

Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals

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Classification criteria and related hazard communication:

Practical classification issues

Revisions to the effects on or via lactation hazard category

Transmitted by the expert from the United States of America

Introduction

1. As it was developing guidance materials in the course of its implementation of the GHS, the United States became aware of issues with the GHS criteria and hazard statement for effects on or via lactation. This category captures two effects:

- (i) substances that can interfere with lactation and
- (ii) substances and their metabolites that may be transmitted through breast milk to children in amounts sufficient to cause concern for the health of the breast feeding child.

However, the criteria, decision logic, and hazard statement do not adequately distinguish between these two effects.

2. The criteria for effects on or via lactation read as follows in Rev. 6, Figure 3.7.1(b):

“Effects on or via lactation are allocated to a separate single category. It is appreciated that for many substances there is no information on the potential to cause adverse effects on the offspring via lactation. However, substances which are absorbed by women and have been shown to interfere with lactation, or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, should be classified to indicate this property hazardous to breastfed babies. This classification can be assigned on the basis of:

- (a) absorption, metabolism, distribution and excretion studies that would indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or
- (b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or
- (c) human evidence indicating a hazard to babies during the lactation period.”

2. The first problem has both grammatical and substantive aspects and is found in the third sentence:

“However, substances which are absorbed by women and have been shown to interfere with lactation, or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, should be classified to indicate *this property hazardous to breastfed babies.*” (emphasis added)

3. The italicized phrase is not grammatically correct. Moreover it is not correct as a matter of substance because it ignores the effect on lactation. Perhaps the best way to deal with this problem would be to delete the words “to indicate this property hazardous to breastfed babies”.

4. Along these same lines, the language in the decision logic should be changed. The initial box in 3.7.5.2.1 reads “Does the substance according to the criteria (see 3.7.2) cause concern for the health of breastfed children.” Again, this language does not include the *on* lactation effect, and should be changed. One way to do this would be to revise the text as follows (addition italicized and underlined):

“Does the substance according to the criteria (see 3.7.2) *interfere with lactation or* cause concern for the health of breastfed children.”

5. Another problem is in the categories of evidence listed in paragraphs (a) through (c) of Figure 3.7.1(b). They all provide evidence for effects *via* lactation rather than effects *on* lactation. One way to be more accurate would be to revise the last sentence of the introductory to read:

“The classification for effects via lactation can be assigned on the basis of.” This would avoid confusion on how to apply those criteria to effects on lactation.

6. A third problem is the hazard statement (H362) for effects on or via lactation: “May cause harm to breast-fed children.” This hazard statement does not clearly warn of the *on* lactation effect. A possible additional hazard statement to address this effect could read:

“May interfere with lactation.”

Proposal

7. It is proposed that the practical classification issues (PCI) informal working group consider revisions to the effects on or via lactation hazard category criteria and decision logic to adequately distinguish between the *on* and *via* lactation effects, and also consider whether an additional hazard statement that clearly addresses the *on* lactation effect should be adopted.
