

## Comments

on the European Commission's working paper

### **"Classification of TiO<sub>2</sub> and mixtures containing TiO<sub>2</sub>"**

(Doc. CA/90/2017) for the

25th meeting of the Competent Authorities for REACH and CLP (CARACAL),  
15-16 November 2017

We welcome the opportunity to provide comments on the European Commission's working paper on the proposal for a classification of titanium dioxide for discussion in CARACAL on 16 November 2017.

### **Fundamental aspects**

- **Non substance-specific dust effects**

The Commission correctly points out that the RAC does not assume an "intrinsic" toxicity of titanium dioxide and that its recommendation is based on the "poorly soluble" property and the resulting particle effects. (*"The mode of action cannot be considered "intrinsic toxicity" in a classical sense but is characterised as particle toxicity."*). We welcome this clarification.

- **Applicability of the CLP regulation to dust effects**

Unfortunately, the Commission subsequently neglected to draw the corresponding conclusions or at least to cast a doubt on whether the CLP regulation is even applicable regarding such particle effects. The recommendation made by the RAC to extend the scope of applicability of the CLP regulation by using substance-unspecific properties for the classification would create a precedent for the classification of all poorly soluble substances in powder form. Such approach raises considerable regulatory, legal, economical and health policy concerns, which are not reflected in the working document.

On the contrary, the working paper indicates that the Commission is willing to think about adaptations or exceptions without prior clarification of this fundamental question (*"As correctly remarked by RAC, the CLP regulation does not exclude a health hazard classification triggered by physico-chemical characteristics of a chemical, and the Commission has no reasons to question the correctness of the proposed classification of TiO<sub>2</sub> if inhaled as small particles."*).

The CLH-proposal and the recommendation by the RAC have already given rise to significant uncertainties in the affected industries and their customers. We therefore recommend that the open questions are clarified by an impact assessment and a statement by the European Commission Legal Service. A mere continuation of the CLP process would otherwise substantially increase the uncertainties, with negative effects for the industry throughout Europe.

- **Scientific basis for the classification**

It is our opinion that the existing scientific data do not justify a classification of titanium dioxide:

There is an ongoing controversial debate about how relevant studies with high dust concentrations on rats are for humans. In particular, there is a great uncertainty regarding the extent to which knowledge gained from inhalation tests with rats can even be transferred to humans at all. The recommendation made by the RAC is fundamentally based on a single study with rats that goes back 20 years and is clearly not conform with the guidelines. The RAC did not take the numerous epidemiological studies into account which showed that under real-life conditions there is no connection between the exposure to titanium dioxide and the risk of developing cancer.

Unfortunately, the working paper uncritically accepts the recommendation made by the RAC without pointing out the open scientific questions and the weaknesses of the study the recommendation is based on.

### Questions asked

- **Question 1:** *Do CARACAL members and observers consider that the proposed classification of  $\text{TiO}_2$  can be **translated directly into Annex VI**, or, taking into account the scientific evidence, is there a **possibility for adaptations** (e.g. through further footnotes to differentiate between particles that can be inhaled and larger particles/massive forms of  $\text{TiO}_2$ )?*

The classification of titanium dioxide under the CLP regulation is not justified because the protection against dust is primarily an occupational safety matter and such classification would also have disproportionate consequences.

The classification as recommended by the RAC is based on a substance-unspecific general particle effect of dust. A specific toxicity of titanium dioxide has not been determined and the property has been assumed for the entire group of PSLT (Poorly Soluble Low Toxicity Particles). In Germany and many other EU Member States there are already general limits for dust in occupational health and safety legislation. The necessity of a classification of individual substances without a specific toxicity has not been determined.

An inhalative exposure to titanium dioxide dust that could at least theoretically be within the critical dose range, is only to be expected at highly exposed workplaces. However, the general limits for dust at the workplace effectively protect humans from this particle effect already. In contrast, a classification of titanium dioxide as potentially carcinogenic would not have any direct legal consequences with regard to occupational health and safety (beyond the obligation to consider a substitution), thereby it would be neither suitable for improving occupational health and safety, nor would it be necessary.

Such a classification would also be disproportionate, as its consequences would also affect products in which titanium dioxide is firmly bound in a matrix so that it cannot be inhaled.

- **Question 2:** *What are the views of CARACAL members and observers on the application of **derogations** such as Article 12(b) or Annex I, section 1.3.4?*

The rules in Annex I, 1.3.4, of the CLP regulation are only valid for a very restricted range of products and they merely allow to forego the *labelling*. The derogation does not have any effect on the *classification* of mixtures and products that include the substance. Therefore, all the legal consequences linked to the classification, e.g. in the waste legislation, continue to remain in force. A derogation on the basis of Article 12(b) CLP regulation would require comprehensive and bureaucratic verifications of the “non-bioavailability” for each of the mixtures – which is not feasible in practice. In addition to this, the corresponding criteria for such a verification are not yet defined in detail. Therefore, in our view none of these two approaches for a derogation would be a solution.

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. Therefore, 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.

- **Question 3:** *Is it appropriate to **limit harmonised classification to TiO<sub>2</sub>**? or would it not be preferable to **also classify poorly soluble low toxicity particles (PSLT)**, or a well-defined group of PSLT, in the same way in a **grouping approach**?*

The discussed general dust effect is valid for the entire group of Poorly Soluble Low Toxicity Particles (PSLT) and would therefore be relevant for all of these substances. The threshold limits for dust at the workplace in Germany and many other EU Member States already protects from general particle-related inflammatory processes in the lungs as a result of inhalative dust exposure. These rules thereby already implement the suggested group approach when dealing with PSLTs.

Furthermore, it is our opinion that the scientific basis for the classification of the entire PSLT substances group on the basis of a single – controversial – animal experiment study is not given.

The classification of an entire group of substances is not appropriate under CLP as the CLP regulation assumes the existence of a substance-specific property.

*For further information see presentation "Harmonized Classification of Titanium Dioxide - November 2017" (02 - Titanium dioxide\_EN.pdf)*

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