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VCI Statement

On the proposal for a harmonised classification of titanium dioxide (TiO2)

Executive Summary

The French agency “Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail” (ANSES) elaborated a CLH report[1] with a proposal for a harmonised classification and labelling of titanium dioxide as “potentially carcinogenic to humans” (category 1B) / “may cause cancer by inhalation” (H350i).

In June 2017 the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) deliberated on the above and proposed the following classification in its opinion[2] adopted on 14 September 2017:

- Suspected of causing cancer (cat 2. through the inhalation route) – Labelling with pictogram GHS08 (health hazard), the signal word “Warning” and the hazard statement H351 “Suspected of causing cancer”.

At the European level, the RAC opinion is currently undergoing the discussion and decision-making procedure as prescribed in Article 37 of the CLP Regulation.

In the light of existing studies, the VCI takes the view that a classification of titanium dioxide as carcinogenic (cat. 2) is neither justified nor appropriate. For this reason, no harmonised classification should be made. The assessment is incomprehensible from the toxicological perspective, causes much uncertainty among consumers and has major consequences for professional users and impacted industries. The VCI’s main arguments are summed up in the following:

1. No indication of problems from epidemiological studies and application practice

Titanium dioxide has been used safely for many decades. In large-scale epidemiological studies no connection was found between exposure at the workplace and a cancer risk. This is also noted in the CLH report:

“Human data do not suggest an association between occupational exposure to TiO2 and risk for cancer. […]” [CLP Report, page 8].

[1] http://echa.europa.eu/documents/10162/594bf0e6-8789-4499-b9ba-59752f4eafab

[2] https://echa.europa.eu/documents/10162/682fac9f-5b01-86d3-2f70-3d40277a53c2

2. Insufficient scientific basis

Titanium dioxide ranks among the most frequently studied substances. It has been used for long as a comparator substance, inter alia, for inhalation studies. TiO2 has no toxic effect; it is neither mutagenic nor carcinogenic. Titanium dioxide is (bio)chemically inert and, because of its very low solubility in biological liquids, it is not bioavailable. TiO2 falls in the group of granular biopersistent dusts (GBS).

The classification proposal in the CLH report is based essentially on studies in rats exposed to extremely high concentrations of titanium dioxide dusts, which led to “lung overload” effects. This does not fulfil the requirements to regulatory studies.

All relevant guidance documents by ECHA, OECD and the ECETOC Report unanimously observe that the results from “lung overload” studies in rats should not be transferred to humans, as there is no relevance to the latter. Therefore, a classification as carcinogenic is neither justified nor appropriate from the toxicological perspective and when applying the criteria of the ECHA guidance.

3. Protection through existing legislation

Protection against dust and general particle effects is primarily an occupational health and safety (OHS) issue. With chronic intake by inhalation, the effect mechanism of the substance group GBS consists of particle-induced inflammatory reactions of the lungs, in consequence of an excessive strain on natural lung clearance. This is not substance-specific but characteristic of poorly soluble dusts. For this reason, relevant dust limit values are in place in Germany and other EU Member States, protecting workers against particle-caused inflammatory processes in the lungs due to dust exposure by inhalation. For example, in Germany the general dust limit value (Allgemeiner Staubgrenzwert/ASGW) protects against impairments of respiratory organ functions due to general dust burdens. The ASGW applies for all poorly soluble and insoluble dusts.

4. No intrinsic toxicity of titanium dioxide

A substance must have intrinsic toxicity to be classified as carcinogenic, according to both the CLP Regulation and the underlying Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, no such substance-specific toxicity was found by the Committee for Risk Assessment (RAC). Thus, the prerequisite is not given for inclusion in Annex VI to the CLP Regulation on harmonised classification.

In the RAC opinion, the Committee does not refer to an intrinsic toxicity of titanium dioxide but, for the purpose of justification, resorts to the general particle property (GBS or PSLT – poorly soluble low toxicity particles). The discussed particle property is assumed for the entire group of PSLTs. But it is worth noting that the protection against dust and general particle effects is an OHS issue (see argument 3).

5. Major and disproportionate negative impacts due to automatic reference to classification and labelling in existing legislation – across the entire value chain down to waste disposal

In many sets of legislation (e.g. on waste, industrial plant safety) or product-specific rules (e.g. for toys or cosmetics), classification and labelling as carcinogenic cat. 2 automatically gives rise to comprehensive obligations and far-reaching bans and restrictions – without any further examination of whether the use of the substance really poses risks. Thus, a classification would have major and disproportionate impacts for almost all uses. In the existing legal situation, this would hold true also in many fields where titanium dioxide is firmly bound in a matrix (e.g. plastics, other binders) so that there is no intake by inhalation.

As a matter of principle, wastes containing TiO2 in concentrations of 1% or more (e.g. plastics, building materials, wallpapers or paint residues) would need to be classified as hazardous waste, requiring disposal as such. In the existing waste disposal system, that dramatic change could be implemented only with considerable extra work and cost or implementation might not be possible at all – as the ensuing obligations, obstacles and burdens are immense. Resulting from this, the given recovery targets in Germany (under the packaging act/Verpackungsgesetz) and in Europe (within the circular economy package) could not be met any longer. Moreover, no improvement would be generated for the protection of humans and environment.

Toys would be impacted by a classification of titanium dioxide too: Substances classified as carcinogenic cat. 2 are banned from toys and toy components, and placing on the market is restricted according to the Toys Directive (2009/48/EC). For example, coated wooden toys, plastic toys with print or paint boxes with TiO2 components would be no longer permitted.

6. Reduced value of hazard labelling

As a matter of principle, the classification as carcinogenic cat. 2 leads from 1% to the labelling of mixtures with the hazard symbol GHS08 (health hazard) and the hazard statement H351 “Suspected of causing cancer”. This classification and labelling causes much uncertainty without taking into account that there is neither a real health hazard for workers and private end consumers nor a risk for the environment.

7. No suitable alternatives are available

Because of the unique coloristic properties and the outstanding health, safety and environmental characteristics of titanium dioxide, there are no suitable alternatives. According to existing knowledge, potential substitutes are poorly soluble substances too.

8. Considerable negative impacts in all industrial sectors

With its excellent properties, TiO2 is an all-rounder raw material in almost all sectors of industry. This substance is widely used, mainly as a white pigment and particularly in paints, coatings, plastics, textiles, foods and feedstuffs, in paper production and in pharmaceutical and cosmetic products. Therefore, a classification would have considerable negative impacts on almost all value chains.

9. Multiplication of notifications to poison centres

The CLP Regulation governs not only the classification, labelling and packaging of hazardous substances and mixtures but also the obligations for reporting to information and treatment centres for cases of poisoning (poison centres). According to Article 45 CLP, such reporting is required for all mixtures that are placed on the market and classified as hazardous to human health.

A classification of titanium dioxide as carcinogenic cat. 2 would multiply the number of reports to poison centres, as large numbers of products would suddenly fall under the reporting requirement.

Conclusion:

The proposal for classification and labelling of titanium dioxide is inappropriate from the toxicological and epidemiological perspective. The criteria for classification are not met. Therefore, no harmonised classification should be made. A classification would not contribute to improving the protection of health and environment, while it would have serious and disproportionately problematic effects in almost all legal fields.

Moreover, a classification under the CLP Regulation would contravene the principle of proportionality enshrined in European law, as such a classification is neither suitable and necessary nor appropriate and thus uncalled for according to Article 37(5) of the CLP Regulation.

In the future, an impact assessment should be mandatory for all substances before a harmonised classification is proposed. Classification decisions must not lead to the withdrawal of established and safely used substances.