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DETAILED REVIEW DOCUMENT ON CLASSIFICATION SYSTEMS FOR SUBSTANCES WHICH POSE AN ASPIRATION HAZARD

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DETAILED REVIEW DOCUMENT ON CLASSIFICATION SYSTEMS FOR SUBSTANCES WHICH POSE AN ASPIRATION HAZARD

Environment Directorate

Organisation for Economic Co-operation and Development

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The work of the OECD related to chemical safety is carried out in the Environment, Health and Safety Programme. As part of its work on chemical testing, the OECD has issued several Council Decisions and Recommendations (the former legally binding on Member countries), as well as numerous Guidance Documents and technical reports. The best known of these publications, the OECD Test Guidelines, is a collection of methods used to assess the hazards of chemicals and of chemical preparations. These methods cover tests for physical and chemical properties, effects on human health and wildlife, and accumulation and degradation in the environment. The OECD Test Guidelines are recognised world-wide as the standard reference tool for chemical testing.

More information about the Environment, Health and Safety Programme and its publications (including the Test Guidelines) is available on the OECD's World Wide Web site http://www.oecd.org/ehs/.

The Environment, Health and Safety Programme co-operates closely with other international organisations. This document was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organisations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organisation. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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HARMONIZATION OF CLASSIFICATION AND LABELLING
SUBSTANCES WHICH POSE AN ASPIRATION HAZARD

DETAILED REVIEW DOCUMENT

INTRODUCTION

1. At the 9th Meeting of the Task Force for the Harmonization of Classification and Labelling (OECD, Paris, 17-18 February 2000), the Task Force agreed to begin work on the Step 1 document to explain the rationale behind current national criteria and approaches.

2. The 31st Joint Meeting agreed that the Task Force should do this work for the Harmonization of Classification and Labelling.

3. The Step 1 document including comments from U.S., Slovenia, BIAC (Europe and U.S.) and Canada.

SCOPE

4. This endpoint covers substances, which pose an aspiration hazard. "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 or lower respiratory system.

DESCRIPTION OF THE CLASSIFICATION SYSTEMS IN PLACE

The Canadian System:

5. The Canadian Consumer Chemical and Container Regulations define aspiration hazard as: 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 tract.

6. The classification criteria are:

A chemical product must be classified in the sub-category “toxic” if it has a viscosity of 14 mm^2/sec or less at 40°C and 10% or more of the product is composed of hazardous ingredients that pose an aspiration hazard, including in particular the following substances:

a) an n-primary alcohol with a composition of at least 3 carbon atoms but not more than 13;
b) an isobutyl alcohol;
c) a terpene alcohol;
d) a ketone with a composition of at least 3 carbon atoms but not more than 13;
e) a hydrocarbon with a composition of at least 3 carbon atoms but not more than 13; or
f) a substances that has been determined to be an aspiration hazard based on its viscosity, surface tension, and water solubility through the application of generally accepted standards of good scientific practices.

7. Classification can also be based on practical experience in humans.

8. It is assumed that mixtures will be tested.

The EU System:

9. EU Directive 67/548/EEC includes the following:

R 65: Harmful: May cause lung damage if swallowed.

Liquid substances and preparations presenting an aspiration hazard because of low viscosity.

A: For substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10% and having either:

a) a flow time of less than 30 seconds in a 3 mm ISO cup according to ISO 2431;
b) a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7 x 10-6 m^2/sec at 40°C; or
c) a kinemetic viscosity derived from measurements of rotational viscometry in accordance with ISO 3129 of less than 7 x 10-6 m^2/sec at 40°C.

Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33mN/m at 25°C as measured by the du Nouy tensiometer or by the test methods shown in Annex V. Part A(5).

B. For substances and preparations, based on practical experience in humans.

10. It is assumed that preparations will be tested.

The US System:

Consumer Product Safety Commission

11. The Consumer Product Safety Commission classifies consumer products containing 10% or greater concentration of certain solvents as posing aspiration hazards if swallowed.

12. The statutory authority for this is the Federal Hazardous Substances Act at section 3(b) and regulations at 16 CFR 1500.14 (b)(3)(5) and 16 CFR 1700.14 (a)(31).

13. The regulations call for special labeling for products containing 10 percent or more by weight of
a) toluene;
b) xylene; or
c) petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates; or
d) 5% or more of benzene.

14. The regulation says that such products may be aspirated into the lungs, with resulting chemical pneumonitis, and pulmonary edema.

The Environmental Protection Agency

15. The Office of Pesticide Programs calls for special labelling for formulated products containing 10% or more petroleum distillate. This is based on broad general authority under Section 2q Misbranded, of the Federal Insecticide, Fungicide and Rodenticide Act and regulations at 40 CFR 156.10(h)(iii) Statement of practical Treatment.

OSHA

16. OSHA's Hazard Communication Standard (29 CFR 1910.1200) does not specifically address aspiration hazards or define the term in the standard. The term "health hazard" addresses a chemical for which acute or chronic health effects may occur in an exposed employee. In Appendix A of the standard, aspiration may be covered under target organ toxicity since aspiration affects the lungs. [It would be up to the manufacturer to determine whether it is appropriate to put such information on a label.] OSHA would expect anything that is known about inducing vomiting would be addressed in the MSDS. Health hazards are identified in the standard at (c). Appendix A 7(e) describes target organ effects.

DISCUSSION

17. Some of the factors that are common in the classification of an aspiration hazard among various regulatory authorities are the inclusion of chemical class such as either a hydrocarbon or petroleum distillate, a total concentration limit of 10% or greater and a viscosity measurement. However, not all viscosity test methodologies and criteria are in agreement. For example, the EU and Canada measure viscosity using a kinematic measurement at 40°C (104°F). The Canadian viscosity limit is 14 mm2 /s (73.5 SUS) while the EU has a limit of 7 mm2 /s (48.8 SUS). The U.S. uses the units Standard Saybolt Units measured at 100°F (38°C) with an upper limit of 100 SUS (20,525 mm2 /s). In addition, there are provisions for surface tension in both the EU and Canadian regulations that is lacking in the U.S. rules.

ANNEX 1: COMPARISON OF THE CLASSIFICATION SCHEMES

	Does your country/authority have any legislation for this endpoint?	**Classification criteria for substances**	**Classification criteria for mixtures**
Canada	Yes	A chemical product must be classified in the sub-category Atoxic@ if it has a viscosity of 14 mm^2/sec or less at 40°C and 10% or more of the product is composed of hazardous ingredients that pose an aspiration hazard, including in particular the following substances: a) an n-primary alcohol with a composition of at least 3 carbon atoms but not more than 13; b) an isobutyl alcohol; c) a terpene alcohol; d) a ketone with a composition of at least 3 carbon atoms but not more than 13; e) a substances that has been determined to be an aspiration hazard based on its viscosity, surface tension, and water solubility through the application of generally accepted standards of good scientific practices.	It is assumed that mixtures will be tested.

EU	Yes	R 65: Harmful: May cause lung damage if swallowed. Liquid substances and preparations presenting an aspiration hazard because of low viscosity. For substances and preparations containing a) aliphatic, b) alicyclic and c) aromatic hydrocarbons in a total concentration equal to or greater than 10% and d) having either: – a flow time of less than 30 seconds in a 3 mm ISO cup according to ISO 2431; – a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7 x 10-6 m^2/sec at 40°C; or a kinemetic viscosity derived from measurements of rotational viscometry in accordance with ISO 3129 of less than 7 x 10-6 m^2/sec at 40°C. Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33mN/m at 25°C as measured by the du Nouy tensiometer or by the test methods shown in Annex V. Part A(5). For substances and preparations, based on practical experience in humans. Note: Not applicable to substances or preparations which are placed on the market in aerosol containers (or in containers with a sealed spray attachment).	It is assumed that mixtures will be tested

Slovenia	No		
USA	Yes	CPSC: Products containing 10 percent of more by weight of a) toluene, b) xylene, or c) petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates, or d) 5% or more of benzene. • Prepackaged non-emulsion-type liquid household chemical products, including drugs and cosmetics that contain 10% or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°C EPA: Products containing 10% or more petroleum distillate	It is assumed that mixtures will be tested.

ANNEX 2: NATIONAL LEGISLATION/CLASSIFICATION SYSTEMS IN PLACE

COUNTRY	NATIONAL LEGISLATION	CONTROL IN PLACE
Canada	Consumer Chemical and Container Regulations under the authority of Hazardous Products Act (HPA)	Health Canada
EU	Directive 67/548/EEC	Competent Authorities in EU Member States
Slovenia	The same as in the EU	
USA	16 CFR 1500.14 (b)(3)(5) 16 CFR 1700.14 (a)(31) 40 CFR 156.10(h)(iii)	Consumer Product Safety Commission Environmental Protection Agency