



Ti-Pure™

Titanium Dioxide

EU ongoing Classification and Labelling Harmonisation of TiO₂

On 12 October 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) published its scientific Opinion recommending the classification of titanium dioxide (TiO₂) as a suspected carcinogen (cat. 2) by inhalation.

Since then, discussions have taken place between the European Commission, the Member States and interested parties on how the Opinion should be processed at a regulatory level given that this will likely set a precedent beyond TiO₂ and the CLP Regulation.

The EU Commission presented a draft of the full 14th ATP (adaptation to technical progress) including the classification proposal for TiO₂ as a Carcinogen Category 2 by inhalation (with notes). Having failed to achieve a majority vote during three REACH Committee meetings, the EU Commission pursued the classification of TiO₂ as a delegated act for scrutiny by EU Council and Parliament. The scrutiny period ended in February 2020, with publication to the Official Journal on February 18th, 2020. The publication initiates an 18-month implementation period with the act coming into enforcement on October 1st, 2021.

Chemours as an Associate member of the TDMA, has been actively working with the TDMA in view of bringing forward relevant information and seeking a meaningful and effective resolution to address the regulatory questions raised by the RAC in their Opinion and reiterated by the EU Commission.

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/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.

Further questions should be directed to:
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