

**NATIONAL COUNCIL OF TEXTILE ORGANIZATIONS STATEMENT
ON THE PROPOSAL FOR A HARMONISED CLASSIFICATION OF TITANIUM DIOXIDE (TiO₂)**

February 7, 2019

The National Council of Textile Organizations (NCTO) is pleased to provide comments on the Public Consultation under the Better Regulations Initiative as listed in the European transparency register on Titanium Dioxide (TiO₂).

The National Council of Textile Organizations (NCTO), headquartered in Washington, DC, USA, is the national trade association that represents the entire supply chain of the United States Textile Industry from fibers to finished textile products, and from machinery manufacturers to energy suppliers. The U.S. Textile Industry is one of the most innovative and scientifically advanced industries in the world providing products to the automotive, aerospace, military, medical, technical, home furnishings, and apparel industries. For more information about the U.S. Textile Industry, view NCTO's website at www.ncto.org.

Our comments are submitted primarily on behalf of our Fiber Council which is comprised of members who produce synthetic and cellulosic manufactured fibers for numerous industries and end products. U.S. fiber manufacturers produce almost 3 million metric tons of fiber annually and virtually all contain titanium dioxide as a deluster agent, dispersed in the polymer structure. Globally, more than 70 million metric tons of manufactured fibers are produced and practically all contain titanium dioxide. The worldwide impact of classifying titanium dioxide as a carcinogen category 2 would be enormously disruptive.

As we understand the proposed carcinogen classification, it is linked to a dust effect, i.e. the lung overload of solid particles of poor solubility due to inhalation. Therefore, it is imperative that the carcinogenic risk of titanium dioxide be more thoroughly evaluated based on sound science/peer-review research before a harmonized classification can be justified.

Titanium dioxide has been used for decades safely in thousands of products and articles, where there is no risk of inhalation. The hazard is only relevant for workers in industrial environments where there is potentially an inhalation risk. The effect observed in rats is not an intrinsic property of titanium dioxide and the benefits of classifying it have not been demonstrated, whereas the negative consequences are acknowledged. Therefore, we urge that this carcinogenic risk evaluation of titanium dioxide be, more in line with the better regulation initiative.

In the USA, workplace chemical exposures are regulated by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). OSHA issued an interpretation letter in 1997 (<https://www.osha.gov/laws-regs/standardinterpretations/1997-11-19>) on titanium dioxide, which cited a 1985 study by Lee, Trochimowicz, and Reinhardt, "Pulmonary Response of Rats Exposed to Titanium Dioxide (TiO₂) by Inhalation for Two Years." OSHA states that, "the authors of this study concluded that based on the excessive dust loading and overwhelmed clearance mechanism in the lungs

of rats exposed chronically at 250 mg/m³ (6 hrs/day, 5 days/week for 2 years), the biological relevance of lung tumors to man appears to be negligible.”

Currently, OSHA has an inhalation permissible exposure limit regulation (PEL) for titanium dioxide as ‘particulate not otherwise regulated (PNOR)’ or what was previously called ‘nuisance dust.’ The PEL for titanium dioxide is 15mg/m³, as total dust, 8-hour time-weighted average [3 mg/m³, as respirable or fine dust]. From a regulatory standpoint, OSHA does not regulate titanium dioxide as a carcinogen.

Within our fiber industry, titanium dioxide is an essential deluster agent used in virtually all manufactured fibers, both synthetic and cellulosic. The proposed classification of titanium dioxide as a carcinogen category 2, by inhalation, would pose a significant economical and technological impact on our industry. We understand the Commission has held several meetings on this issue; however, we strongly feel the discussions have not sufficiently considered the relevance of the classification to poorly soluble particles imbedded in a polymer structure.