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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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HAZARD COMMUNICATION ISSUES

Additional information on physical and chemical properties for inclusion on the guidance on the preparation of Safety Data Sheets (SDS)

Transmitted by the expert from Australia¹

Introduction

1. Australia is currently preparing guidance material to accompany proposed regulations to implement the GHS for workplace chemicals from 2012.

2. This includes revising the *National Code of Practice for the Preparation of Safety Data Sheets* (SDS), to align with the third revised edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) Annex 4.

¹ In accordance with the programme of work of the Sub-Committee for 2009-2010 approved by the Committee at its fourth session (refer to ST/SG/AC.10/C.4/32, Annex 2 and ST/SG/AC.10/36, paragraph 14).

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3. In revising the SDS Code of Practice, Australia has given consideration to the requirements of SDS for engineered nanomaterials. This topic was previously addressed in the document by the expert from France to the seventeenth session of the GHS Sub-Committee, 29 June – 1 July 2009 (see, ST/SG/AC.10/C.4/2009/3).

4. This document noted that: "Yet, there remain few nanomaterial specific SDSs. Those that exist generally provide insufficient information". Issues with nanomaterial SDS were also recently reported by the National Institute for Occupational Safety and Health (NIOSH)² of the United States of America. Safe Work Australia has also commissioned a report into issues associated with SDS and workplace labelling for engineered nanomaterials, and expects to publish this report before the 18th session of the GHS Sub-Committee.

5. In considering this matter, Australia notes the International Organization Standardization (ISO) Nanotechnology Technical Committee (TC229) Working Group 3 project that is being led by the Republic of Korea to develop a technical report on SDS for nanomaterials. This technical report will provide specific advice on developing an SDS for nanomaterials in GHS format. The technical report is a supplement to ISO 11014:2009 (*Safety data sheet for chemical products — Content and order of sections*) and requirements laid down in Annex 4 to the GHS.

6. ISO TC229 Working Group 3 has also developed a prioritised list of physicochemical parameters of engineered nanomaterials for toxicological assessment:

- (a) Particle size and size distribution;
- (b) Agglomeration state and aggregation;
- (c) Shape;
- (d) Composition, including chemical composition, crystal structure, purity/impurity;
- (e) Surface area;
- (f) Surface chemistry;
- (g) Surface charge; and
- (h) Solubility/Dispersibility.

7. As a result of national developments in nanotechnology policy which incorporates a precautionary approach to the area until hazards are fully known, Australia is proposing to include a number of information items as additional (non-mandatory) parameters in its draft *National Code of Practice for the Preparation of Safety Data Sheets*, including a number of parameters listed above (where not already included in the GHS list). It does not propose these be mandatory as these items are not applicable to all classifiable substances.

² Guidance for Preparation of Good Material Safety Data Sheets (MSDS) for Engineered Nanoparticles. L. Hodson, NIOSH, Cincinnati, OH; C. Crawford, EG&G, Cincinnati, OH. Poster Session, AIHce'09, Toronto, May 30 – June 4 (2009).

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8. Australia recommends that the Sub-Committee considers international agreement to include the following non-mandatory information in Annex 4 to the GHS:

- (a) Particle size and size distribution;
- (b) Shape and aspect ratio;
- (c) Crystallinity;
- (d) Dustiness;
- (e) Surface Area;
- (f) Degree of aggregation or agglomeration; and
- (g) Biodurability or biopersistence.

9. Some of the parameters differ from the ISO list (paragraph 6), as the focus is Occupational Safety and Health management, not toxicological assessment. These parameters are generally applicable to other chemicals and are not nano-specific.

10. Providing information on these physicochemical parameters to adequately describe engineered nanomaterials in SDS was supported during Australian consultations³.

11. For the information of the Sub-Committee, Australia has also included guidance material for the classification of engineered nanomaterials in the draft *Australian Criteria for the Classification of Hazardous Chemicals* that will implement the GHS classification criteria for Australian regulatory reference. The proposed guidance material states that:

- (a) Manufacturers and importers must ensure that their nanomaterials are classified according to this Classification Criteria, and if they meet the classification criteria must comply with the regulations;
- (b) There are no specific provisions in the regulations referring to nanomaterials;
- (c) The regulations deal with all hazardous substances, regardless of size, shape or physical state and do not distinguish between the nanoform or the bulk form of a particular molecular formula;
- (d) Nanomaterials having specific properties may require a different classification and labelling compared to the bulk materials. A substance with different sizes or forms can have different hazard classifications;
- (e) The behaviours and effects of substances at nanoscale are dependent on several characteristics, including size, shape, number concentration, surface area, charge and overall surface reactivity, and classification should take into account these characteristics;

³ It is acknowledged that standard tests for determining dustiness and biodurability of engineered nanomaterials are not yet developed, but information on these parameters will be useful for chemicals in general.

- (f) In order to address the specific hazards, if any, associated with substances at nanoscale, additional testing or information may be required. Due to limited understanding of the characteristics of nanomaterials, their hazard assessment should be done on a case-by-case basis;
- (g) Until specific test guidelines are determined for substances at nanoscale, where required, toxicity testing should be carried out according to existing guidelines. Attention needs to be given to the mode of delivery of the nanoparticle to the test system to ensure that it reflects the relevant exposure scenarios.

12. It is not proposed that this above material be considered for inclusion in the GHS at this stage.

Proposal

13. That the Sub-Committee consider the additional physicochemical information items listed below, proposed by Australia, for inclusion in A4.3.9.3 of Annex 4 – Guidance on the Preparation of the GHS:

- (a) Particle size and size distribution;
- (b) Shape and aspect ratio;
- (c) Crystallinity;
- (d) Dustiness;
- (e) Surface Area;
- (f) Degree of aggregation or agglomeration; and
- (g) Biodurability or biopersistence.
