

COT Statement on the Safety of Titanium dioxide (E171) as a Food Additive - Lay Summary



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1. Food grade titanium dioxide (TiO₂) was an authorised Food Additive (E171) in the EU, but from the 7th of August 2022, its use in food has been banned in light of the European Food Safety Authority's (EFSA's) conclusion that such use could no longer be considered as safe. It currently remains authorised in Great Britain. Food grade TiO₂ comprises a mixture of micro- and nanosized (<100 nm) particles and is used in food as a colour (white pigment). Titanium dioxide is also widely used in cosmetics and medicines.
2. Titanium dioxide has been the subject of multiple safety evaluations including three recent evaluations by EFSA in 2016, 2019 and 2021.
3. In their most recent Opinion (2021), the EFSA Panel concluded that E171 could no longer be considered as safe for use as a food additive, due to uncertainties in some of the data, such as on genotoxicity (DNA damaging effects).
4. Following this, in 2021 the COT published an interim position on titanium dioxide in which the Committee expressed its scientific concern about the basis of the EFSA conclusions. A detailed review has now been undertaken by the COT, which includes the conclusions on genotoxicity (DNA damaging effects) from the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the

Environment (COM), to assess the safety of TiO₂ as a food additive.

5. The COT has reviewed toxicological studies that have been conducted using any form of TiO₂, including nanoparticles, but its conclusions are based primarily on those which used food grade TiO₂ (E171), which predominantly consists of aggregates, of smaller primary particles, with a median particle size of 200 – 300 nm.

6. The following endpoints were reviewed by the COT: the development of aberrant crypt foci (ACF) in the intestine (as a potential indicator of carcinogenicity), inflammation and immunotoxicity, reproductive and developmental toxicity and neurotoxicity. The COM reviewed the data on genotoxicity (damage to DNA which could ultimately lead to cancer) and reported their findings to the COT in May 2024.

7. The COT considered that the data from the relevant studies available indicated that TiO₂ did not induce ACF, nor were there significant effects in studies that assessed inflammation and immunotoxicity, reproductive and developmental toxicity, and neurotoxicity. On balance, the Committee considered that a no observed adverse effect level (NOAEL) of 1,000 mg/kg bw per day, was robust.

8. Overall, the COM concluded that there was little evidence in the literature to suggest that food grade TiO₂ (E171) caused induction of genotoxicity (DNA damaging effects), and that there was unlikely to be any health concern related to genotoxicity induction from use of TiO₂ (E171) as a food additive.

9. Following discussions of the COM report at their meeting in March 2024, the COT included the COM conclusions in their overall review of the evidence.

10. The COT concluded that 1,000 mg/kg bw per day was a robust Point of Departure (POD) on which to base a health-based guidance value (HBGV). This was the highest dose tested, so it is not known how much more TiO₂ would have to be administered before effects were seen.

11. A standard uncertainty factor of 100 (10 for inter-species differences and 10 for inter-individual variability) was agreed by Members and applied to the POD which resulted in a HBGV (acceptable daily intake) of 10 mg/kg bw per day.

12. Titanium dioxide (E171) can be found in a number of food categories, and the exposures calculated and considered by the COT for infants, toddlers, children, adolescents, adults, and the elderly used food consumption data from

UK surveys and maximum occurrence levels of titanium dioxide reported by EFSA (2021).

13. Estimated exposures for adults (18+) and the elderly are below the established HBGV. Although exposures for infants, toddlers, children and adolescents consuming a lot of TiO₂-containing food are estimated to be 1.3 - to 2.6-fold higher than the HBGV, actual exposures are likely to be lower and in addition, the HBGV is likely to be conservative. Therefore, adverse health effects would not be expected.

14. The COT concludes that it is unlikely that there would be a risk to health from current UK dietary exposures of E171 TiO₂.

COT

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