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COMMISSION DIRECTIVE 98/98/EC

of 15 December 1998

adapting to technical progress for the 25 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

(Text with EEA relevance)

(OJ L 355, 30.12.1998, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Decision 2000/368/EC of 19 May 2000	L 136	108	8.6.2000

Corrected by:

►**C1** Corrigendum, OJ L 293, 15.11.1999, p. 1 (98/98/EC)

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COMMISSION DIRECTIVE 98/98/EC

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adapting to technical progress for the 25 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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European 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 Commission Directive 98/73/EC ([2]), and in particular Article 28 thereof,

Whereas Annex I to Directive 67/548/EEC contains a list of dangerous substances, together with particulars of the classification and labelling procedures in respect of each substance; whereas present scientific and technical knowledge has shown that the list of dangerous substances in that Annex should be adapted; whereas in consequence it is necessary to amend the foreword to Annex I so as to include changes in nomenclature, format of entries, notes relating to the identification, classification and labelling of substances and notes relating to the labelling of preparations; whereas the list of dangerous substances in Annex I contains substances for which specific temporary classification and labelling derogations have been granted to Austria and Sweden by the Act of Accession of Austria, Finland and Sweden; whereas the Act of Accession provides for the review of the classification and labelling requirements of those substances; whereas that review leads to the adaptation of classifications for a number of such substances;

Whereas Annex III to Directive 67/548/EEC contains a list of phrases indicating the nature of special risks attributed to dangerous substances and preparations; whereas it is necessary to introduce new phrases indicating the danger to health of certain substances and preparations;

Whereas Annex IV to Directive 67/548/EEC contains a list of the phrases indicating the safety advice concerning dangerous substances and preparations; whereas it is necessary to revise certain safety advice phrases related to the dangers to health and for the environment; whereas it is necessary to introduce certain safety advice phrases related to the dangers to health; whereas it is also necessary to introduce certain combined phrases relating to the use of dangerous substances and preparations;

Whereas Annex VI to Directive 67/548/EEC contains a guide to the classification and labelling of dangerous substances and preparations; whereas it is necessary to amend this guide;

Whereas the measures provided for in this Directive are in accordance 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,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is amended as follows.

1. Annex I is amended as follows:

   (a) the text in Annex 1A to this Directive replaces the corresponding text in the Foreword;

   (b) the entries in Annex 1B to this Directive replace the corresponding entries;

([1]) OJ L 196, 16.8.1967, p. 1.
([2]) OJ L 305, 16.11.1998, p. 1.

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(c) the entries in Annex 1C to this Directive are inserted;

(d) the entries in Annex 1D to this Directive are deleted.

2. Annex 2 to this Directive is inserted in Annex III.

3. Annex IV is amended as follows:

(a) the phrases in Annex 3A to this Directive replace the corresponding phrases;

(b) the phrases in Annex 3B to this Directive are inserted;

(c) the combined phrases in Annex 3C to this Directive are inserted.

4. Annex VI is amended as set out in Annex 4 to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2000 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by this Directive and a correlation table between this Directive and the national provisions adopted.

Article 3

This Directive shall enter into force on the third day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

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ANNEX IA

‘FOREWORD TO ANNEX I

Introduction

Annex I is an index of dangerous substances for which harmonised classification and labelling have been agreed at Community level in accordance with the procedure laid down in Article 4(3) of this Directive.

Numbering of entries

Entries in Annex I are listed according to the atomic number of the element most characteristic of the substance's properties. A list of the chemical elements, arranged according to atomic number is shown in Table A. Organic substances, because of their variety, have been placed in the usual classes, as shown in Table B.

The Index number for each substance is in the form of a digit sequence of the type ABC-RST-VW-Y, where:

— ABC is either the atomic number of the most characteristic chemical element (preceded by one or two zeros to make up the sequence) or the usual class number for organic substances,

— RST is the consecutive number of the substance in the series ABC,

— VW denotes the form in which the substance is produced or placed on the market,

— Y is the check-digit calculated in accordance with the ISBN (International Standard Book Number) method.

As an example, the index number for sodium chlorate is 017-005-00-9.

For dangerous substances in the European inventory of existing commercial chemical substance (Einecs, OJ C 146 A, 15.6.1990) the Einecs number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8.

For dangerous substances notified under the provisions of this Directive, the number of the substance in the European list of notified substance (Elincs) is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 400-010-9.

For dangerous substances in the list of “No-longer polymers” (document of the Office for Official Publications of the European Communities, 1997, ISBN 92-827-8995-0), the “No-longer-polymer” number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 500-001-0.

The Chemical Abstracts Service (Cas) number is also included to assist identification of the entry. It should be noted that the Einecs number includes both anhydrous and hydrated forms of a substance, and there are frequently different Cas numbers for anhydrous and hydrated forms. The Cas number included is for the anhydrous form only, and therefore the Cas number shown does not always describe the entry as accurately as the Einecs number.

Einecs, Elincs, “No-longer-polymer” or Cas numbers are not usually included for entries which comprise more than four individual substances.

Nomenclature

Wherever possible dangerous substances are designated by their Einecs, Elincs or “No-longer-polymer” names. Other substances not listed in Einecs, Elincs or the list of “No-longer-polymers” are designatedusing an internationally recognised chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases.

Impurities, additives and minor components are normally not mentioned unless they contribute significantly to the classification of the substance.

Some substances are described as a mixture of A and B. These entries refer to one specific mixture. In some cases where it is necessary to characterise the substance put on the market, the proportions of the main substances in the mixture are specified.

Some substances are described with a specific percentage purity. Substances containing a higher content of active material (e.g. an organic peroxide) are not included in the Annex I entry and may have other hazardous properties (e.g. explosive). Where specific concentration limits are shown, these apply to the substance or substances shown in the entry. In particular, in the case of entries which are mixtures of substances or substances described with a specific percentage purity, the limits apply to the substance as described in Annex I and not the pure substance.

Article 23(2)(a) requires that for substances appearing in Annex I, the name of the substance to be used on the label should be one of the designations given in the Annex. For certain substances, additional information has been added in square brackets in

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order to help identify the substance. This additional information need not be included on the label.

Certain entries contain a reference to impurities. An example is index No 607-190-00-X: methyl acrylamidomethoxyacetate (containing ⩾ 0,1 % acrylamide). In these cases the reference in brackets forms part of the name, and must be included on the label.

Certain entries refer to groups of substances. An example is index No 006-007-00-5: "hydrogen cyanide (salts of …) with exception of complex cyanides such as ferrocyanides, ferricyanides and mercuric oxycyanide". For individual substances covered by these entries, the Einecs name or another internationally recognised name must be used.

Format of entries

The following information is given for each substance in Annex I:

(a) *the classification:*

(i) the process of classification consists of placing a substance in one or more categories of danger (as defined in Article 2(2) of Directive 92/32/EEC) and assigning the qualifying risk phrase or phrases. The classification has consequences not only for labelling but also for other legislation and regulatory measures on dangerous substances;

(ii) the classification for each category of danger is shown in separate boxes. The classification is normally presented in the form of an abbreviation representing the category of danger together with the appropriate risk phrase or phrases. However, in some cases (i.e. substances classified as flammable, sensitising and some substances classified as dangerous for the environment) the risk phrase alone is used;

(iii) the abbreviation for each of the categories of danger is shown below:

— explosive: E

— oxidising: O

— extremely flammable: F +

— highly flammable: F

— flammable: R 10

— very toxic: T +

— toxic: T

— harmful: Xn

— corrosive: C

— irritant: Xi

— sensitising: R 42 and/or R 43

— carcinogenic: Carc. Cat. (1)

— mutagenic: Muta. Cat. (1)

— toxic for reproduction: Repr. Cat. (1)

— dangerous for the environment: N and/or R 52, R 53, R 59;

(iv) additional risk phrases which have been assigned to describe other properties (see sections 2.2.6 and 3.2.8 of the labelling guide) are shown in separate boxes on the same line although they are not formally part of the classification.

(b) *the label, including:*

(i) the letter assigned to the substance in accordance with Annex II (see Article 23(2)(c)). This acts as an abbreviation for the symbol (if assigned) and the indication of danger;

(ii) the risk phrases, denoted as a series of numbers preceded by the letter R indicating the nature of the special risks, in accordance with Annex III (see Article 23(2)(d)). The numbers are separated by either:

— a dash (-) to denote separate statements concerning special risks (R), or

(1) The category of carcinogen, mutagen or toxic for reproduction (i.e. 1, 2 or 3) is shown as appropriate.