



EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
REACH
Chemicals

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Open Session

CLP

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Room 0B Centre Albert Borschette
Rue Froissart 36
1040 Brussels, Belgium

Concerns: **Classification of TiO₂ and mixtures containing TiO₂**

Agenda Point: **5**

Actions Requested: **For discussion**

SI-UK proposal for a way forward regarding CLASSIFICATION OF TiO2 AND MIXTURES CONTAINING TiO2

Before taking the final decision regarding classification of TiO2 we would like to bring forward our thoughts on this issue, as well as a proposed way forward:

In our opinion three key questions are still open:

1. What is the **intrinsic property of TiO2** reflected in the proposed carcinogenicity classification?
2. **Does CLP contribute to risk management** by providing clear hazard communication to address potential effects from exposure to respiratory TiO2 dust?
3. What would be the regulatory, environmental and socio-economic **consequences of classification**?

1. Intrinsic property of TiO2

Tumorigenic effect of TiO2 in the form of a respirable powder: The mechanism of TiO2 tumour induction is a secondary genotoxic mechanism due to prolonged exposure to inhaled particles at sufficiently high concentrations. In experimental animals, high exposure to any particle (including TiO2) may lead to impairment of normal particle clearance mechanisms in the alveolar region of the lung, resulting in a continued build-up of particles that eventually leads to excessive lung burdens accompanied by chronic alveolar inflammation. The inflammatory response may give rise to increased generation of reactive oxygen species, cell injury, cell proliferation, fibrosis, induction of mutations, and, ultimately, cancer.

In our opinion **TiO2 has no intrinsic or extrinsic property to cause cancer**. TiO2 is not a carcinogenic substance, but exposure overload may result in compromised particle clearance (by macrophage) leading to inflammation. One of the consequences of chronic alveolar inflammation is tumour formation. This is a secondary, non-specific effect.

Presently there is uncertainty and a lack of guidance on whether such effects are within scope of CLP. It is clear to us that such effects do not fit easily within the existing CLP system. However, if it is decided that such effects are in scope, guidance is needed on how they should be addressed, and some changes to the details of CLP are needed to accommodate particle toxicity.

2. Contribution to risk management and effective hazard communication

We are also concerned that the hazard communication CLP currently provides if TiO2 is classified as carc cat 2 is often misleading for users of products such as paints. There is survey evidence to show that when consumers read the hazard statement *Suspected of causing cancer by inhalation* (H351i) on a can of paint, they (understandably) conclude that the hazard arises from inhalation of vapour from the paint. However, this is misleading because the hazard only arises on inhalation of unbound respiratory particles of solid TiO2. Furthermore, where the hazard may arise, e.g. in sanding down a wall that has been painted, communicating the hazard via the paint label is generally not helpful, as sanding may take place years after paint application when the container is no longer available. Therefore we believe that at the moment **CLP may not be an appropriate tool** to help ensure safe use of TiO2, particularly when formulated in liquid and solid mixtures as generally placed on the market.

Consequences of TiO2 classification

The proposed classification would affect also solid and liquid formulations, because in solid and liquids products' life cycles dust is very often generated (at least at the end of a life

cycle). Therefore, the classification **would negatively impact the circular economy** and would cause **problems for recycling and reuse** with little compensating benefit for the protection of people and the environment.

In addition, classification of TiO₂ as a hazardous substance would affect non-professional as well as professional users (i.e. consumers as well as industry, waste disposal sector...). Therefore we believe that there is a need to take a look into the wider effects of the proposed classification. In our opinion hurry would not be justified.

Our proposal:

Taking into account these considerations we suggest taking time to:

- Explore fully whether 'particle toxicity' is indeed in scope of CLP
- If 'particle toxicity' is considered to be in scope, ensure that:
 - Guidance is available on how to classify for secondary, non-specific effects; and
 - CLP provides clear and appropriate hazard communication on particle toxicity for substances and mixtures
- If particle toxicity is not considered to be in scope of CLP, explore the suitability and sufficiency of other risk management options.

In taking forward this proposal it may be helpful to establish a working group.