

Submission

By the German Social Accident Insurance (Deutsche Gesetzliche Unfallversicherung e.V., DGUV) on 15 October 2019

Concerning a Commission delegated regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation

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Statement by the German Social Accident Insurance (DGUV, umbrella association of the German Social Accident Insurance Institutions) on a draft regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation

In Annex III, titanium dioxide should be deleted and the new comments V and 10 should not be inserted. In Annex I, text should be inserted under 2.12 to the effect that the two EUH phrases EUH211 and EUH212 (supplemental information on the label) apply only to consumer products.

Reasoning

1. No incidence of occupational disease: The German Social Accident Insurance has no evidence of cases of lung cancer arising at workplaces at which work involving titanium dioxide is performed. We have no knowledge of such cases of occupational diseases. Our experience is supported by numerous epidemiological studies, including those cited in the CLH report (Proposal for Harmonised Classification and Labelling).
2. Weaknesses of the toxicological evaluation: The toxicological studies supporting the proposed classification of titanium dioxide as a carcinogenic substance are based upon "lung overload" effects in rats and do not therefore satisfy the applicable scientific requirements (OECD, ECHA and ECETOC guidelines). Owing to the particular sensitivity of rats to overload effects on the one hand and the questionable relevance of exposure of the respiratory tract and lung of test animals on such a massive scale on the other, these results cannot be transferred to human beings and should not therefore be used as a basis for classification as a Category 2 carcinogen.
3. Not substance-related, and therefore with considerable repercussions for the classification of further, similar substances and substitute substances: As the Risk Assessment Committee (RAC) itself has ascertained, the effect in the studies referred to is not substance-related, but based solely upon the fact that the substance is an insoluble dust with a certain particle size. For the hazard class of carcinogenicity in particular, Annex I, 3.6.2.2.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP Regulation) concerns substances with the intrinsic property of causing cancer. A classification that is based purely upon physical parameters and thus not upon intrinsic substance properties is not therefore appropriate in this hazard class. Should such an entry nevertheless be made in Annex VI of the CLP Regulation, the same reasoning would also require iron oxide, aluminium oxide, magnesium oxide, talcum, graphite, coal dust and other inorganic pigments to be classified in the next step in the same way. Even plastic dusts would be affected as a result.
4. Unsettling of users and inflation in the classification and labelling as suspected carcinogens: Classification as a Category 2 carcinogen of titanium dioxide in a first step followed by further insoluble substances in a second step would lead to a considerable expansion of product labelling. In the absence of a change in the hazard (see Point 1: we observe no corresponding incidence of occupational diseases), this inflation is more likely to lead to a part of the population increasingly adopting a casual attitude towards substances marked in this way. This in turn would lead to a greater risk being presented by substances for which demonstrable justification does exist for this classifi-

cation. Another part of the population would be seriously unsettled by this classification and labelling. Exposure in the past would be a cause of anxiety, even where the exposure lay below specified limit values.

5. Alternative proposal: For workplaces, the introduction of a workplace guideline limit or binding occupational exposure limit for granular biopersistent dusts in accordance with Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work would be an effective measure for assuring adequate occupational safety and health. A health-based limit value (general dust limit value) of this kind exists in Germany, namely 1.25 mg/m^3 (in terms of the respirable dust fraction and a mean density of 2.5 g/cm^3).
6. Limiting of EUH211 and EUH212 to consumer products: The EUH phrases EUH211 and EUH212 are a sensible means of warning consumers of dust exposure of this kind. They can however be limited to consumer products when a workplace guideline limit or occupational exposure limit exists for professional use.