (e.g. certain organic peroxides).
- S 48 Keep wetted with ... (appropriate material to be specified by the manufacturer)
- Applicability
 - Substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out.
 - Criteria for use
 - Normally limited to special cases, e.g. nitrocelluloses.
- S 49 Keep only in the original container
- Applicability
 - Substances and preparations sensitive to catalytic decomposition.
 - Criteria for use
 - Normally limited to substances and preparations sensitive to catalytic decomposition; e.g. certain organic peroxides.
- S 50 Do not mix with ... (to be specified by the manufacturer)
- Applicability
 - Substances and preparations which may react with the specified product to evolve very toxic or toxic gases.
 - Organic peroxides.
 - Criteria for use
 - Recommended for substances and preparations mentioned above which are likely to be used by members of the general public, when it is a better alternative to R 31 or R 32.
 - *Obligatory* with certain peroxides which may give violent reaction with accelerators or promoters.

S 51 Use only in well-ventilated areas

- Applicability
 - Substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, etc. which give rise to inhalation risks or to a fire or explosion risk.
- Criteria for use
 - Recommended when use of S 38 would not be appropriate. Thus important when such substances and preparations are likely to be used by members of the general public.

S 52 Not recommended for interior use on large surface areas

- Applicability
 - Volatile, very toxic, toxic and harmful substances and preparations containing them.
- Criteria for use
 - Recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of its volatilization from large treated surfaces in the home or other enclosed places where persons congregate.

5. LABELLING PROPOSAL

- 5.1. The labelling proposal for a substance should be derived from the total number of symbols, risk phrases and safety phrases assigned
- 5.2. The labelling proposal for a preparation should be derived in a way analogous to that for a substance and in particular be based on:
- (a) determination of the risk categories according to the specific criteria laid down in each particular directive (on preparations);
 - (b) choice of the most relevant R and S phrases; whereas some risk phrases follow directly from the risk categories, other risk and safety phrases which are applicable shall be derived mainly from the R and S phrases assigned in accordance with sections 2 and 4 above to the constituent which most contributes to the dangerous properties of the preparation;
 - (c) in certain cases, particular directives give obligatory phrases for certain preparations (e.g. cyanoacrylate glues, paints intended for spraying). In these cases, these phrases shall always be mentioned.
- 5.3. Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given to the clarity and impact of the label. With clarity in mind, the necessary information should be expressed in a minimum number of phrases. Generally, up to four risk phrases and up to four safety phrases will be sufficient; for this purpose the combination phrases listed in Annexes III and IV are considered as single phrases. Whilst it may be possible to reduce the total number of phrases for substances and preparations classified for example as harmful, irritant or flammable, more than four risk and four safety phrases should only be specified in very particular cases.
- 5.4. When more than four risk phrases are assigned to a substance or preparation, it is generally possible to eliminate phrases which refer to the lowest degree of hazard providing that the overall effectiveness of the special warning is not thereby reduced. It is frequently found that certain such risk phrases are rendered superfluous by a suitable choice of safety phrase.

The risk phrases which correspond to the symbols indicated on the label are obligatory except that the risk phrases 'extremely flammable' or 'highly flammable' need not be indicated where they repeat the wording of the indication of danger used with a symbol.

- 5.5. The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation:
- safety phrases which give obvious advice in relation to risk phrases are generally omitted from the label unless used to give particular emphasis to a specific warning;
 - certain safety phrases, e.g. S 2, have particular relevance to substances and preparations intended to be used by the public, other phrases have particular relevance to persons at work. Phrases should be chosen with the intended use in view;
 - particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, e.g. spraying or other aerosol effects.

Commission statement

With regard to 3.1.3, and in particular to the last paragraph of 3.1.3, the Commission states that, should it envisage making use of the procedure of Article 21, it is prepared to consult in advance appropriate experts designated by Member States and having special qualifications with respect to either carcinogenicity, mutagenicity or teratogenicity.

This consultation will take place in the framework of the normal consultation procedure with national experts and/or in the framework of existing committees. The same will be the case when substances already included in Annex I must be reclassified in respect of their carcinogenic, mutagenic or teratogenic effects.

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