

**Sub-Committee of Experts on the Globally  
Harmonized System of Classification  
and Labelling of Chemicals**  
(Third session, 10-12 July 2002,  
agenda item 2)

**Sensitisation criteria in GHS**

**Transmitted by the experts from Netherlands and Sweden**

**Background and rationale**

The criteria for skin and respiratory sensitisation, as proposed under the GHS, are dealing with the induction of sensitisation. The induction of sensitisation in an individual may occur after a single exposure to an allergen or after long-time exposure, depending on factors such as the nature of the allergen and the type of exposure. Once an individual has become sensitised and the immunological memory has been established, an elicitation reaction may occur upon further exposure to the allergen. The elicitation reaction usually occurs at very low concentrations; much lower than the concentration which is needed for induction.

In the EU legislation there are labelling provisions aiming to prevent the outbreak of elicitation reactions among sensitised individuals. These provisions apply to all mixtures containing a sensitizer without the mixture being classified. The rationale is that once you are sensitised you may have an elicitation reaction when exposed to very small doses of the sensitizer; this occurs at much lower concentrations (doses) than the one that gave rise to the induction of sensitisation. Thus, when a mixture is tested and the outcome is negative for induction of sensitisation, elicitation reactions from the same mixture are still possible among already sensitised individuals.

**Proposal**

For the GHS to give a possibility for competent authorities to include these provisions we propose the addition of the following sentence in Notes 1, 3 and 5 to Table 1 of chapter 3.4 in document ST/SG/AC.10/C.4/2002/12 (OECD document "Proposal for revision of Table 1 and footnotes of ENV/JM/MONO(2001)6, chapter 3.4", dated 16 May 2002):

*"In addition, some competent authorities may require a special labelling phrase for all mixtures containing sensitizers above 0.1%."*

In order to keep the sensitisation criteria for mixtures as transparent as possible we also propose that a reference to the three notes to Table 1 is added after §19 and after §24 of chapter 3.4 of document ST/SG/AC.10/C.4/2001/22 (OECD document ENV/JM/MONO(2001)6, chapter 3.4). This is under the headings for classification of mixtures having data for the complete mixture and for mixtures where bridging data apply, respectively. Our proposal is to add the following:

*"For special labelling required by some competent authorities, see Notes 1, 3 and 5 to Table 1 of this chapter."*

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