



Industry statement on the case of TiO₂ For the CARACAL meeting 15-16 November 2017

October 2017

The undersigned associations welcome the opportunity to explain our views on the proposed harmonized classification of titanium dioxide (TiO₂).

In June 2017 the Risk Assessment Committee concluded that TiO₂ should be classified as a Carc. Cat 2 by inhalation.

We recognize that the CLH process is purely hazard based, but in this case we question the relevance of classifying such inert ‘dusts’, and highlight the unwelcome consequences that such decision would have should it be confirmed.

Following the publication of the RAC opinion, we take note that it itself clearly points to persistent uncertainties in the scientific community on the topic of lung overload. On Page 16 of the RAC opinion it states that: “The CLP Guidance refers to overload conditions in general terms, stating that the “relevance of lung overload in animals to humans is currently not clear and is subject to continued scientific debate”. As downstream users of TiO₂, we strongly believe that this issue should be clarified prior to classifying TiO₂, or any substance, on this basis.

Should TiO₂ be classified, any article covered with or containing it (toys, painted walls, printed packaging, paper, plastic, rubber and more) would be vulnerable to negative perception, irrespective of the risk of the given article.

In the annex of this letter is a detailed overview of our position. A critical impact that CARACAL Members may wish to consider is on CLP itself if ‘over classification kills classification’. It is our joint interest to ensure that CLP fulfills its primary objective, which is to communicate on real hazard.

Moreover, given that there is no alternative to this unique pigment, any reformulation to potential substitutes (which have their own classification issues) would directly affect the quality of products, thus requiring greater quantity of product to be applied in order to obtain comparable opacity and bright colours. It would go against efforts on sustainable use and circular economy.

Without TiO₂ bright and resistant colours would no longer be available, leading to general dissatisfaction. Besides this, products and articles containing TiO₂ would be subject to additional legislative impacts (for example increasing complexity of waste management and loss of ecolabels).

We call for a political assessment and decision to determine if CLP should have such ‘dust overload effect’ in scope. We recognize that this is unusual to have such discussion under a CLH process, however, based on the arguments developed in this paper we think that this is a key element that deserves thorough consideration.

We remain available to discuss this after the November CARACAL meeting if necessary.



Yours sincerely,

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ANNEX

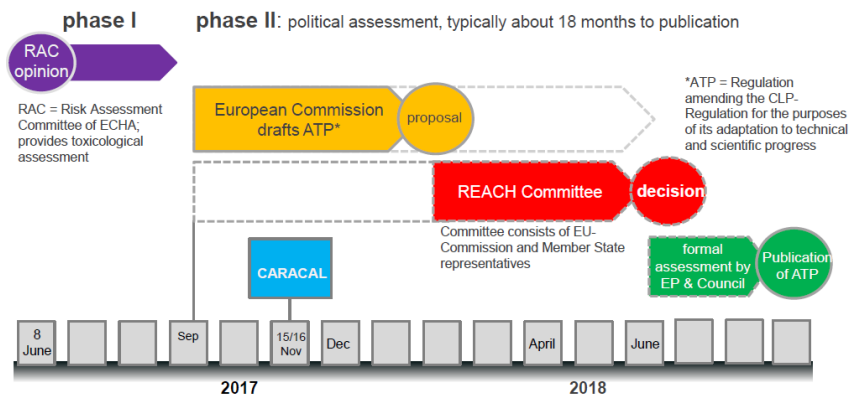
Titanium dioxide – Ensuring effective hazard communication in Europe

Introduction

The European coatings industry are major users of titanium dioxide (TiO₂), a critical raw material for many sectors, which is under threat of being classified across the EU as a substance suspected of causing cancer through inhalation.

Working under the EU's CLP (Classification, Labelling and Packaging) Regulation, the Committee for Risk Assessment (RAC) of the European Chemical Agency (ECHA) on 8 June agreed on a scientific opinion to classify titanium dioxide as a category 2 carcinogen. **We interpret the application of the CLP criteria to the toxicological data on TiO₂ differently to the RAC. We also question that this substance should have been proposed for harmonized classification under CLP in the first place.** It is now up to the European Commission and the REACH Committee to take a final decision.

The implication of this draft RAC TiO₂ opinion needs to be understood – it will lead to unnecessary confusion for users, burdens for Authorities and Business, it will affect sustainable initiatives and will not serve the purpose of effective hazard communication. Classifying TiO₂ as suspected of causing cancer due solely to a 'dust effect' will distort communication of hazards in finished products containing such dusts.



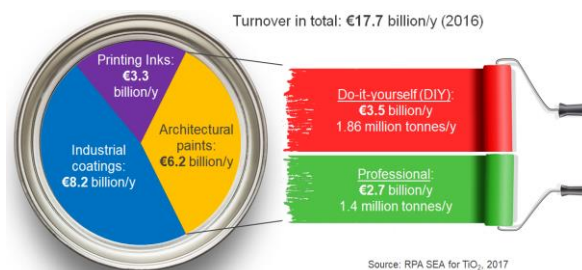
What is titanium dioxide?

Titanium dioxide is a white pigment that consists of titanium and oxygen. It is the most important raw material in the production of paints, coatings, printing inks and plastics.

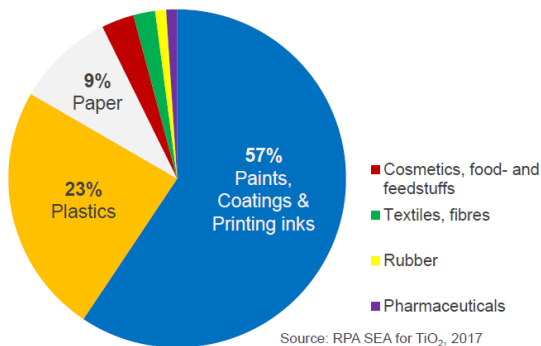
Titanium dioxide has the highest opacity amongst all white pigments. The substance is widely used to provide whiteness and opacity to paints and printing inks, and has no direct substitute raw material. It is also used in products such as plastics and paper, and is also an additive in foods, toothpastes, cosmetic and skin care products, cementitious products (like rendering and plastering mortars), sealants, adhesives and other construction products. It is present in many sunblocks, where it helps protect the skin from cancer due to ultraviolet light. **Titanium dioxide is indispensable for the coatings industry as no alternative pigment of equal performance exists.**



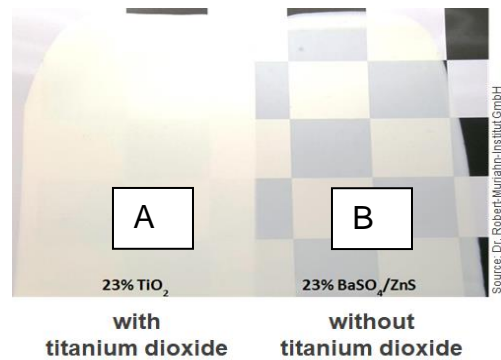
The total turnover of the coatings sector in Europe is **€17.7 billion**. The unnecessary classification would seriously harm the positive economic contribution made by the coatings industry.



Where is titanium dioxide used?



Titanium dioxide has the highest opacity of all white pigments.



Sample B- paint formulation with best alternative pigment to titanium dioxide

The Industry's Position

Handling TiO₂ Powder

The scientific data on titanium dioxide shows that the potential for carcinogenicity by inhalation is related to the effects of inhaling the chemically inert dust. It is not a substance-specific or shape effect, therefore industry questions whether titanium dioxide falls within the scope of the CLP Regulation.

Furthermore, the effect is seen only in rats and is a characteristic of many chemically inert dusts. Exposing your lungs to too much dust is not good for you. Legislation is not needed to communicate this. Hence, we question that CLP should be used to cover such a 'dust effect'.

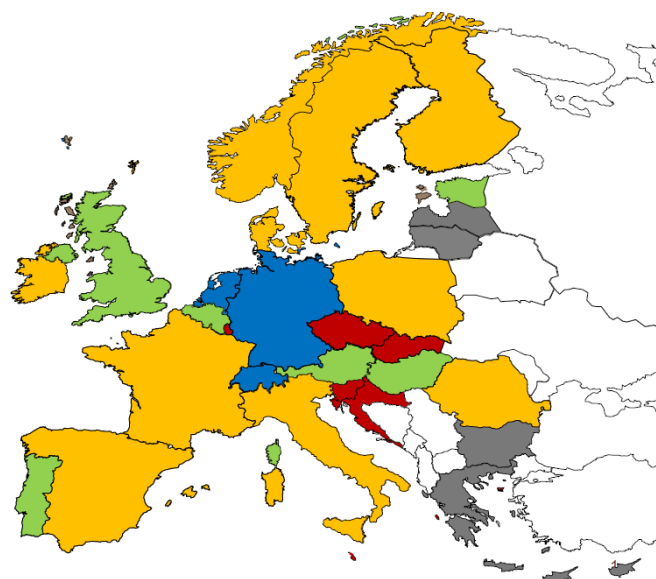
Within the EU, if humans are exposed to dusty working environments, they are bound by occupational dust limits which mean they are obliged to take the proper protective measures, e.g. appropriate ventilation or wearing a mask.

Protection against dust emissions is an occupational health and safety issue. In many EU Member States, safety is already ensured by way of effective occupational dust limit values.

Occupational Dust Limit Values in the EU (+NO & CH):

- No known limit value
- 10 mg/m³ (inhalable fraction)
- 4-6 mg/m³ (respirable fraction)
- ≤ 3 mg/m³ (respirable fraction)
- Currently no information

Source: VdL, CEPE



Paints and other products can be safely used

Any classification of the substance would also carry across to a mixture containing TiO_2 (>1% for category 2). Nearly all paints would, therefore, become classified as suspected of causing cancer. However, once incorporated into a paint or printing ink or resins for construction applications, the dust hazard is no longer present. We strongly believe that the use of paint, printing ink and artist colours does not present a risk for users.

The classification of TiO_2 as a Category 2 carcinogen will establish a precedent that extends the current interpretation of CLP criteria. Due to the disproportionate consequences of this interpretation it must be carefully considered by the appropriate political body, realizing that it makes no contribution to the protection of workers or the general public.

Impacts of Classification

Impacts for Consumers and trade partners

- **Unnecessary fear and confusion.** The perception of paint, resins and other concerned products would change rapidly with the inclusion of an alarming label marked “Suspected of causing cancer”, even though titanium dioxide in finished coatings products cannot be inhaled.



Warning
Suspected of causing cancer



- **Dissatisfaction with products without TiO_2 .** The substitution of titanium dioxide would result in less durable products, the need for additional layers of products to achieve the required opaque end-effect, as well as more frequent application due to a significantly quicker deterioration. It would at the same time increase the environmental burden of painting a house.



Impacts for Authorities and Industries alike

- **CLP would overshoot its purpose.** Labelling all titanium dioxide-containing products would render the entire hazard labelling worthless – to the detriment of consumer protection. A core concern is that the labelling of products as mandated by CLP would not be able to convey a clear and strong message when a product presenting a real risk is offered to users.



Example:

- **Increased complexity in waste management.** Leftover paint together with all other waste products containing more than 1% titanium dioxide (such as paper and plastic) could have to be treated as “hazardous waste”, at much higher costs

Impact on other ‘dusts’

- A classification of titanium dioxide could lead to a “domino effect” for other poorly soluble substances, inter alia many other pigments.
- This would also affect many other industries.

