United Nations ST/SG/AC.10/C.4/2013/4

Secretariat

Distr.: General
18 April 2013

Original: English

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

Twenty-fifth session
Geneva, 1–3 July 2013
Item 2 (f) of the provisional agenda
Classification criteria and hazard communication: nanomaterials

Classification and hazard communication of nanomaterials

Transmitted by the expert from Australia[1]

I. Introduction

1. At the 24th session, the Sub-Committee agreed to include an item in its programme of work to review the applicability of the GHS to manufactured nanomaterials taking into account the progress of international scientific work, if necessary.

2. The expert from France volunteered to lead an informal correspondence group on this issue. In order to avoid duplication of work, it was agreed that the group will take stock of the current work undertaken at the international level before proposing possible issues to be considered by the Sub-Committee. This paper reports on recent work undertaken on this topic in Australia.

II. Classification of nanomaterials

3. INF.11 (24th session) describes the work to produce a recommended classification of carbon nanotubes in Australia. Australia's National Industrial Chemical Notification and Assessment Scheme (NICNAS) used the same classification approach that is used for chemicals generally to classify for each health endpoint. This illustrates that the existing classification criteria can be used for both the bulk and nanoforms of materials.

[1] In accordance with the programme of work of the Sub-Committee for 2013-2014 approved by the Committee at its sixth session (refer to ST/SG/AC.10/C.3/84, para. 86 and ST/SG/AC.10/40, para. 14).

4. This study demonstrates how a GHS classification may be performed for emerging materials where not all hazards are fully known or established, using a precautionary approach. Classification was recommended based on the information available for each health endpoint as follows:

(a) **Not classified as hazardous** – OECD test guideline studies and/or other suitable scientific data acceptable for regulatory decision making are available for single-walled carbon nanotubes (SWCNTs)/single-walled carbon nanohorns (SWCNHs) and/or multi-walled carbon nanotubes (MWCNTs), however the data do not meet the criteria for classification;

(b) **Cannot be classified** – Guideline studies or other suitable scientific data acceptable for regulatory decision making (i.e. administration route relevant for human exposure) are not available for SWCNTs/SWCNHs or MWCNTs, or the available data are not sufficient to make a classification decision;

(c) **Classified as hazardous** – At least one guideline toxicity study or other suitable data for SWCNTs/SWCNHs and/or MWCNTs are available for which the outcomes meet the criteria for classification.

A Applying a precautionary approach

5. Using a case-by-case assessment when specific toxicity data become available.

6. Using information on analogous substances, where the mechanism of toxicity implies this is relevant. NICNAS commented, in relation to classification for specific target organ toxicity repeated exposure:

Although there are no supportive data for SWCNTs, given the adverse effects have been postulated due to lung overloading, SWCNTs are not expected to behave differently to MWCNTs[1]*. Therefore, the report recommends that the above classification should also be applied on a precautionary basis to SWCNTs until data to the contrary become available, particularly as the applicability of the pathogenic fibre hypothesis to granuloma and fibrosis induction is not clear.*

B Application of classification cut-offs

7. A technical issue is whether the cut offs/concentration limits that trigger the classification of a mixture are appropriate for nanomaterials. Nanomaterials are generally more hazardous than the larger sized particle ranges of the chemical, e.g. due to high surface area per unit mass. Relating to this issue, section 1.3.3.2.2 of the GHS states:

Normally, the generic cut-off values/concentration limits adopted in the GHS should be applied uniformly in all jurisdictions and for all sectors. However, if the classifier has information that the hazard of an ingredient will be evident below the generic cut-off values/concentration limits, the mixture containing the ingredient should be classified accordingly.

8. One option for providing advice in the GHS text on this matter is to provide an example, such as:

This may occur is when a chemical has very high surface area per unit mass, e.g. in the case of engineered nanomaterials.

III. Hazard communication for nanomaterials

9. A number of initiatives and developments can inform the proposed guidance.

10. Safe Work Australia has published Codes of Practice in GHS format for:

(a) Preparation of Safety Data Sheets (SDS) for hazardous chemicals, and

(b) Labelling of workplace hazardous chemicals.

These include recommendations and information relating to nanomaterials.

11. The Codes recommend that SDS and workplace labels should be provided for engineered or manufactured nanomaterials unless there is evidence they are not hazardous. The following label statements are recommended for products containing nanomaterials when the hazards are not fully characterised:

(a) Contains engineered/manufactured nanomaterials. Caution: Hazards unknown.

(b) Contains engineered/manufactured nanomaterials. Caution: Hazards not fully characterised.

It is noted that these phrases are for use on an interim basis, as the manufacturer/importer has a duty to correctly classify the chemical and include information on known hazards on the label in accordance with the Model Waste Health and Safety Regulations (WHS Regulations).

12. In Australia, additional parameters relevant to nanomaterials are recommended in the physical and chemical properties part of the SDS Code (Section 9).

13. The correspondence group on the revision of Section 9 of the SDS, led by Germany, has considered the Australian proposal to add extra parameters to Section 9 for nanomaterials. While the work of the group is yet to be finalised and approved, the group supports the addition of the parameter *particle characteristics* to the list of parameters in Section 9, with the addition of the following text:

- *applicable to solids only;*
- *indicate the particle size (median and range);*
- *if available, further properties may be indicated in addition:*
    - *size distribution;*
    - *shape and aspect ratio;*
    - *specific surface area.*

14. The International Organization for Standardization (ISO) published the technical report ISO/TR 13329:2012 *Nanomaterials – Preparation of material safety data sheets (MSDS)* in December 2012. This technical report provides guidance on the development of SDS for manufactured nanomaterials (and materials or products that contain manufactured nanomaterials), and provides additional information on safety issues associated with manufactured nanomaterials. The technical report takes into account the GHS, including Annex 4 (SDS).

IV. Safety hazards of nanomaterials

15. A review by Toxikos Pty Ltd entitled *Evaluation of potential safety (physicochemical) hazards associated with the use of engineered nanomaterials* was published by Safe Work Australia in March 2013. The review found that:

(a) The current understanding of safety hazards of engineered nanomaterials arising from their physical and chemical properties is primarily associated with combustibility and explosivity of airborne dusts.

(b) Accidental explosions have been reported involving metal nanopowders that have resulted in deaths of workers during the production of aluminium nanopowder by mechanical attrition milling, and in the premix plant of a slurry explosive factory when loading a batch mixer with very fine aluminium flake.

(c) Dust clouds of some engineered nanomaterials are able to result in very strong explosions if the concentrations of engineered nanomaterials in air are sufficiently high and the dusts can be ignited. However, the severity of explosion for engineered nanomaterials is no higher than that seen for their micron-sized counterparts.

(d) In a well-managed workplace, concentrations of airborne emissions from nanotechnology processes will be substantially lower than concentrations needed for an explosion.

(e) The minimum ignition energy varies considerably with nanomaterial type. Nanoscale metal powders are easily ignitable (low minimum ignition energy), but carbon nanomaterials are not (high minimum ignition energy).

A Information in safety data sheets

16. For the engineered nanomaterials SDS reviewed for the report, there was a lack of information provided to enable persons conducting a business or undertaking and workers to identify safety hazards associated with the use of the engineered nanomaterials.

17. Arising from this report, the recommendation for manufacturers and importers is that even if a nanomaterial is not classified as hazardous according to the GHS, if there is potential for a dust explosion hazard to exist when handling the engineered nanomaterial, this should be reported in the SDS.

B GHS classifications

18. In the GHS there is no specific hazard category for the explosivity of dust clouds.

19. Some nanomaterials may potentially be readily combustible solids and hence classifiable as flammable solids.

V. Proposal

20. The same overall approach that is used for chemicals generally can be used to classify nanomaterials and provide hazard information.

21. However, in regard to classification and hazard communication there are some nanomaterial-specific issues. Thus, Australia considers that guidance specifically on

nanomaterials or general guidance that covers nanomaterial issues should be included in the GHS text.

22. Issues to be considered include clarifying the extent to which a precautionary approach can be used to contribute to classification where necessary and also whether current concentration cut-offs are appropriate for nanomaterials.

23. This guidance can build on previous or current work, as described in this paper. The work of the informal correspondence group for the revision of Section 9 of Annex 4 (SDS) is contributing towards this outcome.

24. Findings of the report on *Evaluation of potential safety (physicochemical) hazards associated with the use of engineered nanomaterials* may inform the work of the informal correspondence group on dusts explosion hazards.

25. Dust clouds of some engineered nanomaterials are able to result in very strong explosions if the concentrations of engineered nanomaterials in air are sufficiently high and the dusts can be ignited. The recommendation for manufacturers and importers is that even if a nanomaterial is not classified as hazardous according to the GHS, if there is potential for a dust explosion hazard to exist when handling the engineered nanomaterial, this should be reported in the SDS.

26. Australia requests that these issues be tasked by the Sub-Committee to the informal correspondence group being led by the expert from France.