

## Industry Actions for Responsible Assessment and Classification of Cobalt Compounds

An inhalation carcinogenicity study of cobalt metal powder (NTP<sup>1</sup> Study 60311 – 05) was released online as draft technical report on 19 September 2013 at

<http://ntp.niehs.nih.gov/?objectid=ABD1DF87-A7F0-5D9B-0C6BA115E3117F5B>

This report and the conclusions therein were discussed and accepted during a peer review meeting with external experts at the NTP (Raleigh Durham, NC, USA) on 29 October 2013. The NTP and the technical peer review panel concluded that, under the conditions of the 2-year inhalation studies, there was clear evidence of carcinogenic activity of cobalt metal in male and female mice and rats.

The members of the CDI and CoRC<sup>2</sup> would like to communicate the following points, based on their external and internal review of the report:

- The systemic exposure-related effects seen in rats are not considered relevant for humans, whereas the effects seen in the respiratory tract of the rats and mice are considered relevant for human hazard analysis.
- Only inhalable forms of cobalt metal are hazardous.
- The members of the CDI and CoRC have self-classified cobalt metal as a Category 1B carcinogen by inhalation (H350i; May cause cancer by inhalation).
- Under the GHS mixture rules, all mixtures (i.e. alloys) containing >0.1% cobalt metal would carry the same classification.
- All physical forms of cobalt metal are classified, based on the risk that a massive form may become partially inhalable through abrasion during normal handling and use. Massive forms of cobalt metal and alloys do not need to be labelled, if they do not present a hazard to human health by inhalation in the form in which they are placed on the market<sup>3</sup>.

---

<sup>1</sup> NTP = National Toxicology Program (USA)

<sup>3</sup> CDI = Cobalt Development Institute; CoRC = Cobalt REACH Consortium

<sup>3</sup> Regarding labelling, **point 1.3.4 of Annex I to CLP** provides that metals in the massive form, as well as alloys, do not require a label if they do not present a hazard to human health by inhalation [...] in the form in which they are placed on the market, although classified as hazardous in accordance with the classification criteria of CLP. However, the supplier shall provide the information on the classification of an alloy to downstream users or distributors by means of the Safety Data Sheet. From “ECHA CLP Frequently Asked Questions” at <http://echa.europa.eu/web/guest/support/faqs/>. Under GHS, fourth revised edition (2011); page 33, section 1.4.10.5.5 “Special labelling arrangements” is stated that “The competent authority may choose to allow communication of certain hazard information for carcinogens [...] on the label and on the SDS, or through the SDS alone. Similarly, for metals and alloys, the competent authority may choose to allow communication of the hazard information through the SDS alone when they are supplied in the massive, non-dispersible form.”

- Companies are responsible for their own self-classification, labelling and communication with their supply chains (e.g. Safety Data Sheets), as appropriate for their products.
- The results of the NTP cobalt metal study are also being carefully assessed together with other available information on their possible relevance for the science-based evaluation of other cobalt compounds. Further guidance will be provided when a suitable approach has been determined.

19 December 2013