

COMMENT ON**Consultation on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4)**

WVMetalle would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4). In essence, WVMetalle emphasize that the classification criteria are not conclusively met and that specifically the classification proposal as a reproductive toxicant is premature. Proposing this classification when an agreement at ECHA and Member State level was already achieved to perform a full EOGRT study (under EU REACH; including DIT and DNT cohorts) is not coherent with a sustainable chemicals management strategy for addressing potential hazards of silver.

WirtschaftsVereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, represents the German Non-Ferrous (NF) metals industry towards politics and economy in order to maintain and establish measures at a very high level. Today, WVMetalle has about 670 member companies, including producers and processors of most base and special metals and compounds including silver and silver compounds. WVMetalle is member of the German Industry Association (BDI) and of the European Non-Ferrous Metals Association (Eurometaux).

General Comments

- Silver is as an indispensable material for many branches downstream the WVMetalle members. Silver is used in a very wide range of essential uses like in electrical applications and electronic parts, in energy generation and transmission, in solar panels and wind turbines, in solders and brazing sticks, in medical equipment and healthcare products etc. A lot of further examples and detailed technical aspects for the non-substitutable nature of silver will be delivered during this consultation by a brought range of European and national federations as well as by individual companies. Therefore, we have serious concerns about the potentially far-reaching consequences of the proposed classification.
- WVMetalle support the scientific comments submitted by the European Precious Metals Federation (EPMF). We especially agree with EPMF that a read-across from silver salts to metallic silver is not scientifically justified as bioavailability is an intrinsic property which needs to be considered when assessing the hazards of metals.

Specific Information Requests raised within the consultation:

- **Reproductive toxicity**

We think that the criteria for classifying silver as a reproductive toxicant have not been conclusively met due to the very limited available human information that do not support a classification. The key studies used in the read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver is therefore premature. In agreement with the REACH regulation procedures and following the decision at ECHA level in June 2019 EPMF is currently performing a TG443 compliant EOGRT study (including DIT and DNT cohorts) which is designed to fill the identified data gaps for this endpoint. The results of this study will allow a conclusive judgement for this endpoint and should be waited for instead of starting a CLH discussion on silver now.

- **Germ cell mutagenicity**

We think that the criteria for classifying silver as a germ cell mutagen have not been conclusively met as there is no direct human evidence that elemental silver (or ionic silver) is able to induce heritable genetic mutations and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint. The proposed classification is based on low-reliability studies which are inadequate for classification purposes.

- **Skin sensitization**

We think that the criteria for classification as a skin sensitizer are not fulfilled as reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking. In addition, a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver.

- **Hazardous to the aquatic environment**

We think that the criteria for classification of massive silver as toxic to the aquatic environment are not fulfilled either. The available scientific information as well as evidence from internal industry data confirm that a split classification for silver massive versus silver powder is justified. Following the specific guidance developed for the hazard assessment of metals would result in a non-classification of massive silver.

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