



June 9, 2017

## **RAC supports classification of titanium dioxide (TiO<sub>2</sub>) as suspected of causing cancer, category 2, through the inhalation route**

### **KRONOS considers RAC opinion to be unsupported by prevailing science**

#### **Scientific studies do not demonstrate a hazard to humans**

The RAC opinion is based solely on studies conducted decades ago exposing rats to TiO<sub>2</sub> dust concentration levels far in excess of those that realistically occur in the use or manufacture of TiO<sub>2</sub> products. These studies, if performed today, would not be accepted as valid for consideration in this hazard determination process due to the rate of rat lung overload.

#### **RAC conclusion is based on lung overload of rats**

In the studies considered by the RAC, the effects observed were specific to the rat species and have not been observed in scientific studies on any other species, including humans. They relate to a mode of action that only occurs in rats. These effects in rats are only observed via inhalation at an exposure level many times higher than those encountered by product end users or workers.

#### **RAC conclusion is based upon particle-specific, not TiO<sub>2</sub>-specific, hazard**

The limited effects cited by the RAC result not from a substance-specific hazard of TiO<sub>2</sub>, but rather from a particle-based effect, common to all poorly soluble dusts. We believe the RAC erred by misapplying a generic, particle-specific hazard, only observed under the excessive conditions of the cited study, to this substance-specific hazard determination process for TiO<sub>2</sub>.

#### **Studies on 24,000 workers in the TiO<sub>2</sub> industry have not demonstrated similar or other adverse effects on humans**

Epidemiology studies of over 24,000 TiO<sub>2</sub> industry workers, in 15 manufacturing plants, from a period of over 50 years have not shown any increased carcinogenic effect from TiO<sub>2</sub> dust on the human lung.

The Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) issued an opinion to classify TiO<sub>2</sub> as a category 2 suspected carcinogen based on a certain inhalation study of rats. **KRONOS, as a member of the European Titanium Dioxide Manufacturers Association (TDMA), does not agree that TiO<sub>2</sub> is a suspected carcinogen.** Of the many TiO<sub>2</sub> studies of animals and humans, very limited effects were observed, and were specific to the rat species. These limited effects were not observed in scientific studies of any other species, including humans. In addition, this effect in a single animal species was only observed via inhalation, and at an exposure level elevated many times higher than those levels encountered by workers or consumers. It is further important to note prevailing scientific standards do not support



# KRONOS<sup>®</sup>

---

the methodology of the rat study used by the RAC to support its opinion. **The RAC ruled out carcinogenicity for oral and dermal routes of exposure.**

This proposed classification is based only on the inhalable form of TiO<sub>2</sub>; however, the structure of the EU regulatory framework may prevent limitation of the classification to end use applications with inhalation risks. **Similar effects are seen with all poorly soluble dusts and are not specific to TiO<sub>2</sub>.** Therefore, ultimate approval by the EU Commission could set a precedent for similar classification recommendations for many other similar substances and will be hotly debated by multiple industries.

## Next Steps

Once the formal opinion is completed it will be forwarded to the EU Commission for evaluation and a determination of what, if any, regulatory measures will be imposed for TiO<sub>2</sub>. The opinion will face additional scrutiny and potential clarification as it moves through the formal consideration process. The TDMA and its members will continue to strongly oppose this opinion and vigorously defend the safety of TiO<sub>2</sub> by seeking out every opportunity to provide important information to the EU Commission during its review and decision-making concerning TiO<sub>2</sub>. A final decision is not expected until 2018.

The scientific assessment made by the EU manufacturers of TiO<sub>2</sub>, as outlined in the REACH dossier, fully supports a “no classification” for the substance, in both pigmentary and nano forms. TDMA and its members will continue to explore regulatory pathways ensuring the continued safe use of TiO<sub>2</sub> across all industries and applications, and look forward to a constructive dialogue with the EU Commission on this topic. We urge other stakeholders to work within their industry groups to do the same.

For further information on titanium dioxide please also refer to the following websites:

[www.tdma.info](http://www.tdma.info)

[www.brilliantwhite.life](http://www.brilliantwhite.life)

[www.kronostio2.com](http://www.kronostio2.com)