

Unclassified

ENV/JM/HCL(2003)1/REV5



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

19-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 13 July 2004

Task Force on Harmonisation of Classification and Labelling

PROPOSAL FOR CLASSIFICATION AND LABELLING FOR ASPIRATION HAZARDS

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JT00167574

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PROPOSAL FOR CLASSIFICATION AND LABELLING FOR ASPIRATION HAZARDS
CHAPTER 3.X: ASPIRATION HAZARDS
DEFINITIONS AND GENERAL CONSIDERATIONS

1. The purpose of this proposal is to provide a means of classifying substances or mixtures that may pose an aspiration toxicity hazard to humans.
2. "Aspiration" means the entry of a liquid or solid chemical product directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.
3. Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.
4. Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.
5. Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labelling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

CLASSIFICATION CRITERIA FOR SUBSTANCES

Table 1: Hazards categories for aspiration toxicity

Categories	Criteria
<p>Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard (applies to all authorities)</p>	<p>A substance is classified in Category 1:</p> <ul style="list-style-type: none"> (a) Based on reliable and good quality human evidence. Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil; or (b) If it is a hydrocarbon and has a kinematic viscosity of 20.5 mm²/s or less, measured at 40° C.
<p>Category 2: Chemicals which cause concern owing to the presumption that they cause human aspiration toxicity hazard (applies to only some authorities)</p>	<p>On the basis of existing animal studies and expert judgment that takes into account surface tension, water solubility, boiling point, and volatility, substances, other than those classified in Category 1, which have a kinematic viscosity of 14 mm²/s or less, measured at 40° C . Taking this into account, some authorities would consider the following to be included in this Category: n-primary alcohols with a composition of at least 3 carbon atoms but not more than 13; isobutyl alcohol, and ketones with a composition of no more than 13 carbon atoms.</p>

CLASSIFICATION CRITERIA FOR MIXTURES

Classification when data are available for the complete mixture

6. A mixture is classified in Category 1 based on reliable and good quality human evidence.

Classification of mixtures when data are not available for the complete mixture

Bridging Principles

Dilution

7. If a mixture is diluted with a substance that does not pose aspiration toxicity, and which is not expected to affect the aspiration toxicity of other ingredients or the mixture, then the new mixture may be classified as equivalent to the original mixture. However, the concentration of aspiration toxicant(s) should not drop below 10%.

Batching

8. The aspiration toxicity of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product, and produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the aspiration toxicity, reflected by viscosity or concentration, of the batch has changed. If the latter occurs, new classification is necessary.

Concentration of category 1 mixtures

9. If a mixture is classified in Category 1, and the concentration of the ingredients of the mixture that are in Category 1 is increased, the new mixture should be classified in Category 1 without additional testing.

Interpolation within one toxicity category

10. For three mixtures with identical ingredients, where A and B are in the same toxicity category and mixture C has the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.

Substantially similar mixtures

11. Given the following:

- (a) Two mixtures:
 - (i) A + B
 - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Aspiration toxicity for A and C is substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the aspiration toxicity of B;

If mixture (i) is already classified based on test data, then mixture (ii) can be assigned the same hazard category.

Classification of mixtures when data are available for all components or only some components of the mixture

Category 1:

12. A mixture which contains a total of 10% or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20.5 mm²/s or less, measured at 40 ° C.

13. In the case of a mixture that separates into two or more distinct layers, one of which contains 10 % or more of a substance or substances classified in Category 1 aspiration toxicity hazard and has a kinematic viscosity of 20.5 mm²/s or less, measured at 40 ° C, then the entire mixture is classified in Category 1.

Category 2:

14. Some authorities may choose to classify in Category 2, a mixture, which contains a total of 10% or more of a substance or substances classified in Category 2 and has a kinematic viscosity of 14 mm²/s or less, measured at 40 ° C.

15. In classifying mixtures in this category, the use of expert judgment that considers surface tension, water solubility, boiling point, volatility is critical and especially when Category 2 substances are mixed with water.

16. In the case of classifying a mixture that separates into two or more distinct layers, one of which contains 10 % or more of a substance or substances classified in Category 2 aspiration toxicity hazard and has a kinematic viscosity of 14 mm²/s or less, measured at 40 ° C, then the entire mixture is classified in Category 2.

SPECIFIC CONSIDERATIONS

17. A review of the medical literature on chemical aspiration revealed that some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans. Primary alcohols, and ketones have been shown to pose an aspiration hazard only in animal studies.

18. While a methodology for determination of aspiration hazard in animals has been utilized, it has not been standardized. Positive experimental evidence with animals can only serve as a guide to possible aspiration toxicity in humans. Particular care must be taken in evaluating animal data for aspiration hazards.

19. The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\text{Dynamic viscosity (mPas)/density (g/cm}^3\text{)}=\text{kinematic viscosity (mm}^2\text{/s)}$$

20. Classification of aerosol/mist products: Aerosol and mist products are usually dispensed in containers

such as self-pressurized containers, trigger and pump sprayers. The key to classifying these products is whether a pool of product is formed in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then it should be considered for classification.

HAZARD COMMUNICATION

21. General and specific considerations concerning labelling requirements are provided in *Hazard Communication: Labelling* (Chapter 1.4). Annex 2 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms, which can be used where allowed by the competent authority. The table below presents specific label elements for substances and mixtures that are classified as posing an aspiration toxicity hazard, Categories 1-2 based on the criteria set forth in this chapter.

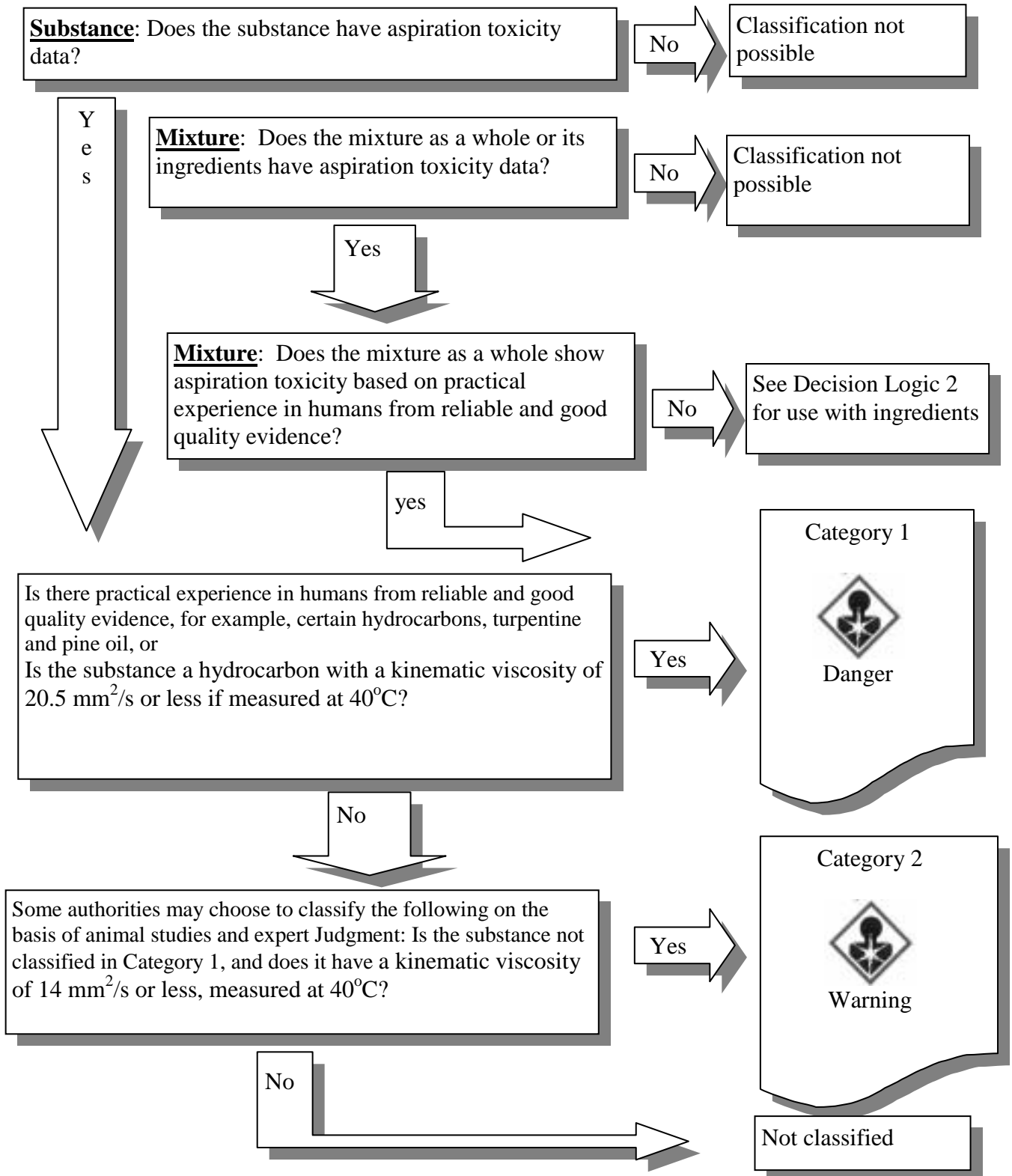
Table 2: Aspiration Toxicity Label Elements

	Category 1	Category 2
Symbol	Health Hazard	Health Hazard
Signal word	Danger	Warning
Hazard statement	May be fatal if swallowed and enters airways	May be harmful if swallowed and enters airways

DECISION LOGIC FOR ASPIRATION TOXICITY

22. The decision logic that follows is not part of the harmonized classification system but is provided here as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

Decision Logic 1 for Aspiration Toxicity



Decision Logic 2 for Aspiration Toxicity

