

Outcome of step 2 of the call for data on titanium dioxide (E 171)

Toxicological data

The Titanium Dioxide Manufacturers Association (TDMA) have committed to carrying out a dietary Extended One-Generation Reproductive Toxicity Study (EOGRTS) with E171 grade titanium dioxide in rats. The study design is expected to include cohort 1 (extension by mating of F1 animals to the F2 generation), cohort 2 (for developmental neurotoxicity) and cohort 3 (for developmental immunotoxicity). In addition, various endocrine parameters as well as blood/serum, tissue and urine levels of titanium will be monitored.

TDMA initially expected a completion time of 24 months from 1 August 2017 (subject to availability of laboratory capacity in view of the backlog created under REACH for such studies). However, in July 2018 EFSA issued a scientific opinion on the "Evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171)" (see <http://www.efsa.europa.eu/en/efsajournal/pub/5366>) recommending that biomarkers for putative preneoplastic lesions in the colon (aberrant crypt foci - ACF) should be examined as additional parameters in the EOGRTS. TDMA have committed to carrying out this work and therefore increased the scope of the original study with an additional 10 male and 10 female satellite animals per group from all dose groups for a total of 80 animals. The expected date for submission of data on the full EOGRTS including ACF is June 2020.

Data on particle size and particle size distribution

The Titanium Dioxide Manufacturers Association (TDMA) has committed to providing the requested particle size and particle size distribution data for E 171 products.

The data will be submitted by 30 June 2018.

Data on the lowest achievable limits for the impurities of toxic elements

TDMA has committed to providing data on the lowest achievable limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) in titanium dioxide (E171). TDMA members will gather data and an overview will be provided by TDMA. The possibility of reducing those levels will be reviewed by the manufacturers and a proposal for revised specifications will be made. Data will be submitted by 29 September 2017.

In addition, the business operator Merck KGaA has also committed to providing data on the lowest achievable limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) in titanium dioxide (E171) in its products. Data will be submitted before the end of October 2017.

Data on the actual use of alumina (aluminium oxide) in E171 formulations/lowest achievable limit for the use of alumina in those formulations

TDMA has committed to providing data on the levels of alumina in E171 formulations. TDMA members will gather data and an overview will be provided by TDMA. The possibility of reducing those levels will be reviewed by the manufacturers and a proposal for revised specifications will be made. Data will be submitted by 29 September 2017.