

Commission Directive 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st 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)

COMMISSION DIRECTIVE 2009/2/EC

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(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) Article 4(3) of Directive 67/548/EEC sets out the criteria and the procedure to be followed to harmonise the classification and labelling of substances. Paragraphs 4.1.3, 4.1.4 and 4.1.5 of Annex VI to Directive 67/548/EEC oblige industry to provide information to Member States and Member States to make proposals for harmonised classification and labelling as a matter of urgency, when information becomes available justifying that a substance fulfils the criteria as a mutagenic, carcinogenic or reproductive toxic chemical.
- (2) 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.
- (3) Annex I to Directive 67/548/EEC already contains numerous group entries in particular for metal compounds evaluated using a grouping and read across approach based on analogy between substances.
- (4) Annex I to Directive 67/548/EEC also contains certain groups where members of the group are identified and where the classification was derived by applying grouping and read across approaches, notably the petroleum streams and gasses.

- (5) Annex VI to Directive 67/548/EEC states that the data required for classification and labelling may be obtained from a number of different sources, including the results of validated structure-activity relationships and expert judgement.
- (6) The classifications of the nickel compounds listed in this Directive are based on the effects originating from the Ni(2+) ion and on the available data for nickel compounds. The classifications were derived by grouping nickel compounds into categories on the basis of water solubility (e.g. groups insoluble, slightly soluble and soluble nickel compounds respectively). Water solubility was used as an initial criterion to define these categories, based on the argument that nickel substances having similar water solubility will indicate similar bioavailability of the Ni(2+) ion and similar systemic toxicity. This justifies a read across within groups from the substances for which the available adequate test data demonstrate a specific systemic effect to those lacking such test data. For some effects, read across between groups is justified, as similar effects have been observed across the range of water solubility. For example, epidemiological studies show that both soluble and insoluble nickel compounds (at opposite ends of the range of solubility) have local carcinogenic effects in the respiratory tract. There is, therefore, good reason to conclude that slightly soluble compounds (at the middle of this range) have similar carcinogenic properties.
- (7) As part of an evaluation of all the available information for the nickel compounds, water solubility can be used as an approximation of systemic bioavailability of the Ni(2+) ion for many effects and substances.
- (8) The classification and labelling of the substances listed in this Directive should be reviewed if new scientific knowledge becomes available. In this context, noting in particular that the nickel industry has recently submitted preliminary, partial and not peer-reviewed information, special attention should be paid to the outcome of future discussions within the World Health Organisation's International Agency for Research on Cancer on the carcinogenicity of nickel substances, or to any relevant new scientific findings or interpretations of the data used to establish the classifications for the nickel compounds included in this Directive.
- (9) 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,

HAS ADOPTED THIS DIRECTIVE:

(1) OJ 196, 16.8.1967, p. 1.