

UN/SCEGHS/3/INF.6

English

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

Modification of the GHS Classification criteria for sensitization

Transmitted by the Organisation for Economic Co-operation and Development (OECD)

ENV/EHS/HK/wc/2002.53

27 May, 2002

Mr. Olivier Kervella
Transport Division
Palais des Nations
Geneva 10
Switzerland

Subject: Modification of the GHS Classification Criteria for Sensitisation

Dear Mr Kervella,

Please find attached a proposal for the revision of Table 1 of Chapter 3.4 of the draft GHS dealing with Respiratory or Skin Sensitisation, together with a series of 6 footnotes. Attached to the proposal you will find a copy of the covering letter of 16th May 2002 from Rob Visser to the Heads of Delegation to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, requesting formal approval of the proposal and explaining the issue.

Both attachments are in french and english for your convenience.

I would appreciate if you could make these attachments available to the members of the GHS Sub-Committee for their consideration and discussion at the third session of the Sub-Committee in July. At the time of the meeting in July I will be able to report on the formal OECD approval of the proposal.

Yours sincerely,

Herman B.W.M.Koëter
Principal Administrator
Environment, Health and Safety Division

To: Heads of Delegation to the Joint Meeting
Copy: National Delegation

Subject: Modification of the GHS Classification Criteria for Sensitisation

Dear Madam/Sir,

A footnote to Chapter 3.4 of the Harmonised Integrated Hazard Classification System for Chemical Substances and Mixtures [ENV/JM/MONO(2001)6] that was approved by the 32nd Joint Meeting explained that a revision of cut-off values/concentration limits of sensitising ingredients of a mixture that would trigger the classification of the mixture as sensitising should be considered before the implementation of the GHS. This revision was considered necessary by the TF HCL as well as the ILO Working Group on Chemical Hazard Communication to better cover the hazard of pre-exposed individuals.

Room Document ENV/JM/RD(2002)4, as noted by the 33rd Joint Meeting in February this year, reported the agreement reached by the Task Force on Harmonisation of Classification and Labelling (TF HCL) on the indicated revision. The Room Document also explained that additional proposals made by Sweden to further refine and clarify the classification of mixtures for this hazard class needed further discussion.

Unfortunately, despite efforts made by all experts involved, the Task Force appeared unable to reach full agreement on the additional wording as requested by Sweden. Consequently, the proposal for revision of Table 11 of Chapter 3.4 of ENV/JM/MONO(2001)6 (included in the draft GHS as Table 1 of Chapter 3.4) includes only the agreement reached by the TF HCL. The proposal is attached to this letter for your review and approval. It is simultaneously submitted to the secretariat of the UN ECOSOC Subcommittee of Experts on the GHS for circulation to the members of the Subcommittee for their information and consideration. The formal OECD submission will be made after approval by the Joint Meeting.

The Joint Meeting is invited to review and approve the revision of the Sensitisation Chapter and to respond to the Secretariat **before 26th June 2002**. No response received by that date would be considered as your approval of the proposal.

Yours sincerely,

Rob Visser

**PROPOSAL FOR REVISION OF TABLE 1 AND FOOTNOTES OF
ENV/JM/MONO(2001)6, CHAPTER 3.4: HARMONISED SYSTEM FOR THE
CLASSIFICATION OF CHEMICAL MIXTURES WHICH CAUSE
RESPIRATORY OR SKIN SENSITISATION**

Table 1: Cut-off values/concentration limits of ingredients of a mixture classified as either skin sensitizers or respiratory sensitizers, that would trigger classification of the mixture

Ingredient Classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Skin Sensitizer	Respiratory Sensitizer	
	All physical states	Solid/Liquid	Gas
Skin Sensitizer	≥ 0.1% (Note 1)	-	-
	≥ 1.0% (Note 2)	-	≥
Respiratory Sensitizer	-	≥ 0.1% (Note 3)	≥ 0.1% (Note 5)
	-	≥ 1.0 % (Note 4)	≥ 0.2% (Note 6)

Note 1: If a skin sensitizer is present in the mixture as an ingredient at a concentration between 0.1% and 1.0%, both an SDS and a label would generally be expected. The label warning for skin sensitizers between 0.1% and 1.0% may differ from the label warning for skin sensitizers ≥ 1.0%, depending on competent authority requirements. While the current cut-off values reflect existing systems, all recognise that special cases may require information to be conveyed below that level.

Note 2: If a skin sensitizer is present in the mixture as an ingredient at a concentration of ≥ 1.0%, both an SDS and a label would generally be expected.

Note 3: If a solid or liquid respiratory sensitizer is present in the mixture as an ingredient at a concentration between 0.1% and 1.0%, both an SDS and a label would generally be expected. The label warning for solid or liquid respiratory sensitizers between 0.1% and 1.0% may differ from the label warning for solid or liquid respiratory sensitizers ≥ 1.0%, depending on competent authority requirements. While the current cut-off values reflect existing systems, all recognise that special cases may require information to be conveyed below that level.

Note 4: If a solid or liquid respiratory sensitizer is present in the mixture as an ingredient at a concentration of ≥ 1.0%, both an SDS and a label would generally be expected.

Note 5: If a gaseous respiratory sensitizer is present in the mixture as an ingredient at a concentration between 0.1% and 0.2%, both an SDS and a label would generally be expected. The label warning for a gaseous respiratory sensitizers between 0.1% and 0.2% may differ from the label warning for a gaseous respiratory sensitizers ≥ 0.2%, depending on competent authority requirements. While the current cut-off values reflect existing systems, all recognise that special cases may require information to be conveyed below that level.

Note 6: If a gaseous respiratory sensitizer is present in the mixture as an ingredient at a concentration of ≥ 0.2%, both an SDS and a label would generally be expected.
