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(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

DIRECTIVES

COMMISSION DIRECTIVE 2008/58/EC

of 21 August 2008

amending, for the purpose of its adaptation to technical progress, for the 30th 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⁾, and in particular Article 28 thereof,

Whereas:

- (1) Annex I to Directive 67/548/EEC contains a list of dangerous substances, together with particulars of the classification and labelling of each substance. That list needs to be updated to include further notified new substances and further existing substances, as well as to adapt certain entries to technical progress. In addition, it is necessary, in that Annex, to delete entries for certain substances. The classification and labelling of substances containing benzene should be changed in order to reflect that benzene is classified as a mutagen and some entries should be split because the newly added or revised physico-chemical classification no longer applies to all the substances under those entries.
- (2) The classification and labelling of the substances listed in this Directive should be reviewed if new scientific knowledge becomes available. In this respect, considering recent preliminary, partial and not peer-reviewed information submitted by industry, special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China and the outcome of the IARC

discussion of the classification of Nickel substances or any new relevant scientific findings or interpretations given to the data used to establish the current proposals for the Nickel compounds concerned by this Directive.

- (3) Certain notes in the foreword of Annex I should be amended or added to clarify the obligations on manufacturers, distributors and importers of certain substances, to reflect that benzene has, in addition to other effects, been classified as mutagenic, and to reflect that the classification and labelling in Annex I relating to physico-chemical properties need not be applied when testing shows that the specific form of a substance marketed has different physico-chemical properties. Note 6 in the foreword of Annex I should be deleted as the provisions of this note no longer apply from the date on which Commission Directive 2001/60/EC ⁽²⁾ enters into force. Consequently, the reference to Note 6 should be deleted from certain entries in the Annex. A new Note 7 should be added to the foreword of Annex I to reflect that alloys containing nickel are to be classified for sensitisation on the basis of their release rate rather than on the concentration of nickel.
- (4) 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 with Dangerous Substances and Preparations,

⁽¹⁾ OJ L 196, 16.8.1967, p. 1.

⁽²⁾ OJ L 226, 22.8.2001, p. 5.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I of Directive 67/548/EEC is amended as follows:

1. the foreword is amended as follows:
 - (a) Note H is replaced by the text set out in Annex 1A;
 - (b) Note J is replaced by the text set out in Annex 1B;
 - (c) Note P is replaced by the text set out in Annex 1C;
 - (d) The text set out in Annex 1D is added as Note T;
 - (e) Note 6 is deleted;
 - (f) The text set out in Annex 1E is added as Note 7;
2. the entries corresponding to the entries set out in Annex 1F are replaced by the entries set out in that Annex;
3. The entries set out in Annex 1G to this Directive are inserted in accordance with the order of the entries set out in Annex I to Directive 67/548/EEC;
4. The entries set out in Annex 1H to this Directive are deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 1 June 2009 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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 text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 21 August 2008.

For the Commission

Stavros DIMAS

Member of the Commission