

February 10, 2019

**JBMIA's Comments on G/TBT/N/EU/629, Draft Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669**

Japan Business Machine and Information System Industries Association (JBMIA) appreciates the opportunity to give our comments on the WTO/TBT notification G/TBT/N/EU/629 on the proposal for classification and labelling of titanium dioxide.

JBMIA represents the global leading companies of business machines industry. Our main products are copying machines, multifunction devices (MFDs), page printers, digital duplicators and their consumables. The number of annual sales of our printers and MFDs is about 4.2 million units, and the volume of annual sales of toners is about 190 thousand tons (fiscal year 2016) worldwide.

Toner is a powder mixture used in laser printers and photocopiers to form the printed text and images on the paper, in general through a toner cartridge. Titanium Dioxide is used in our industry for many years/decades in toners. Over this time span, no health and safety issues have been recorded by our member companies resulting from the use of TiO<sub>2</sub> either as a raw material or in their products brought on the market for professional and/or consumer use. As a raw material TiO<sub>2</sub> can be used in industrial environment in a controllable way, minimizing the exposure to operator and to the environment, and respecting hereby the regulatory defined exposure levels. Imaging and printing products (toner) sold on the market do not expose the users to inhalable or respirable forms of TiO<sub>2</sub> dust, as the substance is embedded in the products in bound form. The proposed classification is based on inhalation exposure route, which is not relevant for the imaging and printing products. No free TiO<sub>2</sub> was found under normal use conditions of said products.

JBMIA has closely followed the developments of proposal of classification for titanium dioxide (TiO<sub>2</sub>) as a suspected carcinogen (Category 2) by inhalation under CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures), and has concerns about the proposal, which will have serious socio-economic and trade impacts on our industry without enhancing any human health benefits or further protecting workers or consumers. Specifically, we believe the proposed classification and required labeling has the potential to result in a significant impact on international trade, as the EU would be advancing a stricter approach in terms of unwarranted hazard and precautionary labeling application in EU markets for less hazardous widely used consumer products (mixtures), not required anywhere in the world.

**The Basis for the proposed classification:**

The reason for classification on TiO<sub>2</sub> as carcinogen might be health effect on rats by exposure of TiO<sub>2</sub> by inhalation route.

According to RAC opinion issued in September 2017, the classification proposal is based essentially on studies on rats exposed to extremely high concentrations of titanium dioxide dusts which led to so-called “lung overload” effects.

Such lung overload situations could only occur with unrealistic long-term exposure to high concentrations. In its opinion, RAC also stated that the carcinogenicity profile described for TiO<sub>2</sub> is not exclusively characteristic for TiO<sub>2</sub>, but applies to a group of chemicals with similar toxicity profile addressed as “poorly soluble low toxicity particles”.

It is also 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<sub>2</sub> has its own hazard.

**Legal effects and consequences of the proposed classification:**

Classification of the substance by the CLP regulation differ from GHS system in other countries, because the classification is legally bound and affect to other regulations like REACH restriction, waste regulation, etc. Therefore, classification should be made more carefully.

We suggest to not include TiO<sub>2</sub> in the 14th ATP to CLP.

We believe there are more effective better regulatory options available and it should be managed by exposure limit value in the workplace.

**Impact of Proposed Classification for Mixtures containing TiO<sub>2</sub>:**

The proposed Annex VI entry with Notes does not effectively limit the scope of the hazard described in the RAC opinion. The hazard described by RAC applies only to the unbound/free and respirable TiO<sub>2</sub> particles.

Although TiO<sub>2</sub> is used in toner for printers and copiers, TiO<sub>2</sub> is bound in a toner matrix and TiO<sub>2</sub> particles will not be released from toner. In addition, toner is supplied in sealed cartridges and used by setting them into machines. Toner particles are not observed in the emission from printer or copiers when they are printing.

Therefore, exposure to high concentration of TiO<sub>2</sub> will never occur in the normal and foreseeable use conditions of toner.

However, proposed wording of classification for powder mixtures will inappropriately broaden the scope to cover the powder mixtures containing 1% or more of TiO<sub>2</sub>, are classified as carcinogen regardless of exposure of TiO<sub>2</sub> by inhalation would occur or not.

*Note 10 as proposed:*

*The classification as carcinogen by inhalation applies only to mixtures placed on the market in powder form containing 1% or more of titanium dioxide particles with diameter ≤ 10 µm.'*

Even if the European Commission reach the conclusion that, in general, a classification of titanium dioxide as carcinogenic category 2 is justified, proposed Note 10 wording is not appropriate and should be revised as follows:

*Note 10 should be revised to read as follows:*

*The classification as a carcinogen by inhalation applies only to mixtures placed on the market ~~in powder form~~ containing 1% or more of unbound, airborne, respirable titanium dioxide particles with diameter ≤ 10 µm.'*

*(Delete “in powder form” and add “unbound, airborne, respirable”)*

## Conclusion:

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. Consequently, it is essential not to include titanium dioxide in the 14. ATP.

1. The alternative proposal to harmonize the different general dust limits currently applied in Europe gives the right answer for European occupational safety standards. The proposed classification (in Annex VI CLP regulation) and warning label for liquid/solid mixtures (in Annex II CLP regulation) is misleading and not appropriate.
2. Reconsideration is necessary for the proposed classification, including the Notes and the additional warnings in Annex II.  
If a classification of titanium dioxide as carcinogenic category 2 is justified, proposed Note 10 does not effectively limit the scope of the hazard described in the RAC opinion and should be revised to read as follows:

*Note 10 should be revised to read as follows:*

*The classification as a carcinogen by inhalation applies only to mixtures placed on the market ~~in powder form~~ containing 1% or more of unbound, airborne, respirable titanium dioxide particles with diameter  $\leq 10 \mu\text{m}$ .*

*(Delete "in powder form" and add "unbound, airborne, respirable")*

3. Classification and labelling of TiO<sub>2</sub> would have disproportionate socio-economic effects compared to the expected health benefits and is not the most efficient measure to improve safety. The full impacts of the proposed classification for global business and value chain should be assessed. We believe that more time is needed to reflect on this complexity.

## About JBMIA

Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.

The advancement of information technology has brought about sophistication of the age of digitalization and networking and resulted in significant changes in the office environment accordingly. In response to the shift of business emphasis from the hardware to total business solutions including products, JBMIA carries out active committee/group activities regarding important issues that the industries are confronting in and outside Japan by conducting investigations and researches regarding the policy proposals, international cooperation, prevention of warming, environment preservation, standardization, product safety, etc., by deepening the association with the sales and software-related companies, as well as the manufacturers.

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