BDI

Answers to the questions raised concerning the proposal to classify titanium dioxide as carcinogenic (Cat. 2) (Doc. CA/MS/07/2018 and CA/27/2018)

Umwelt, Technik und Nachhaltigkeit

We welcome CARACAL's decision on 8 March 2018 to set up a working group to clarify the issues raised in relation to the proposed classification of titanium dioxide. We believe it is essential for the working group to be able to discuss the issues openly and in the necessary breadth and depth. Therefore, we consider all questions which were raised by the UK (CA/MS/07/2018) as relevant and that they should be discussed by the working group in detail.

With regards to the complexity of the issue, we are therefore in favour of not including titanium dioxide in the proposal for an amendment to Annex VI of the CLP Regulation (CA/08/2018). We strongly suggest to wait for the results of the discussion first.

1. **Is non-substance specific 'particle toxicity' within scope of CLP, as it appears to be different from 'classical chemical toxicity' as generally understood in the CLP context?**

   The scope of the CLP Regulation is limited to "intrinsically" toxic substances (CLP Regulation, Annex I, 3.6.2.2.1). Intrinsic is a property if it can be specifically assigned to a substance and does not apply to an entire group of substances, for example. The RAC denied such intrinsic toxicity "in the classical sense" (see pages 38, 40 of the explanatory statement) and instead based its recommendation on general particle effects. The property was assumed for the entire group of PSLT (poorly soluble low toxicity particles).

   Protection against dust and general particle effects is primarily a matter of health and safety at the workplace. There are therefore corresponding dust limit values in Germany and other EU Member States in order to protect against particle-related lung inflammation processes caused by exposure to and inhalation of dust. The German general dust limit value (German abbreviation ASGW; TRGS 900) is intended to prevent a deterioration in the functioning of respiratory organs caused by a general dust effect and applies for all poorly soluble or insoluble particles. At European level, exposure to dust could be regulated in a harmonised way via directive 98/24/EC on protection of the health and safety of workers.

2. **a) If 'particle toxicity' is in scope, is CLP an appropriate way to address this hazard?**

   We do not see CLP as the right tool to address a possible inhalation hazard of PSLTs (see point 1). Particle-induced inflammatory processes are not substance-specific. The threshold limits for dust at the workplace in Germany and EU Member States already protect from general

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particle-related inflammatory processes in the lungs as a result of inhalative dust exposure. These rules thereby already implement a group approach when dealing with PSLTs.

We are afraid that individual substances are arbitrarily classified, although the protection objective is already regulated in occupational safety for the whole group of dusts without specific toxicity. In our view, such a procedure can lead to a decision that could be legally challenged and is not proportionate and not appropriate after CLP (Article 37(5)).
The example of titanium dioxide and the further discussion lead hopefully to the realization that this is not a sensible and appropriate approach, but does a great deal of damage.
For further details see the CARACAL documents:
- “04 - German_Industry_Federation_BDI_position_paper_TiO2.pdf”
- “11 - VdL_Position_TiO2.pdf”
- “03 - BDI-VCI-VdL-VdMi Comments_CA_90_2017_TiO2.PDF”
- “04 - VCI_Presentation_Titanium_dioxide.PDF”

b) What would be the regulatory, environmental (e.g. waste disposal) and socio-economic consequences of classification?

Classifying titanium dioxide as substance suspected of causing cancer would have serious consequences for consumers and the economy without increasing health protection. The consulting company RPA has compiled a comprehensive overview of the effects on all industries affected under the title "Analysis of the socio-economic impacts of a harmonised classification of Carcinogen Category 2 for titanium dioxide (TiO2)".

In summary, it should be noted from this report:

The Carc Cat 2 harmonised classification would impact upon a multitude of downstream user sectors with a combined Gross Added Value of hundreds of billions of Euros; paints and plastics alone, the most important uses for TiO2, account for over €120 billion per annum. Downstream users might consider the reformulation of their products, however, in the vast majority of cases this could not be successful due to the lack of alternative pigments that match TiO2’s performance in technical terms and availability. Waste regulations would impact upon the recycling and reuse of waste that contains over 1.0% TiO2 and might impose an additional cost ranging from a few thousand Euros to millions of Euros per site for the disposal of packaging and manufacturing waste classified that would be newly classified as hazardous.

The Carc Cat 2 harmonised classification could lead to the removal from the market of a multitude of consumer formulations and products due to a decreasing consumer acceptance. This could apply to e.g. toys, cosmetics, food contact materials, pharmaceuticals and currently ecolabelled products (including textiles).

Importantly, the labelling of mixtures containing TiO2 as suspected carcinogens (CLP requires the label to read “suspected of causing cancer”) and the stigmatisation of the substance would drive negative consumer and industrial/professional user perceptions thus leading to market losses for manufacturers of TiO2-containing products and their downstream supply chains.

In many statutory regulations such as plant safety, environmental and consumer protection, or in downstream legislation on toys, food contact

materials or cosmetics, extensive obligations as well as wide-ranging bans and restrictions arise through classification and labelling as carcinogenic in category 2, automatically and without further verification as to whether the use of the substance actually poses risks. In this respect, the classification and its consequences must not be considered in isolation. The automatic knock-on legal effects in other areas must always be evaluated in the overall context and, where necessary, at least temporarily decoupled so that holistic risk-oriented considerations can be elaborated in a differentiated way. Industry takes a critical stance in particular on the following consequences and automatic legal effects associated with the proposed classification of titanium dioxide:

- **Waste legislation:**
  Classification of waste in European waste legislation is based on EU chemical legislation. The hazardous properties of waste (so-called “HP criteria”) were aligned on GHS at the end of 2014. The HP criteria stipulate the point from which the property of hazardous waste obtains. The principles for waste classification are set out in the EU waste framework directive (2008/98/EU) and in the European waste catalogue. If a waste contains a substance suspected of causing cancer (category 2) at a concentration of ≥ 1.0%, the waste has to be classified as hazardous in accordance with HP 7. As a consequence of this, essentially all wastes which contain titanium dioxide at a concentration of 1% or more would have to be classified as hazardous and processed accordingly. These wastes could range from plastics, building materials, wallpapers, paint remnants and speciality papers through to porcelain or furniture. Exceptions would be possible only if the wastes in question is unreservedly assigned to a waste heading not marked with an asterisk to which, in turn, no corresponding “mirror entry” of a waste heading marked with an asterisk is assigned (“absolute classification”). The associated obligations arising automatically for processing such waste classified as hazardous would go hand in hand with numerous complications and additional burdens for companies and end users, e.g. plant permits in accordance with the 4th decree on implementation of the federal emission protection law (4. BImSchV, Germany), requirements under the decree on provision of proof with substantial documentation obligations or notification and release obligations under sub-federal legislation as well as requirements on cross-border transport. By contrast with the CLP regulation, broadly speaking no provision is made for derogations in the HP criteria for waste legislation. It is also questionable whether recycling of these wastes would still be possible or even sensible, since markets for the recycled material will also change as a result of classification. Household or local separate collection of recyclable materials as occurs in the German “dual system” would no longer be possible in its current form and it would also no longer be possible to meet the quotas established nationally (in the packaging law) and at European level (in the circular economy package).

- **Disappearance of important quality indicators for consumers**
  Ecolabels such as Blauer Engel, Nordic Swan or the EU-Ecoflower must not be issued for products containing substances suspected of

causing cancer (category 2). As a result, important quality indicators for consumers would disappear.

- **Toys Safety**
  Toys are also affected by a classification of titanium dioxide. Substances classified as suspected of causing cancer in category 2 are banned in toys and toy components, and placing them on the market is restricted under the provisions of the toys directive (2009/48/EC). For example, painted wooden toys, plastic toys, printed stickers or paint boxes with titanium dioxide components would no longer be allowed.

- **Air quality standards**
  National air quality standards like the German TA Luft establish a direct link between classification of a substance under CLP and limits on emissions to air which are not based on the provisions of the IED directive or other European requirements. This linkage can lead to disproportionate retrofitting requirements on industrial plant.

- **Classification and labelling of mixtures**
  At a concentration above 1%, classification in category 2 leads to labelling of mixtures with the hazard symbol GHS08 “health hazard” and the hazard statement H351 – “suspected of causing cancer” (category 2, on inhalation). This classification and labelling leads to great uneasiness in the downstream legal areas without taking into account that there is no real health risk either for employees and private end users or a threat to the environment. It can be assumed that acceptance of a substance “suspected of causing cancer” is not a given in consumer products. It is therefore highly probable that consumers will avoid products labelled as such even though there is no danger. Classification of titanium dioxide leads to over-labelling and, as a result, to consumer rejection. An evaluation of the real risks by the user is no longer possible and this leads to a downgrading of risk labelling and the CLP regulation.

- **Use of titanium dioxide as a negative control in studies**
  Titanium dioxide has been used as a negative control in many inhalation tests in order to assess a range of substances. As a rule, these tests have been used in REACH dossiers. Classification of titanium dioxide would lead to all relevant animal tests having to be repeated with other control substances. However, since the effect is particle-related rather than toxicological, as already described, corresponding control substances would not be available. Accordingly, the dossiers in question would be worthless de facto.

3. **What is the scope of ‘Poorly Soluble Low Toxicity Substances’ (PSLTs) and how could they be defined?**
   RAC acknowledges that the toxicological profile described for titanium dioxide is not exclusively characteristic for titanium dioxide but applies to the whole group of chemicals referred to as “poorly soluble low toxicity particles” (PSLT particles). PSLT are poorly soluble dusts which do

not show a specific toxicity (see also TRGS 900 and “Allgemeiner Staubgrenzwert”, Germany”).

4. **How could PSLTs be incorporated in CLP in a way that is practicable and robust from both scientific and policy perspectives, and workable in practice?**
   Protection against dust and general particle effects is primarily an occupational safety issue. In Germany and many EU member states there are therefore corresponding dust limits to protect against inhaled dust exposure at the workplace. At European level, dust exposure could be regulated uniformly via Directive 98/24/EC on health and safety at work. Therefore, we do not consider it as appropriate to include PSLTs as an entry under CLP.

5. **If PSLTs were to be included in CLP Annex VI, either in a generic entry or substance-by-substance, how could such entries be presented to make clear that the hazard is ‘particle toxicity’ and as such relevant for inhalation of respirable particles, and of very limited relevance for liquid or solid forms of the substance or for mixtures?**
   Due to the reasons explained above we do not consider it appropriate to include PSLTs in CLP Annex VI. Even if the European authorities should reach the conclusion that, in general, a classification of titanium dioxide as carcinogenic category 2 is justified, a differentiated approach of hazard classification would be necessary. Fundamentally, the particle effect can only occur if titanium dioxide appears in the “form” (Articles 5(1) and 6(1) of CLP regulation) of alveolar (respirable) powder. It should be validated that uses where a respirable exposition is not possible are not impacted by the classification. A specification of the entry in Annex VI of the CLP regulation – and thereby a restriction of the classification entry – to titanium dioxide in a powder form would be in principle legally possible. However, in view of the serious negative consequences we strongly oppose the classification proposal.

6. **Should an entry in CLP Annex VI for titanium dioxide be delayed until these considerations are concluded?**
   Yes, because a classification of titanium dioxide due to a non-substance specific property is not appropriate. Therefore we believe it is essential for the working group to be able to discuss the issues openly and in the necessary breadth and depth and the questions raised should be answered in full before titanium dioxide is even considered for inclusion in Annex VI of the CLP Regulation.

7. **What changes are needed to update the existing ECHA guidance to reflect the outcomes of this discussion?**
   What changes would be needed to update the ECHA guidance depends on the outcome of the discussion and could not be discussed in advance.

Further detailed information are available by:

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