

## **ADDITIONAL INFORMATION REGARDING TITANIUM DIOXIDE AND E171**

Thank you for giving the TDMA an opportunity to provide further information about food grade titanium dioxide. The following information is meant to clarify and supplement the brief information we provided on March 19<sup>th</sup>, 2015 in response to media inquiries about titanium dioxide used in food.

E171 titanium dioxide is supplied as an additive to the food industry. The function of the product is to improve the appearance of food by providing whiteness to the food itself.

To best answer your questions we need to explain the difference between the manufactured forms of titanium dioxide because there is a lot of confusion and misrepresentation in published literature and the media.

Titanium dioxide (TiO<sub>2</sub>) products are manufactured in two forms, pigmentary and ultrafine (or nanomaterial). Approximately 99% of all titanium dioxide is produced and sold in the pigmentary form where it is used to provide whiteness and opacity to products. E171 is one example of a pigmentary titanium dioxide product.

The other 1% of the TiO<sub>2</sub> in the market is ultrafine product. It doesn't have the properties of E171 and it would not provide the desired white color. Therefore it cannot be used in food applications when E171 is required.

The TiO<sub>2</sub> produced in the pigmentary form, including E171, has an average particle size greater than 100 nm and so, it is not a nanomaterial.<sup>1</sup> However, as in all production processes of particulate materials, there will be a distribution of primary particle (the smallest indivisible unit) sizes around the average value and it is likely that a minor fraction of the primary particles will be below 100 nm. There is no evidence that this small quantity of particles less than 100 nm in size can cause any safety health risk.

E171 has been assessed by EFSA as safe for food applications<sup>2</sup>. Other international authorities including FDA<sup>3</sup> and JECFA<sup>4</sup> have made similar assessments. E171 is currently being reassessed by EFSA as part of the regular update program<sup>5</sup>.

<sup>1</sup> Commission Recommendation of 18 October 2011 on definition on nanomaterial ([http://ec.europa.eu/environment/chemicals/nanotech/faq/definition\\_en.htm](http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm)).

<sup>2</sup> <http://www.efsa.europa.eu/fr/scdocs/doc/163.pdf>

<sup>3</sup> Food and Drug Administration, USA

<sup>4</sup> The Joint FAO/WHO Expert Committee on Food Additives

<sup>5</sup> Regulation EU No 257/2010, <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010R0257>

The E171 product has not changed since it was introduced onto the market and used as a food additive many decades ago. It has not changed since it was assessed as safe by the food safety authorities. There have been no reported health effects from its use as a food additive.

Furthermore, the dossier produced under REACH<sup>6</sup> included testing of both the pigmentary form and the ultrafine form. From the huge amount of data assembled it was concluded that both forms are non-hazardous. All tests carried out on the pigmentary form included the minor fraction of particles below 100 nm, since their presence is an unavoidable consequence of manufacture of any particulate material.

The TDMA and its members consider the health and safety of consumers of titanium dioxide products as a highest priority and will continue to closely monitor and assess new credible information that becomes available.

We hope that this additional information is helpful.

Best Regards,

TDMA Secretariat

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<sup>6</sup> Regulation (EC) No 1907/2006, as amended, concerning the Registration, Evaluation Authorisation and Restriction of Chemicals