



Ti-Pure™
Titanium Dioxide

Update on EU Classification and Labelling of TiO₂

On February 18, 2020, the European Commission published the 14th ATP to CLP Regulation (EU) 2020/217 which includes a harmonized classification for certain powder forms of TiO₂ as a Carcinogen Category 2 by inhalation (with notes). The classification came into enforcement on October 1, 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 TiO₂ contain <1% of particles with aerodynamic diameter ≤ 10 µm and therefore, based on this testing, do not meet the criteria for classification.

On November 23, 2022 the General Court of the European Commission delivered a judgement annulling the classification of certain powder forms of titanium dioxide as a Carcinogen Category 2 by inhalation as introduced by Regulation (EU) 2020/217. The principal reasons for the annulment were that an error had been made in the assessment of the reliability and acceptability

of the study on which the classification was based and that a carcinogen classification can only apply to a substance that has the intrinsic property to cause cancer.

France and the European Commission have appealed the judgement of the General Court of the European Union of 23 November 2022 concerning titanium dioxide (TiO₂) in certain powder forms. The appeal process is expected to take 1 to 2 years. In practice, the classification will remain in place until the end of the appeal process.

Although none of the Chemours Ti-Pure™ pigments fulfill the classification criteria of the EU CLP regulation, our TMP surface treated TiO₂ pigments, which are considered mixtures, do carry additional CLP Annex II labelling warning phrases related to powder mixtures containing TiO₂ (as published under Regulation (EU) 2020/217). These warning phrases will remain on the packagings and SDS's of our TMP surface treated Ti-Pure™ grades until the regulatory process is finalized. Once finalized, we will assess any required changes to our Chemours Ti-Pure™ packaging and labeling.

Chemours, as an Associate member of the TDMA, has actively worked to bring forward relevant information related to the safety of TiO₂ and will continue to seek meaningful and effective discussions with authorities to improve worker safety. With TDMA we continue to invest in a major scientific programme with the objective to generate additional safety data and new scientific studies in line with the latest guidelines and scientific techniques related to the use of TiO₂ and our Chemours Ti-Pure™ pigments. This [Link](#) brings you to the TDMA publication from February 16, 2023 on the appeal.

Information available on Chemours 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/m³ of respirable TiO₂. Slight lung fibrosis was observed at 50 and 250 mg/m³ levels. Microscopic lung tumours were also observed in 13 percent of the rats exposed to 250 mg/m³, 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 TiO₂ 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 TiO₂ industry workers in Europe and the USA did not suggest a carcinogenic effect of TiO₂ dust on the human lung. Mortality from other chronic diseases, including other respiratory diseases, was also not associated with exposure to TiO₂ 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.

Additional EU SDS Info: Section 11.1 Information on toxicological effects Carcinogenicity — Remarks

The Commission Regulation (EU) 2020/217, amending REGULATION (EC) No 1272/2008, introduces a new harmonized classification for certain forms of TiO₂ as a category 2 carcinogen by inhalation which applies from 1 October 2021. To be classified, the TiO₂ must be in powder form and contain 1% or more of particles with aerodynamic diameter ≤ 10 µm. Through a rigorous evaluation of available test methods and available standards, EN 15051-2 (Workplace exposure – Measurement of the dustiness of bulk materials – rotating drum method) was identified as the best available method for complying to the regulation. Data from the testing following EN 15051-2 consistently shows that Ti-Pure™ grades of TiO₂ contain < 1% of particles with aerodynamic diameter ≤ 10 µm and therefore do not meet the criteria for classification. The respirable and thoracic dust content of Ti-Pure™ grades fall in the very low or low dustiness categories by the EN 15051-2 method.

Further questions should be directed to:
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