

Unclassified

ENV/JM/HCL(2004)5/REV



Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

13-Jul-2004

English - Or. English

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

Cancels & replaces the same document of 09 July 2004

Task Force on Harmonisation of Classification and Labelling

**PROPOSAL FOR REVISION OF CHAPTER 3.7 IN ORDER TO INTRODUCE CRITERIA FOR THE
CLASSIFICATION OF MIXTURES IN THE CATEGORY "EFFECTS ON OR VIA LACTATION"**

Mme Laurence Musset
Tel: (33) 1 45 24 16 76, Fax: (33) 1 45 24 16 75, E-mail: Laurence.Musset@oecd.org

JT00167428

Document complet disponible sur OLIS dans son format d'origine
Complete document available on OLIS in its original format

ENV/JM/HCL(2004)5/REV
Unclassified

English - Or. English

Rationale

1. Harmonized criteria for the classification of substances which have effects on lactation have been included in Figure 3.7.1 (b) of the GHS. However, no such criteria have been developed for mixtures containing substances which have effects on or via lactation. Paragraph 3.7.3.4 points out the need to consider this issue in the future.
2. The general concentration limits of $\geq 0.1\%$ and $\geq 0.3\%$ for lactational effects are identical to those for a category 1 reproductive toxicant and are proposed simply because **toxicity in breast feeding infants resulting from effects on or via lactation can be regarded as an adverse effect of equivalent seriousness to effects on fertility or developmental toxicity**. The selection of somewhat low concentration limits is further supported by the knowledge that lactational effects can potentially occur at relatively low dose levels.

Proposal for Revision of Chapter 3.7 in order to Introduce Criteria for the Classification of Mixtures in the Category “Effects on or via Lactation”

3.7.3.3 Insert the following sentence after the first sentence:

“The mixture will be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit as shown in Table 3.7.1 for the additional category for effects on or via lactation.”

Table 3.7.1 Replace the table title and the table with the following:

“Table 3.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that would trigger classification of the mixtures”

Ingredients classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Category 1 reproductive toxicant	Category 2 reproductive toxicant	Additional Category for effects on or via lactation
Category 1 reproductive toxicant	≥ 0.1% (note 1)		
	≥ 0.3% (note 2)		
Category 2 reproductive toxicant		≥ 0.1 % (note 3)	
		≥ 3.0% (note 4)	
Additional category for effects on or via lactation			≥ 0.1 % (note 1)
			≥ 0.3% (note 2)

In Note 1 to Table 3.7.1, first line, insert “or substance classified in the additional category for effects on or via lactation” after “category 1 reproductive toxicant”;

In Note 2 to Table 3.7.1, first line, insert “or substance classified in the additional category for effects on or via lactation” after “category 1 reproductive toxicant”.

3.7.3.4 Delete Paragraph 3.7.3.4 and Footnote 4.

3.7.6 Replace the title “**Decision logic 3.7.3**” with the following:

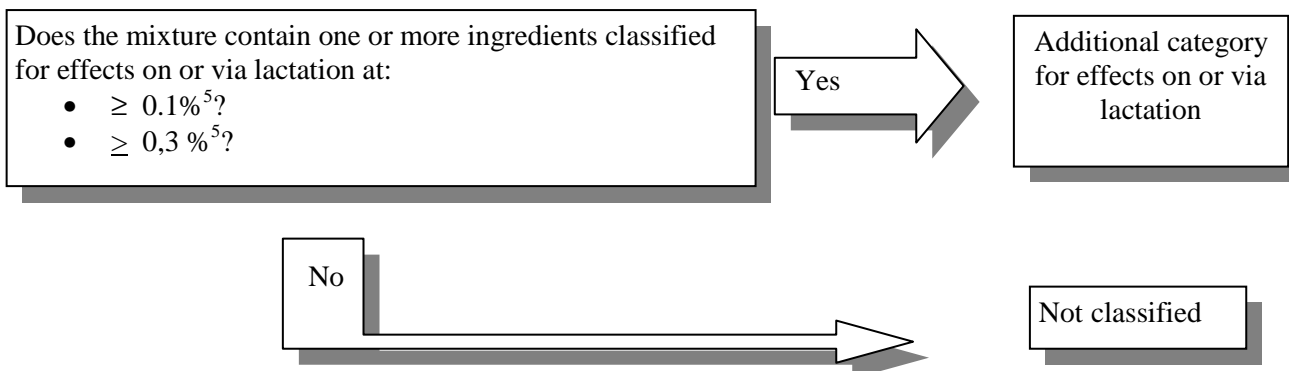
“3.7.6.1 Decision logic 3.7.3 for substances”

Insert after the boxes of Decision logic 3.7.3 the title and decision logic as follows:

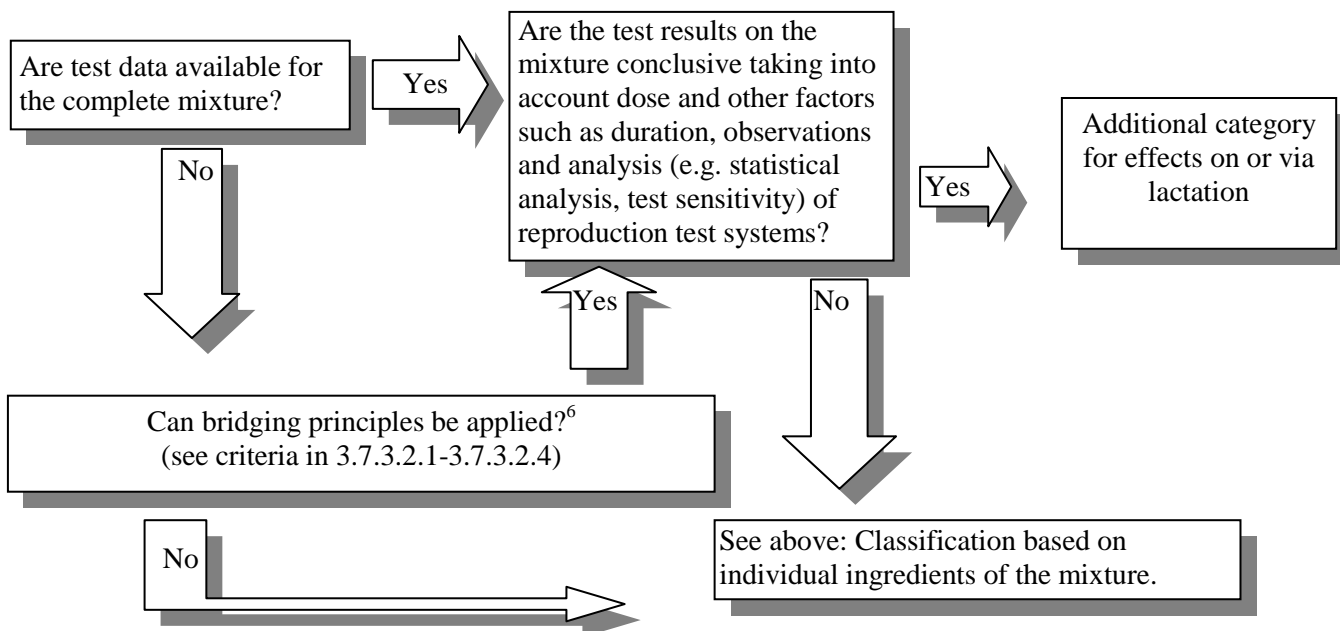
“3.7.6.2 Decision logic 3.7.4 for mixtures”

Mixture: Classification of mixtures will be based on the available test data for the **individual ingredients** of the mixture, using cut-off values/concentration limits for those ingredients. The classification may be **modified on a case-by-case basis** based on the available test data for the mixture as a whole or based on bridging principles. See modified classification on a case-by-case basis below. For further details see criteria (See 3.7.3.1, 3.7.3.2 and 3.7.3.3).

Classification based on individual ingredients of the mixture



Modified classification on a case-by-case basis



⁵ For specific concentration limits, see "The use of Cut-off Values/Concentration Limits" in Chapter 1.3, para. 1.3.3.2, and in Table 3.7.1 of this Chapter.

⁶ If data on another mixture are used in the application of bridging principles, the data on that mixture must be conclusive in accordance with paragraph 3.7.3.2.