Status: 02.08.2019

Verband der Mineralfarben-industrie e. V.

Evaluation and Classification of the EFSA Report on Titanium Dioxide E 171 published on 12th July 2019

Background

The discussion about titanium dioxide especially as food additive E 171 reached all levels of society. Unfortunately, this discussion is conducted rather non-scientifically and arguments concerning titanium dioxide/E 171 as food additive get mixed up with arguments concerning nanomaterials in general. To avoid such mistakes, we want to highlight some details of the EFSA report on E 171 published on 12th July 2019.[1]

In the last evaluation[2] in 2016, some uncertainties concerning the actual particle size in E 171 and more specifically the share of nanoparticles (diameter < 100 nm) remained due to non-uniform measurement methods. However, this is essential information for the transferability of toxicologic investigations and therefore, resulted in uncertainties regarding the applicability of such study results. For example, French ANSES considered in their evaluation of titanium dioxide E 171 also studies that looked at pure nanoparticle samples. This approach was **rightly** considered invalid by EFSA in its review of these studies in 2018.[3]

To proof this non-transferability and to eliminate the uncertainties found in the last evaluation, EFSA compiled this new report on particle size and particle size distributaion of currently availble E 171 samples on the market. Furthermore, reference is made to the currently on-going toxicological studies on E 171 whose results shall close gaps in the risk assessment and enable the determination of an ADI value.[4] This has been dispensed so far due to the lack of suitable data sets because of precisely this poor comparability of studies on other titanium dioxide materials.

Content of the Report

In total, data on 6 different, non-coated E 171 samples were compiled in this report. The particle size was determined using different methods and by different labs. Both, the measured data as well as an error estimation are shown.

Typical average particle sizes were between 150-250 nm. The share of nanoparticles which means acording to the EU definition particles with at least one external diameter in the range of 1-100 nm, varied depending on the method whereby the share determined by electron microscopy always tended to be higher. However, all measurements showed that the majority of the particles (>50 % in the number distribution) have larger diameters which means that **clearly no nanomaterial**[5] is present!

From these results, the competent EFSA panel deduces the recommendation to include in the specification of E 171 a minimum median diameter of >100 nm determined by electron microscopy in the future.

Evaluation of the Report by VdMi

The VdMi welcomes the detailed analysis and data representation in the EFSA report. The comparison between different methods in combination with the error estimation eliminates the expressed doubts on the present particle size. As a result, the report clarifies: E 171 is no nanomaterial! Thus, more clarity regarding the applicability of toxicological studies should be created and the remaining knowledge gaps can be filled with valid data sets from new studies on E 171.

The addition of a median diameter of > 100 nm to the specification of E 171 is supported to exclude mixing of arguments or studies on nanomaterials in the future as well.

Your contact partner at VdMi: Giuliana Beck (+49 69 2556 1354, beck@vdmi.vci.de)

[1] Report available for download at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5760.
[2] Report published on 14th Septembre 2019, download available at https://www.efsa.europa.eu/de/efsajournal/pub/4545.
[3] Report published on 14th Septembre 2019, download available at https://www.efsa.europa.eu/en/efsajournal/pub/5366.
[4] ADI = allowable daily in-take
[5] According to the EU recommendation on a definition for nanomaterials (2011/696/EU), readable at http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm.