



# Ti-Pure™

## Titanium Dioxide

## EU ongoing Classification and Labelling Harmonisation of TiO<sub>2</sub>

On February 18<sup>th</sup>, 2020, the European Commission published Regulation (EU) 2020-217 which included the 14<sup>th</sup> ATP and the classification proposal for the powder form of TiO<sub>2</sub> as a Carcinogen Category 2 by inhalation (with notes). The publication initiated an 18-month implementation period with the classification coming into enforcement on October 1<sup>st</sup>, 2021.

Chemours, together with TDMA, has worked to interpret and put into practice the classification proposal under the CLP guidelines. In the absence of an officially designated method to measure compliance with the classification criteria, TDMA undertook a comparative study of available test-methods and came to the conclusion that of all methods tested, the internationally recognized test method for dustiness of bulk materials in the workplace environment, EN 15051-2 provides the most consistent and repeatable results and was also chosen by Chemours to determine classification criteria. Chemours has carried out testing on all Ti-Pure™ titanium dioxide pigments to measure the content of particles with aerodynamic diameter ≤10 µm, (one of the two criteria for classification – the other being the “powder” form). The data from the Chemours testing consistently shows that all the Ti-Pure™ grades of TiO<sub>2</sub> contain <1% of particles with aerodynamic diameter ≤10 µm and therefore, based on this testing, do not meet the criteria for classification.

Chemours, as an Associate member of the TDMA, has actively worked to bring forward relevant information related to the classification of TiO<sub>2</sub> and continually seeks meaningful and effective discussions with the EU Commission and ECHA to address open regulatory questions raised by our customers and stakeholders.

### Chemours info as available on our SDS's:

**Carcinogenicity — Assessment: Weight of evidence does not support classification as a carcinogen.**

In lifetime inhalation studies rats were exposed for 2 years to respectively 10, 50 and 250 mg/m<sup>3</sup> of respirable TiO<sub>2</sub>. Slight lung fibrosis was observed at 50 and 250 mg/m<sup>3</sup> levels. Microscopic lung tumours were also observed in 13 percent of the rats exposed to 250 mg/m<sup>3</sup>, an exposure level that caused lung overloading and impairment of rat lungs clearance mechanisms. In further studies, these tumours were found to occur only under particle overload conditions in a uniquely sensitive species, the rat, and have little or no relevance for humans. The pulmonary inflammatory response to TiO<sub>2</sub> particles exposure was also found to be much more severe in rats than in other rodent species. In February 2006, IARC has re-evaluated Titanium dioxide as pertaining to Group 2B: “possibly carcinogenic to humans”, based upon inadequate evidence in humans and sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. IARC evaluation guidelines consider the generation of tumours, in 2 different studies within the same animal species, to be adequate criteria for an assessment of sufficient evidence. The conclusions of several epidemiology studies on more than 20000 TiO<sub>2</sub> industry workers in Europe and the USA did not suggest a carcinogenic effect of TiO<sub>2</sub> dust on the human lung. Mortality from other chronic diseases, including other respiratory diseases, was also not associated with exposure to TiO<sub>2</sub> dust. Based upon all available study results, Chemours scientists conclude that titanium dioxide will not cause lung cancer or chronic respiratory diseases in humans at concentrations experienced in the workplace.

Further questions should be directed to:  
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