

To European Commission,

I am glad to have this opportunity to submit out opinion toward WTO/TBT notification.

We are Titanium Dioxide Manufactures Association in Japan. (JTDMA)

The proposal for the powder containing 1 % and over of 10 μm or less TiO_2 to be classified as carcinogenicity 2 (inhalation) holds varied problems in predicted practical operations. Specific explanations will be pointed out as under;

1. Measuring method of 10 μm TiO_2

It is easily known by analogy that without precisely regulating integrated reliable international examination method, confusion could be raised not only among manufacturers but also throughout supply chain distribution network. The reason is that particle diameter values obtained from the pre-treatment are enormously different depending on the measuring methods for the samples. Therefore, measuring method of TiO_2 should cover also pre-treatment in the clear specification.

In addition, for TiO_2 the limitation of 10 μm or less is set up, but the ground of setting 10 μm as cut off value is ambiguous. An explicit explanation is required.

2. About NOTE V and 10

NOTE V requires that the hazard of surface-treated TiO_2 is to be equal or more than untreated TiO_2 . The surface treating materials widely varied like as silica, aluminum and metallic soap, however NOTE V specifies that whatever surface treatment material doesn't reduce hazard of untreated TiO_2 . Scientific ground of the statement is to be clarified.

In addition, NOTE 10 says that carcinogenicity classification of TiO_2 is applied only to the mixture linked to inhalation. The limitation to mixture is rather unclear, as it doesn't mention what other forms than mixture are excluded. An explicit explanation is required to avoid confusion throughout supply chain network.

3. About ground of carcinogenicity classification

In May 2016, ECHA acknowledged the submission from France of a dossier that claims classification of TiO_2 carcinogenicity. The ground to classify carcinogenicity on TiO_2 is IARC examination results. It has become a big topic that the method of examination has to be re-scrutinised including whether it is consistent with OECD TG.

It is to be carefully noted that IARC Monographs VOLUME 93 recognized that the lung epithelial cancer developed due to secondary factor by overloaded powder, not because of an assumption that TiO_2 has its own hazard.

4. Respect for RAC OPINION

In June 2017, ECHA issued RAC OPINION on TiO₂ carcinogenicity classification. The opinion also noted that the lung epithelial cancer developed due to secondary factor by overloaded powder, not because of an assumption that TiO₂ has its own hazard. It means that the opinion confirmed the conclusion of IARC Monographs VOLUME 93.

From the fact it is explicit that TiO₂ has no hazard of its own.

5. Inconsistent restricting with CLP regulation and future response

CLP regulation is the law system to put restrictions on chemical substances with their own hazard. The legal spirit doesn't allow to regulate TiO₂ with no hazard of its own. In other words regulating TiO₂ with no hazard of its own is against the legal spirit of CLP.

So it is the most suitable solution to address the substance matter as PSLT (Poor Soluble Low Toxicity). For the purpose, it is necessary to deepen findings about PSLT, research definition of PSLT and, threshold values of PS and LT, and then address the applicable chemical substances appropriately.

We express strong objection against the European Commission's proposal but supporting the currently recognised alternative proposal.

The European Commission should seriously consider this public comment but should not move TiO₂ toward hazard classification more in discussion until these indicated points are properly solved.

3rd Feb, 2019


Nano TiO₂ committee of Japan Titanium Dioxide Industry Association
