

Food additive titanium dioxide (E 171) under scrutiny: Re-evaluation by the European Food Safety Authority

BfR Communication No. 14 of 6 May 2021

Titanium dioxide (TiO₂) is a white colour pigment, which is authorised as the food additive E 171. It can be contained in confectionery and coatings, e.g. in dragees and chewing gum. The European Food Safety Authority (EFSA) has re-evaluated possible health risks associated with the use of titanium dioxide as a food additive and published the result on 6 May 2021. In total, almost 12,000 publications were considered.

EFSA opinion of 6 May 2021:

<https://www.efsa.europa.eu/en/efsajournal/pub/6585>

After evaluation of the available data, the concern with respect to genotoxicity of titanium dioxide could not be ruled out. According to EFSA, there are uncertainties, in particular regarding the molecular mechanism of the genotoxic effects. Furthermore, the studies do not allow any conclusion on a correlation between certain properties of titanium dioxide, such as size and composition of the (nano-) particles, and the results of the genotoxicity studies. Therefore, EFSA's experts concluded that the use of titanium dioxide as a food additive can no longer be considered as safe. No acceptable daily intake (ADI) was derived. EFSA's assessment is based on animal experiments and mechanistic studies. Human studies and targeted epidemiological studies on possible health effects are currently not available.

The BfR has looked into the available studies on genotoxicity and comes to comparable conclusions in an initial assessment. It has updated its questions and answers on titanium dioxide and will publish an opinion.

FAQ

<https://www.bfr.bund.de/cm/349/faq-titanium-dioxide-are-there-health-risks.pdf>

In principle, many foods contain ingredients with a genotoxic potential. These are very often of natural origin and unavoidable in the daily diet. For some genotoxic substances in food there are findings on adverse health effects in humans. In the case of titanium dioxide, this correlation has not yet been proven by human studies. However, food additives are subject to particular health requirements. They are strictly tested and regulated.

In 2016, EFSA concluded that the available toxicological data were not sufficient to derive an acceptable daily intake (ADI), but that there were no health concerns for the use of titanium dioxide as a food additive. Even taking into account further studies in 2018, EFSA saw no reason to change its 2016 conclusion. However, there were uncertainties due to the limited data available, including the question if the substance could affect the reproductive system. The BfR and EFSA saw a need for further research and recommended additional studies to close the data gaps. For its assessment of the use of titanium dioxide as a food additive (E 171) published on 6 May 2021, EFSA has now taken into account all relevant scientific knowledge currently available. This is based on a review of almost 12,000 publications. EFSA's experts applied the 2018 "Guidance on the risk assessment of the application of nanoscience and nano-technologies in the food and feed chain" (available at: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2011.2140>) issued by EFSA's Scientific Committee.

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EFSA concluded that studies with titanium dioxide on general toxicity and organ toxicity did not provide evidence of adverse effects. In animal studies, no adverse effects on fertility and offspring development have been observed. In an older study with rats and mice, no carcinogenic effects were observed after oral exposure to titanium dioxide, which was not characterised with regard to particle size. No appropriate animal study on the carcinogenic potential of titanium dioxide nanoparticles after oral exposure is currently available. EFSA's experts also concluded that although titanium dioxide is absorbed from the gastrointestinal tract only at a very low level, it takes a long time to be eliminated from the body and has the potential to accumulate in tissues.

After evaluation of the available numerous studies on in vitro and in vivo genotoxicity, the suspicion of genotoxicity of titanium dioxide could not be invalidated. According to EFSA, there are uncertainties, especially regarding the molecular mechanism of the genotoxic effects. Furthermore, the studies do not allow any conclusion on a correlation between certain properties of titanium dioxide, such as size and composition of the (nano-) particles, and the result of the genotoxicity studies. Therefore, and due to several scientific uncertainties, EFSA's experts concluded that the use of titanium dioxide as a food additive can no longer be considered as safe. No acceptable daily intake level was derived. The evaluations of the European Food Safety Authority usually form the basis for risk management decisions (EU Commission, Member States and EU Parliament) on the authorisation and use of the evaluated food additives.

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In principle, many foods contain ingredients with genotoxic potential. These are very often of natural origin and unavoidable in the daily diet. For some genotoxic substances in food there are findings on adverse health effects in humans. In the case of titanium dioxide, this correlation has not yet been proven by human studies. However, food additives are subject to particular health requirements. They are strictly tested and regulated. Consumers who do not want to consume products containing certain food additives can avoid them as the use of additives is subject to labelling, i.e. they must be indicated in the list of ingredients of packaged food

Further information on food additives from the BfR website:

https://www.bfr.bund.de/en/health_assessment_of_food_additives-69534.html

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<https://www.bfr.bund.de/cm/349/faq-titanium-dioxide-are-there-health-risks.pdf>

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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